Separater Anhang 4-G: Ergänzende Unterlagen

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1 Auswertungen zu Nerandomilast (als zu bewertendes Arzneimittel)

1.1 Auswertungen zur Studie FIBRONEER®-ILD

1.1.1 Database Lock 2

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I.1 Nerandomilast PPF HTA Analysis: DBL2 Analysis

I.1.1 Population with Nintedanib background

I.1.1.1 Efficacy Analysis

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I.1.1.1.1.1.1 Time to first confirmed or suspected acute ILD exacerbation, respiratory hospitalisation or death

Table I.1.1.1.1.1.1: 1 Cox model for time to first confirmed or suspected acute ILD exacerbation, respiratory hospitalisation or death over the whole trial - 18mg - FAS (NIN background)

Subgroup	Placebo							Nera 18mg							Nera 18mg vs Placebo				
Category	N	n	(e/	h/	d)	%	Rate°	N	n	(e/	h/	d)	%	Rate°	Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	60	(19/	33/	8)	35.5	29.30	170	57	(14/	39/	4)	33.5	28.20	0.88	(0.61,	1.27)	0.5098	
Age																			0.9912
<65 years	65	18	(3/	12/	3)	27.7	21.58	64	16	(5/	9/	2)	25.0	21.12	0.89	(0.45,	1.77)	0.7399	
>=65 years	104	42	(16/	21/	5)	40.4	34.61	106	41	(9/	30/	2)	38.7	32.45	0.89	(0.58,	1.37)	0.5831	
Sex																			0.6072
Male	114	49	(16/	25/	8)	43.0	36.28	108	43	(11/	28/	4)	39.8	34.27	0.86	(0.57,	1.30)	0.4701	
Female	55	11	(3/	8/	0)	20.0	15.78	62	14	(3/	11/	0)	22.6	18.27	1.09	(0.49,	2.40)	0.8394	
Baseline FVC percent predicted																			0.2552
<=70%	95	38	(15/	19/	4)	40.0	34.61	97	34	(10/	21/	3)	35.1	30.22	0.75	(0.47,	1.20)	0.2319	
>70%	74	22	(4/	14/	4)	29.7	23.17	73	23	(4/	18/	1)	31.5	25.66	1.16	(0.65,	2.10)	0.6144	
Baseline HRCT pattern																			0.4180
UIP-like	116	40	(14/	23/	3)	34.5	28.29	121	45	(11/	31/	3)	37.2	31.55	0.97	(0.63,	1.49)	0.8928	
Other fibrotic patterns	53	20	(5/	10/	5)	37.7	31.56	49	12	(3/	8/	1)	24.5	20.18	0.69	(0.34,	1.41)	0.3046	
Underlying ILD diagnosis																			0.2135
iNSIP	32	10	(1/	8/	1)	31.3	25.74	27	13	(5/	7/	1)	48.1	44.56	1.52	(0.66,	3.51)	0.3255	
Unclassifiable IIP	46	23	(9/	10/	4)	50.0	42.51	32	9	(3/	5/	1)	28.1	22.21	0.54	(0.25,	1.18)	0.1222	
HP	38	8	(2/	4/	2)	21.1	16.57	43	16	(1/	13/	2)	37.2	32.81	1.68	(0.71,	3.96)	0.2347	
Autoimmune ILD	29	8	(3/	5/	0)	27.6	22.59	43	12	(4/	8/	0)	27.9	23.18	0.70	(0.28,	1.75)	0.4421	
Other ILD	24	11	(4/	6/	1)	45.8	39.13	25	7	(1/	6/	0)	28.0	21.95	0.66	(0.25,	1.74)	0.4040	
Region																			0.9994
Europe	78	27	(8/	15/	4)	34.6	28.43	67	22	(4/	16/	2)	32.8	28.28	0.89	(0.50,	1.57)	0.6875	
Asia	45	18	(6/	10/	2)	40.0	32.41	41	17	(5/	11/	1)	41.5	35.07	0.87	(0.45,	1.70)	0.6891	
Canada and USA	30	9	(4/	5/	0)	30.0	24.79	37	10	(4/	6/	0)	27.0	21.15	0.86	(0.34,	2.18)	0.7562	
Rest of the World	16	6	(1/	3/	2)	37.5	33.46	25	8	(1/	6/	1)	32.0	27.99	0.94	(0.32,	2.74)	0.9125	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb). The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed or suspected acute ILD exacerbations, h:Number of hospitalizations for respiratory cause, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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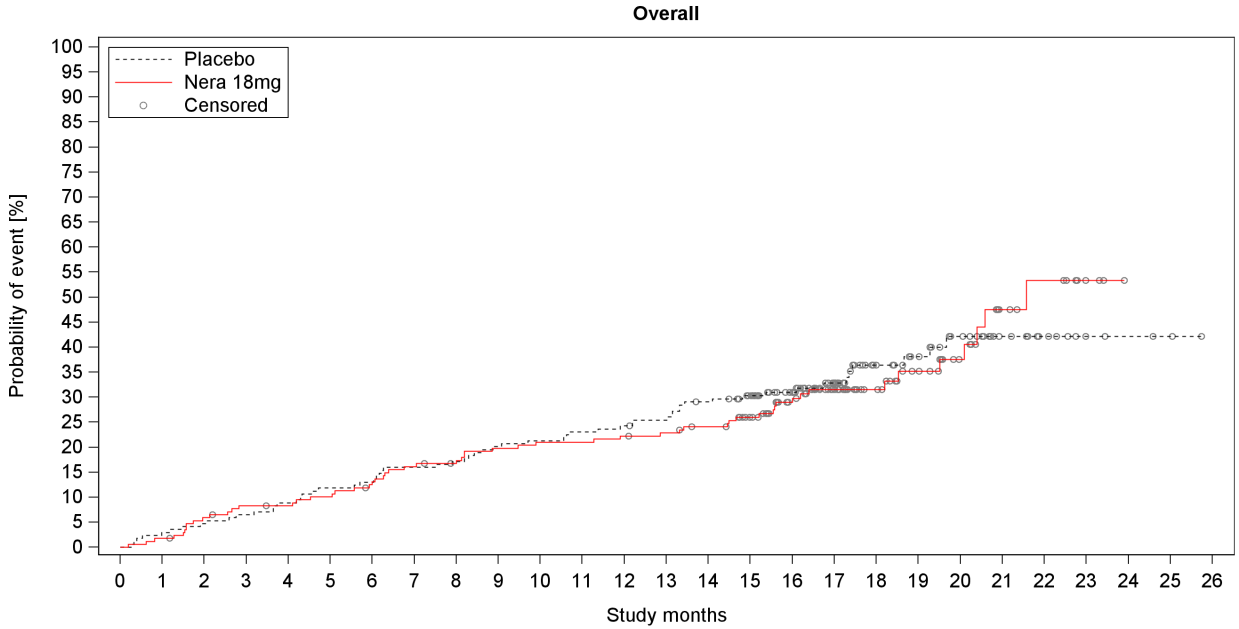

Number at risk (percentage relative to baseline)

Placebo	169	164	161	158	154	149	147	142	140	135	133	130	128	125	118	109	86	66	43	34	25	14	9	4	3	2	0
%	100.0	97.0	95.3	93.5	91.1	88.2	87.0	84.0	82.8	79.9	78.7	76.9	75.7	74.0	69.8	64.5	50.9	39.1	25.4	20.1	14.8	8.3	5.3	2.4	1.8	1.2	0.0
Nera 18mg	170	167	159	154	153	150	145	139	136	131	129	129	127	125	120	108	85	67	43	30	21	11	8	3	0	0	0
%	100.0	98.2	93.5	90.6	90.0	88.2	85.3	81.8	80.0	77.1	75.9	75.9	74.7	73.5	70.6	63.5	50.0	39.4	25.3	17.6	12.4	6.5	4.7	1.8	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	9	31	49	69	77	84	95	100	105	106	107	109
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	1.2	5.3	18.3	29.0	40.8	45.6	49.7	56.2	59.2	62.1	62.7	63.3	64.5
Nera 18mg	0	0	1	2	3	3	4	4	6	6	6	6	6	7	10	19	38	53	77	88	96	103	105	110	113	113	113
%	0.0	0.0	0.6	1.2	1.8	1.8	2.4	2.4	3.5	3.5	3.5	3.5	3.5	4.1	5.9	11.2	22.4	31.2	45.3	51.8	56.5	60.6	61.8	64.7	66.5	66.5	66.5

Study: 1305-0023

Figure I.1.1.1.1.1.1: 1 Time to first confirmed or suspected acute ILD exacerbation, respiratory hospitalisation or death over the whole trial, Kaplan-Meier estimate - 18mg - FAS (NIN background)

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Figure I.1.1.1.1.1: 1

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I.1.1.1.1.1.2 Time to first confirmed acute ILD exacerbation or death

Table I.1.1.1.1.1.2: 1 Cox model for time to first confirmed acute ILD exacerbation or death over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n (e/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (e/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	38 (18/ 20)	22.5	16.92	170	25 (14/ 11)	14.7	10.96	0.58	(0.35,	0.96)	0.0353	
Age													0.5742
<65 years	65	8 (4/ 4)	12.3	8.95	64	6 (4/ 2)	9.4	7.19	0.76	(0.26,	2.19)	0.6073	
>=65 years	104	30 (14/ 16)	28.8	22.20	106	19 (10/ 9)	17.9	13.14	0.54	(0.30,	0.96)	0.0344	
Sex													0.9418
Male	114	31 (15/ 16)	27.2	20.90	108	20 (12/ 8)	18.5	14.17	0.60	(0.34,	1.06)	0.0771	
Female	55	7 (3/ 4)	12.7	9.18	62	5 (2/ 3)	8.1	5.76	0.57	(0.18,	1.81)	0.3430	
Baseline FVC percent predicted													0.1565
<=70%	95	25 (13/ 12)	26.3	20.51	97	13 (9/ 4)	13.4	10.04	0.43	(0.22,	0.85)	0.0154	
>70%	74	13 (5/ 8)	17.6	12.67	73	12 (5/ 7)	16.4	12.18	0.92	(0.42,	2.03)	0.8372	
Baseline HRCT pattern													0.2152
UIP-like	116	24 (13/ 11)	20.7	15.54	121	21 (12/ 9)	17.4	12.92	0.71	(0.39,	1.28)	0.2492	
Other fibrotic patterns	53	14 (5/ 9)	26.4	19.98	49	4 (2/ 2)	8.2	6.11	0.32	(0.10,	0.97)	0.0435	
Underlying ILD diagnosis													0.2393
iNSIP	32	5 (0/ 5)	15.6	11.02	27	8 (5/ 3)	29.6	24.72	1.86	(0.60,	5.75)	0.2825	
Unclassifiable IIP	46	14 (8/ 6)	30.4	24.57	32	6 (3/ 3)	18.8	13.55	0.53	(0.20,	1.38)	0.1921	
HP	38	6 (3/ 3)	15.8	11.58	43	5 (2/ 3)	11.6	8.81	0.58	(0.17,	1.92)	0.3687	
Autoimmune ILD	29	7 (3/ 4)	24.1	17.93	43	4 (2/ 2)	9.3	6.85	0.30	(0.09,	1.04)	0.0569	
Other ILD	24	6 (4/ 2)	25.0	19.13	25	2 (2/ 0)	8.0	5.52	0.35	(0.07,	1.75)	0.2007	
Region													0.8424
Europe	78	17 (8/ 9)	21.8	16.34	67	8 (4/ 4)	11.9	9.06	0.47	(0.20,	1.10)	0.0833	
Asia	45	12 (7/ 5)	26.7	19.74	41	8 (5/ 3)	19.5	14.21	0.55	(0.22,	1.34)	0.1882	
Canada and USA	30	5 (2/ 3)	16.7	12.45	37	5 (4/ 1)	13.5	10.04	0.94	(0.27,	3.25)	0.9175	
Rest of the World	16	4 (1/ 3)	25.0	20.45	25	4 (1/ 3)	16.0	11.90	0.63	(0.15,	2.56)	0.5162	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed acute ILD exacerbations, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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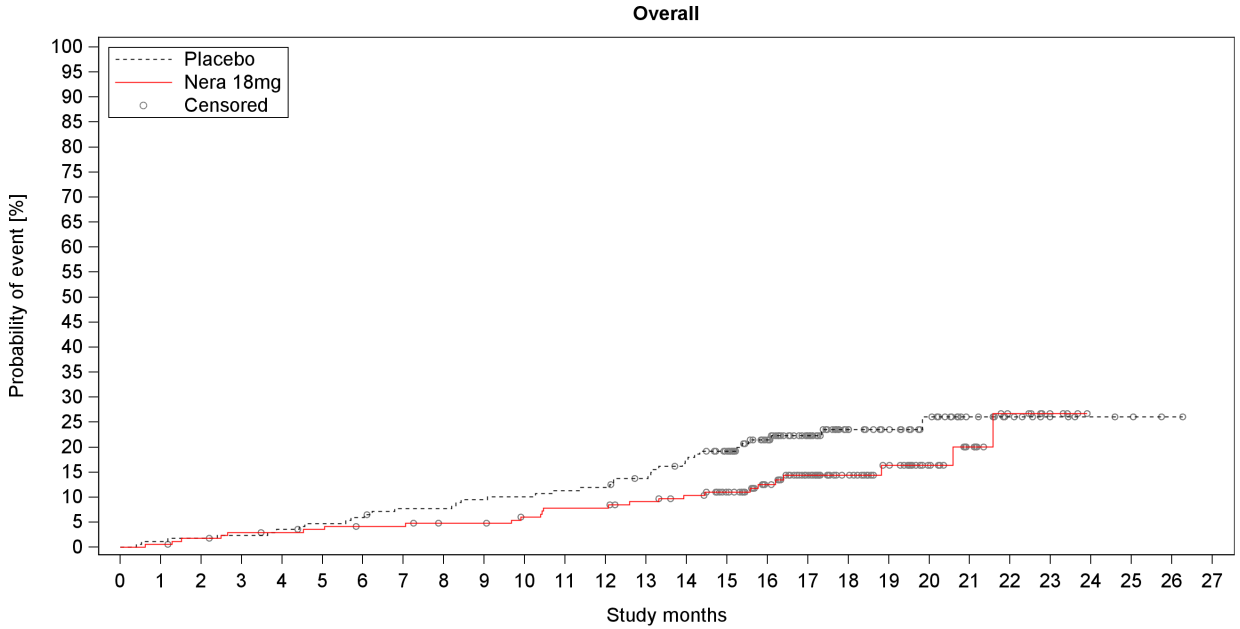

Number at risk (percentage relative to baseline)

Placebo	169	167	166	165	163	160	158	154	154	151	150	148	147	142	135	123	97	77	49	40	29	16	11	6	4	3	1	0
%	100.0	98.8	98.2	97.6	96.4	94.7	93.5	91.1	91.1	89.3	88.8	87.6	87.0	84.0	79.9	72.8	57.4	45.6	29.0	23.7	17.2	9.5	6.5	3.6	2.4	1.8	0.6	0.0
Nera 18mg	170	169	166	163	162	161	159	159	156	156	152	149	149	145	140	129	102	80	53	39	28	16	9	4	0	0	0	0
%	100.0	99.4	97.6	95.9	95.3	94.7	93.5	93.5	91.8	91.8	89.4	87.6	87.6	85.3	82.4	75.9	60.0	47.1	31.2	22.9	16.5	9.4	5.3	2.4	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	1	1	2	2	2	2	2	2	4	5	14	37	56	83	92	102	115	120	125	127	128	130	131
%	0.0	0.0	0.0	0.0	0.0	0.6	0.6	1.2	1.2	1.2	1.2	1.2	1.2	2.4	3.0	8.3	21.9	33.1	49.1	54.4	60.4	68.0	71.0	74.0	75.1	75.7	76.9	77.5
Nera 18mg	0	0	1	2	3	3	4	4	6	6	8	8	8	10	13	23	48	68	95	108	119	130	136	141	145	145	145	145
%	0.0	0.0	0.6	1.2	1.8	1.8	2.4	2.4	3.5	3.5	4.7	4.7	4.7	5.9	7.6	13.5	28.2	40.0	55.9	63.5	70.0	76.5	80.0	82.9	85.3	85.3	85.3	85.3

Study: 1305-0023

Figure I.1.1.1.1.2: 1 Time to first confirmed acute ILD exacerbation or death over the whole trial, Kaplan-Meier estimate - 18mg - FAS (NIN background)

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Figure I.1.1.1.1.2: 1

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I.1.1.1.1.1.3 Time to first confirmed or suspected acute ILD exacerbation or death

Table I.1.1.1.1.1.3: 1 Cox model for time to first confirmed or suspected acute ILD exacerbation or death over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n (e/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (e/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	42 (24/ 18)	24.9	19.04	170	28 (17/ 11)	16.5	12.37	0.58	(0.36, 0.94)	0.0264	
Age												0.2919
<65 years	65	9 (5/ 4)	13.8	10.11	64	8 (6/ 2)	12.5	9.76	0.91	(0.35, 2.36)	0.8393	
>=65 years	104	33 (19/ 14)	31.7	25.08	106	20 (11/ 9)	18.9	13.86	0.50	(0.29, 0.88)	0.0153	
Sex												0.7479
Male	114	34 (19/ 15)	29.8	23.32	108	21 (13/ 8)	19.4	14.91	0.57	(0.33, 0.98)	0.0432	
Female	55	8 (5/ 3)	14.5	10.70	62	7 (4/ 3)	11.3	8.19	0.69	(0.25, 1.90)	0.4697	
Baseline FVC percent predicted												0.2088
<=70%	95	28 (18/ 10)	29.5	23.38	97	16 (12/ 4)	16.5	12.52	0.46	(0.25, 0.85)	0.0135	
>70%	74	14 (6/ 8)	18.9	13.89	73	12 (5/ 7)	16.4	12.18	0.87	(0.40, 1.88)	0.7159	
Baseline HRCT pattern												0.5138
UIP-like	116	27 (17/ 10)	23.3	17.77	121	22 (13/ 9)	18.2	13.60	0.64	(0.36, 1.13)	0.1260	
Other fibrotic patterns	53	15 (7/ 8)	28.3	21.87	49	6 (4/ 2)	12.2	9.29	0.44	(0.17, 1.14)	0.0927	
Underlying ILD diagnosis												0.2517
iNSIP	32	6 (2/ 4)	18.8	13.79	27	9 (6/ 3)	33.3	28.05	1.73	(0.61, 4.91)	0.3057	
Unclassifiable IIP	46	15 (9/ 6)	32.6	26.36	32	6 (3/ 3)	18.8	13.55	0.49	(0.19, 1.28)	0.1476	
HP	38	7 (4/ 3)	18.4	13.62	43	5 (2/ 3)	11.6	8.81	0.50	(0.16, 1.59)	0.2402	
Autoimmune ILD	29	7 (4/ 3)	24.1	18.44	43	6 (4/ 2)	14.0	10.53	0.44	(0.15, 1.32)	0.1440	
Other ILD	24	7 (5/ 2)	29.2	22.72	25	2 (2/ 0)	8.0	5.52	0.27	(0.06, 1.32)	0.1070	
Region												0.9208
Europe	78	19 (12/ 7)	24.4	18.54	67	9 (5/ 4)	13.4	10.28	0.47	(0.21, 1.06)	0.0687	
Asia	45	12 (7/ 5)	26.7	19.74	41	9 (6/ 3)	22.0	16.16	0.61	(0.26, 1.46)	0.2691	
Canada and USA	30	7 (4/ 3)	23.3	18.53	37	6 (5/ 1)	16.2	12.12	0.76	(0.25, 2.27)	0.6211	
Rest of the World	16	4 (1/ 3)	25.0	20.45	25	4 (1/ 3)	16.0	11.90	0.60	(0.15, 2.44)	0.4766	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed or suspected acute ILD exacerbations, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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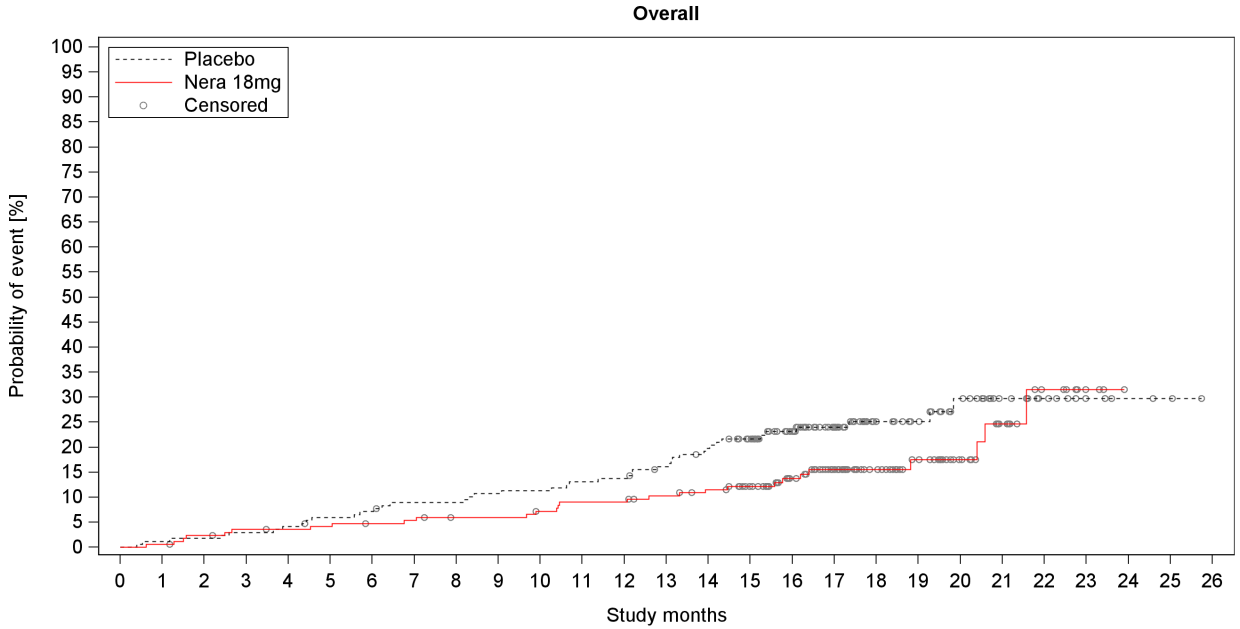

Number at risk (percentage relative to baseline)

Placebo	169	167	166	164	162	158	156	152	152	149	148	145	144	138	131	119	94	74	48	39	27	15	10	5	3	2	0
%	100.0	98.8	98.2	97.0	95.9	93.5	92.3	89.9	89.9	88.2	87.6	85.8	85.2	81.7	77.5	70.4	55.6	43.8	28.4	23.1	16.0	8.9	5.9	3.0	1.8	1.2	0.0
Nera 18mg	170	169	165	162	161	160	158	157	154	154	151	148	148	144	139	128	101	80	53	39	28	15	8	3	0	0	0
%	100.0	99.4	97.1	95.3	94.7	94.1	92.9	92.4	90.6	90.6	88.8	87.1	87.1	84.7	81.8	75.3	59.4	47.1	31.2	22.9	16.5	8.8	4.7	1.8	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	1	1	2	2	2	2	2	2	4	5	14	37	56	81	90	100	112	117	122	124	125	127
%	0.0	0.0	0.0	0.0	0.0	0.6	0.6	1.2	1.2	1.2	1.2	1.2	1.2	2.4	3.0	8.3	21.9	33.1	47.9	53.3	59.2	66.3	69.2	72.2	73.4	74.0	75.1
Nera 18mg	0	0	1	2	3	3	4	4	6	6	7	7	7	9	12	22	47	66	93	106	117	128	134	139	142	142	142
%	0.0	0.0	0.6	1.2	1.8	1.8	2.4	2.4	3.5	3.5	4.1	4.1	4.1	5.3	7.1	12.9	27.6	38.8	54.7	62.4	68.8	75.3	78.8	81.8	83.5	83.5	83.5

Study: 1305-0023

Figure I.1.1.1.1.1.3: 1 Time to first confirmed or suspected acute ILD exacerbation or death over the whole trial, Kaplan-Meier estimate - 18mg - FAS (NIN background)

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Figure I.1.1.1.1.1.3: 1

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I.1.1.1.1.1.4 Time to first respiratory hospitalisation or death

Table I.1.1.1.1.1.4: 1 Cox model for time to first respiratory hospitalisation or death over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n (h/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (h/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio (95% CI)	p-value	Interaction p-value
Overall	169	55 (47/ 8)	32.5	26.08	170	53 (49/ 4)	31.2	25.82	0.90 (0.61, 1.32)	0.5828	
Age											0.7547
<65 years	65	17 (14/ 3)	26.2	20.22	64	14 (12/ 2)	21.9	18.13	0.82 (0.40, 1.69)	0.5894	
>=65 years	104	38 (33/ 5)	36.5	29.98	106	39 (37/ 2)	36.8	30.45	0.94 (0.60, 1.47)	0.7803	
Sex											0.8977
Male	114	44 (36/ 8)	38.6	31.43	108	41 (37/ 4)	38.0	32.23	0.90 (0.59, 1.39)	0.6401	
Female	55	11 (11/ 0)	20.0	15.53	62	12 (12/ 0)	19.4	15.37	0.96 (0.42, 2.18)	0.9207	
Baseline FVC percent predicted											0.2030
<=70%	95	34 (30/ 4)	35.8	29.86	97	30 (27/ 3)	30.9	25.95	0.74 (0.45, 1.22)	0.2365	
>70%	74	21 (17/ 4)	28.4	21.66	73	23 (22/ 1)	31.5	25.66	1.23 (0.68, 2.23)	0.5018	
Baseline HRCT pattern											0.1915
UIP-like	116	35 (32/ 3)	30.2	23.92	121	43 (40/ 3)	35.5	29.68	1.05 (0.67, 1.66)	0.8177	
Other fibrotic patterns	53	20 (15/ 5)	37.7	31.00	49	10 (9/ 1)	20.4	16.56	0.58 (0.27, 1.25)	0.1665	
Underlying ILD diagnosis											0.2584
iNSIP	32	9 (8/ 1)	28.1	22.12	27	11 (10/ 1)	40.7	35.65	1.26 (0.52, 3.08)	0.6108	
Unclassifiable IIP	46	22 (18/ 4)	47.8	39.55	32	9 (8/ 1)	28.1	22.20	0.58 (0.27, 1.27)	0.1712	
HP	38	7 (5/ 2)	18.4	14.26	43	16 (14/ 2)	37.2	32.81	1.93 (0.79, 4.72)	0.1516	
Autoimmune ILD	29	8 (8/ 0)	27.6	21.97	43	10 (10/ 0)	23.3	18.79	0.59 (0.23, 1.54)	0.2787	
Other ILD	24	9 (8/ 1)	37.5	30.97	25	7 (7/ 0)	28.0	21.95	0.91 (0.33, 2.48)	0.8565	
Region											0.9874
Europe	78	25 (21/ 4)	32.1	25.73	67	21 (19/ 2)	31.3	26.70	0.94 (0.52, 1.69)	0.8413	
Asia	45	18 (16/ 2)	40.0	32.39	41	16 (15/ 1)	39.0	32.54	0.82 (0.42, 1.61)	0.5632	
Canada and USA	30	6 (6/ 0)	20.0	14.93	37	8 (8/ 0)	21.6	16.37	1.00 (0.33, 2.98)	0.9987	
Rest of the World	16	6 (4/ 2)	37.5	33.45	25	8 (7/ 1)	32.0	27.99	0.93 (0.32, 2.72)	0.8968	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
h:Number of hospitalizations for respiratory cause, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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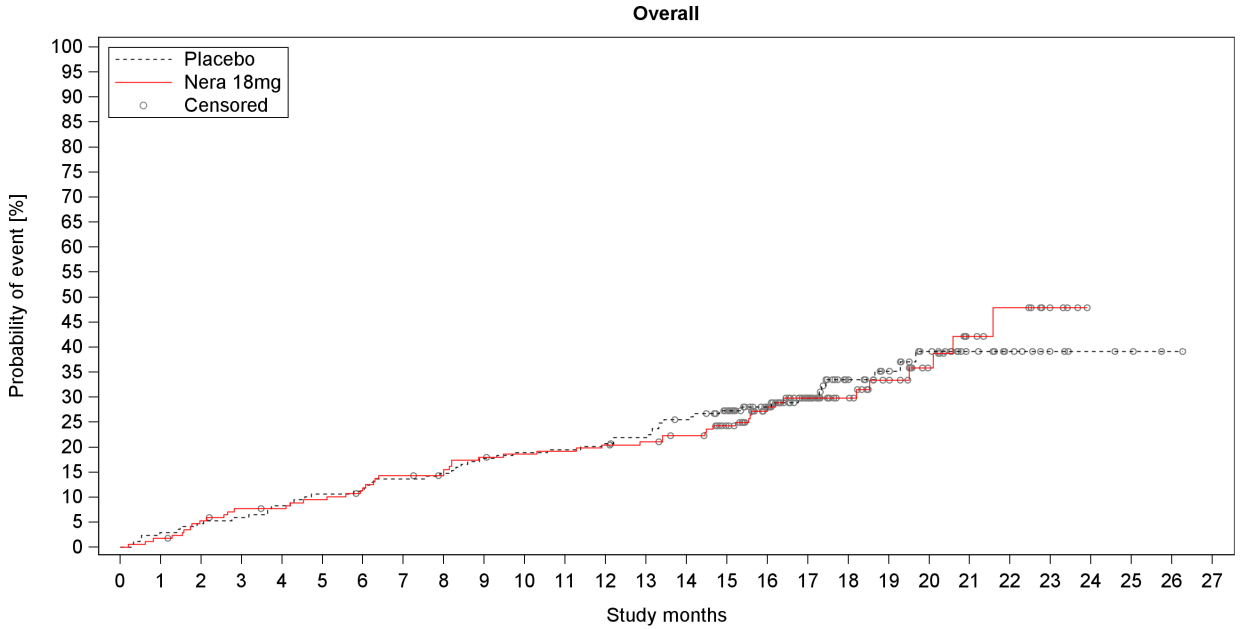

Number at risk (percentage relative to baseline)

Placebo	169	164	161	159	155	151	150	146	144	139	137	136	134	131	124	114	90	69	45	36	27	16	11	6	4	3	1	0
%	100.0	97.0	95.3	94.1	91.7	89.3	88.8	86.4	85.2	82.2	81.1	80.5	79.3	77.5	73.4	67.5	53.3	40.8	26.6	21.3	16.0	9.5	6.5	3.6	2.4	1.8	0.6	0.0
Nera 18mg	170	167	160	155	154	151	147	142	140	134	132	131	129	127	122	110	87	68	44	31	22	12	9	4	0	0	0	0
%	100.0	98.2	94.1	91.2	90.6	88.8	86.5	83.5	82.4	78.8	77.6	77.1	75.9	74.7	71.8	64.7	51.2	40.0	25.9	18.2	12.9	7.1	5.3	2.4	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	9	32	51	72	80	87	98	103	108	110	111	113	114
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	1.2	5.3	18.9	30.2	42.6	47.3	51.5	58.0	60.9	63.9	65.1	65.7	66.9	67.5
Nera 18mg	0	0	1	2	3	3	4	4	6	6	7	7	7	8	11	20	39	55	79	90	98	106	108	113	117	117	117	117
%	0.0	0.0	0.6	1.2	1.8	1.8	2.4	2.4	3.5	3.5	4.1	4.1	4.1	4.7	6.5	11.8	22.9	32.4	46.5	52.9	57.6	62.4	63.5	66.5	68.8	68.8	68.8	68.8

Study: 1305-0023

Figure I.1.1.1.1.4: 1 Time to first respiratory hospitalisation or death over the whole trial, Kaplan-Meier estimate - 18mg - FAS (NIN background)

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Figure I.1.1.1.1.4: 1

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I.1.1.1.1.1.5 Time to first non-elective hospitalisation for any cause or death

Table I.1.1.1.1.1.5: 1 Cox model for time to first non-elective hospitalisation for any cause or death over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n (h/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (h/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	66 (58/ 8)	39.1	32.64	170	68 (66/ 2)	40.0	36.11	1.01	(0.71, 1.42)	0.9669	
Age												0.6958
<65 years	65	21 (18/ 3)	32.3	25.47	64	18 (18/ 0)	28.1	24.76	0.90	(0.47, 1.71)	0.7480	
>=65 years	104	45 (40/ 5)	43.3	37.58	106	50 (48/ 2)	47.2	43.24	1.05	(0.70, 1.57)	0.8237	
Sex												0.5626
Male	114	51 (43/ 8)	44.7	38.31	108	49 (47/ 2)	45.4	41.65	0.96	(0.64, 1.42)	0.8319	
Female	55	15 (15/ 0)	27.3	21.72	62	19 (19/ 0)	30.6	26.88	1.21	(0.61, 2.39)	0.5857	
Baseline FVC percent predicted												0.0099
<=70%	95	43 (39/ 4)	45.3	40.27	97	36 (35/ 1)	37.1	33.01	0.69	(0.44, 1.09)	0.1108	
>70%	74	23 (19/ 4)	31.1	24.11	73	32 (31/ 1)	43.8	40.37	1.75	(1.02, 3.01)	0.0419	
Baseline HRCT pattern												0.3579
UIP-like	116	44 (41/ 3)	37.9	31.62	121	54 (52/ 2)	44.6	41.00	1.11	(0.74, 1.66)	0.6056	
Other fibrotic patterns	53	22 (17/ 5)	41.5	34.90	49	14 (14/ 0)	28.6	24.72	0.77	(0.39, 1.51)	0.4457	
Underlying ILD diagnosis												0.1337
iNSIP	32	11 (10/ 1)	34.4	28.17	27	13 (13/ 0)	48.1	46.69	1.35	(0.60, 3.04)	0.4707	
Unclassifiable IIP	46	26 (22/ 4)	56.5	50.56	32	11 (10/ 1)	34.4	28.08	0.55	(0.27, 1.12)	0.1000	
HP	38	8 (6/ 2)	21.1	16.67	43	17 (16/ 1)	39.5	36.24	1.90	(0.81, 4.42)	0.1380	
Autoimmune ILD	29	11 (11/ 0)	37.9	31.44	43	15 (15/ 0)	34.9	31.28	0.75	(0.34, 1.67)	0.4836	
Other ILD	24	10 (9/ 1)	41.7	34.81	25	12 (12/ 0)	48.0	45.41	1.58	(0.67, 3.71)	0.2922	
Region												0.9002
Europe	78	30 (26/ 4)	38.5	32.07	67	25 (24/ 1)	37.3	34.07	0.98	(0.57, 1.68)	0.9467	
Asia	45	24 (22/ 2)	53.3	46.64	41	23 (23/ 0)	56.1	54.47	0.93	(0.52, 1.65)	0.7931	
Canada and USA	30	6 (6/ 0)	20.0	15.30	37	11 (11/ 0)	29.7	24.32	1.43	(0.52, 3.95)	0.4884	
Rest of the World	16	6 (4/ 2)	37.5	33.45	25	9 (8/ 1)	36.0	32.74	1.11	(0.39, 3.16)	0.8389	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
h:Number of non-elective hospitalizations for any cause, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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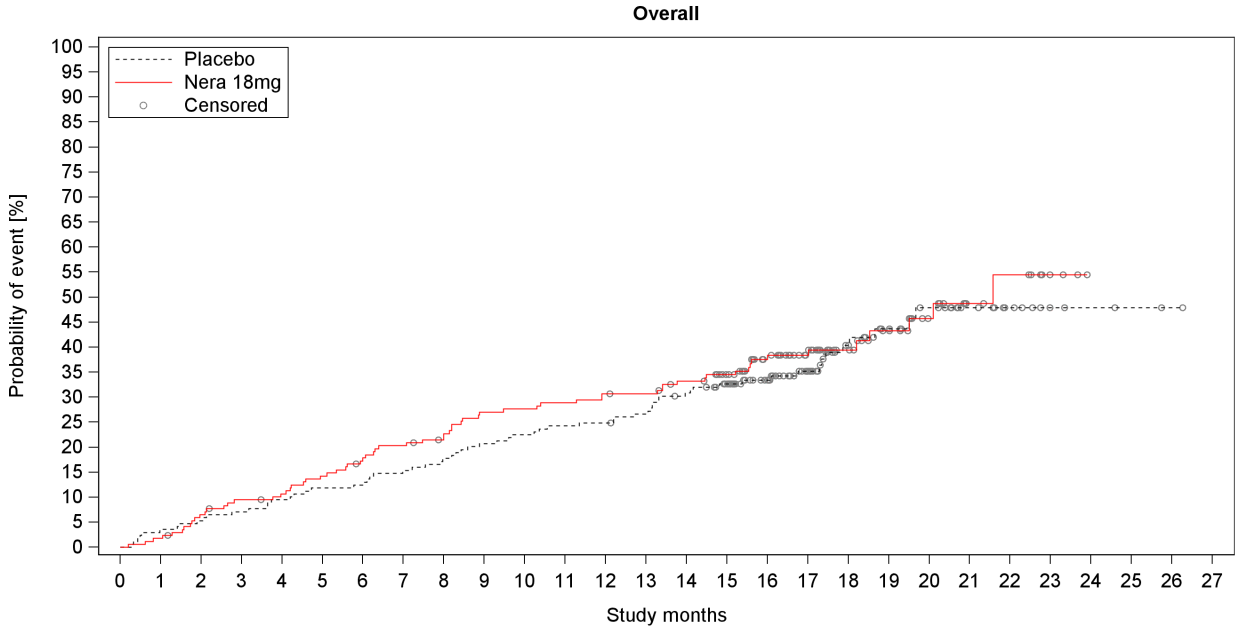

Number at risk (percentage relative to baseline)

Placebo	169	163	160	157	153	149	148	143	139	134	131	128	127	123	115	106	83	63	40	31	23	14	9	4	3	2	1	0
%	100.0	96.4	94.7	92.9	90.5	88.2	87.6	84.6	82.2	79.3	77.5	75.7	75.1	72.8	68.0	62.7	49.1	37.3	23.7	18.3	13.6	8.3	5.3	2.4	1.8	1.2	0.6	0.0
Nera 18mg	170	167	158	152	149	143	137	132	128	119	118	116	113	112	105	94	73	57	36	26	18	10	8	3	0	0	0	0
%	100.0	98.2	92.9	89.4	87.6	84.1	80.6	77.6	75.3	70.0	69.4	68.2	66.5	65.9	61.8	55.3	42.9	33.5	21.2	15.3	10.6	5.9	4.7	1.8	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	8	30	48	67	74	80	89	94	99	100	101	102	103
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	1.2	4.7	17.8	28.4	39.6	43.8	47.3	52.7	55.6	58.6	59.2	59.8	60.4	60.9
Nera 18mg	0	0	1	2	3	3	4	4	6	6	6	6	6	7	10	19	36	51	71	79	86	93	94	99	102	102	102	102
%	0.0	0.0	0.6	1.2	1.8	1.8	2.4	2.4	3.5	3.5	3.5	3.5	3.5	4.1	5.9	11.2	21.2	30.0	41.8	46.5	50.6	54.7	55.3	58.2	60.0	60.0	60.0	60.0

Study: 1305-0023

Figure I.1.1.1.1.5: 1 Time to first non-elective hospitalisation for any cause or death over the whole trial, Kaplan-Meier estimate - 18mg - FAS (NIN background)

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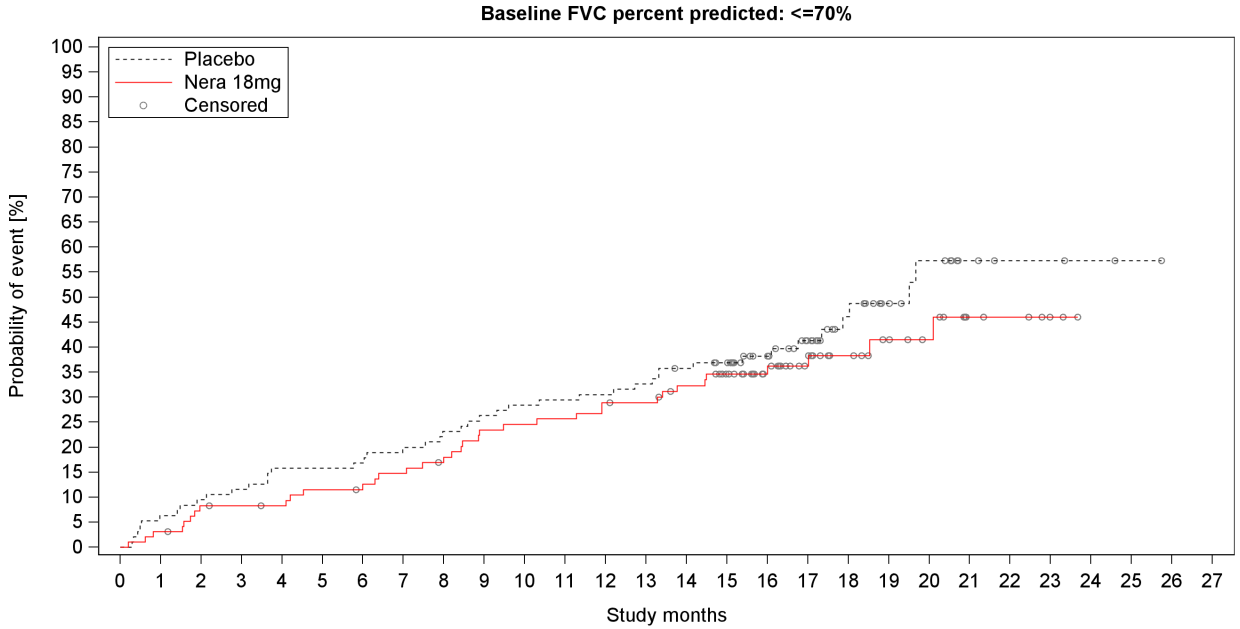

Number at risk (percentage relative to baseline)

Placebo	95	89	86	84	80	80	79	76	73	70	68	67	66	64	60	57	44	33	21	15	10	5	3	3	2	1	0	0
%	100.0	93.7	90.5	88.4	84.2	84.2	83.2	80.0	76.8	73.7	71.6	70.5	69.5	67.4	63.2	60.0	46.3	34.7	22.1	15.8	10.5	5.3	3.2	3.2	2.1	1.1	0.0	0.0
Nera 18mg	97	94	88	87	86	83	82	79	76	70	69	68	65	64	59	53	41	31	22	16	13	6	5	2	0	0	0	0
%	100.0	96.9	90.7	89.7	88.7	85.6	84.5	81.4	78.4	72.2	71.1	70.1	67.0	66.0	60.8	54.6	42.3	32.0	22.7	16.5	13.4	6.2	5.2	2.1	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	3	15	24	34	39	42	47	49	49	50	51	52	52
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	3.2	15.8	25.3	35.8	41.1	44.2	49.5	51.6	51.6	52.6	53.7	54.7	54.7
Nera 18mg	0	0	1	2	3	3	4	4	5	5	5	5	5	6	8	12	24	33	41	46	49	55	56	59	61	61	61	61
%	0.0	0.0	1.0	2.1	3.1	3.1	4.1	4.1	5.2	5.2	5.2	5.2	5.2	6.2	8.2	12.4	24.7	34.0	42.3	47.4	50.5	56.7	57.7	60.8	62.9	62.9	62.9	62.9

Study: 1305-0023

Figure I.1.1.1.1.5: 1 Time to first non-elective hospitalisation for any cause or death over the whole trial, Kaplan-Meier estimate - 18mg - FAS (NIN background)

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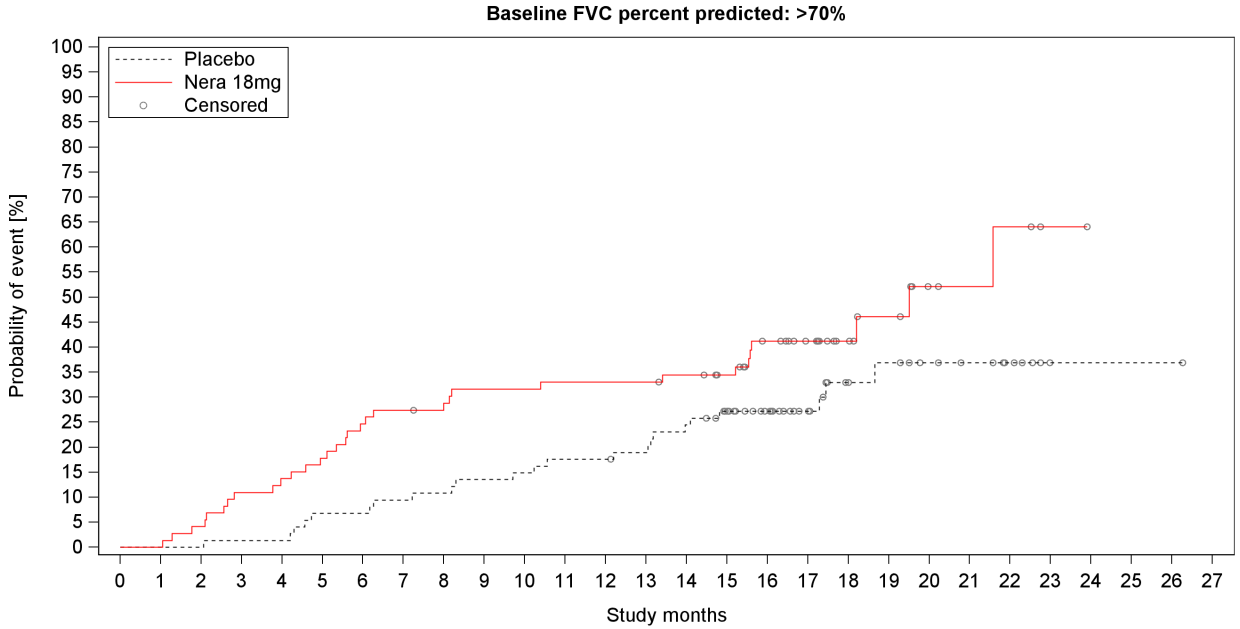

Number at risk (percentage relative to baseline)

Placebo	74	74	74	73	73	69	69	67	66	64	63	61	61	59	55	49	39	30	19	16	13	9	6	1	1	1	1	0
%	100.0	100.0	100.0	98.6	98.6	93.2	93.2	90.5	89.2	86.5	85.1	82.4	82.4	79.7	74.3	66.2	52.7	40.5	25.7	21.6	17.6	12.2	8.1	1.4	1.4	1.4	1.4	0.0
Nera 18mg	73	73	70	65	63	60	55	53	52	49	49	48	48	48	46	41	32	26	14	10	5	4	3	1	0	0	0	0
%	100.0	100.0	95.9	89.0	86.3	82.2	75.3	72.6	71.2	67.1	67.1	65.8	65.8	65.8	63.0	56.2	43.8	35.6	19.2	13.7	6.8	5.5	4.1	1.4	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	5	15	24	33	35	38	42	45	50	50	50	50	51
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.4	1.4	6.8	20.3	32.4	44.6	47.3	51.4	56.8	60.8	67.6	67.6	67.6	67.6	68.9
Nera 18mg	0	0	0	0	0	0	0	0	1	1	1	1	1	1	2	7	12	18	30	33	37	38	38	40	41	41	41	41
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.4	1.4	1.4	1.4	1.4	1.4	2.7	9.6	16.4	24.7	41.1	45.2	50.7	52.1	52.1	54.8	56.2	56.2	56.2	56.2

Study: 1305-0023

Figure I.1.1.1.1.5: 1 Time to first non-elective hospitalisation for any cause or death over the whole trial, Kaplan-Meier estimate - 18mg - FAS (NIN background)

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I.1.1.1.1.2 Analyses of single endpoints

I.1.1.1.1.2.1 Time to death

Table I.1.1.1.1.2.1: 1 Cox model for time to death over the whole trial
- 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	28	16.6	12.01	170	18	10.6	7.72	0.54	(0.30,	0.97)	0.0407	
Age													0.7196
<65 years	65	5	7.7	5.38	64	3	4.7	3.55	0.69	(0.16,	2.90)	0.6118	
>=65 years	104	23	22.1	16.39	106	15	14.2	10.09	0.52	(0.27,	0.99)	0.0480	
Sex													0.8756
Male	114	23	20.2	14.90	108	14	13.0	9.62	0.54	(0.27,	1.04)	0.0668	
Female	55	5	9.1	6.34	62	4	6.5	4.57	0.60	(0.16,	2.26)	0.4532	
Baseline FVC percent predicted													0.1869
<=70%	95	18	18.9	14.09	97	9	9.3	6.78	0.39	(0.18,	0.88)	0.0238	
>70%	74	10	13.5	9.48	73	9	12.3	8.97	0.90	(0.36,	2.23)	0.8121	
Baseline HRCT pattern													0.4952
UIP-like	116	19	16.4	11.89	121	15	12.4	8.96	0.60	(0.31,	1.19)	0.1463	
Other fibrotic patterns	53	9	17.0	12.26	49	3	6.1	4.57	0.36	(0.10,	1.34)	0.1273	
Underlying ILD diagnosis													0.4619
iNSIP	32	5	15.6	11.02	27	7	25.9	20.60	1.33	(0.41,	4.28)	0.6308	
Unclassifiable IIP	46	9	19.6	14.85	32	4	12.5	8.66	0.53	(0.16,	1.75)	0.3004	
HP	38	3	7.9	5.59	43	4	9.3	7.00	0.82	(0.18,	3.76)	0.7941	
Autoimmune ILD	29	6	20.7	14.74	43	3	7.0	5.05	0.24	(0.06,	0.98)	0.0462	
Other ILD	24	5	20.8	15.22	25	0	0.0	0.00	0.00	(NC,	NC)	0.9878	
Region													0.9871
Europe	78	12	15.4	11.17	67	6	9.0	6.77	0.47	(0.17,	1.28)	0.1405	
Asia	45	9	20.0	13.96	41	6	14.6	10.21	0.59	(0.21,	1.66)	0.3148	
Canada and USA	30	3	10.0	7.19	37	2	5.4	3.85	0.52	(0.09,	3.13)	0.4730	
Rest of the World	16	4	25.0	20.41	25	4	16.0	11.89	0.62	(0.15,	2.57)	0.5145	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment,
baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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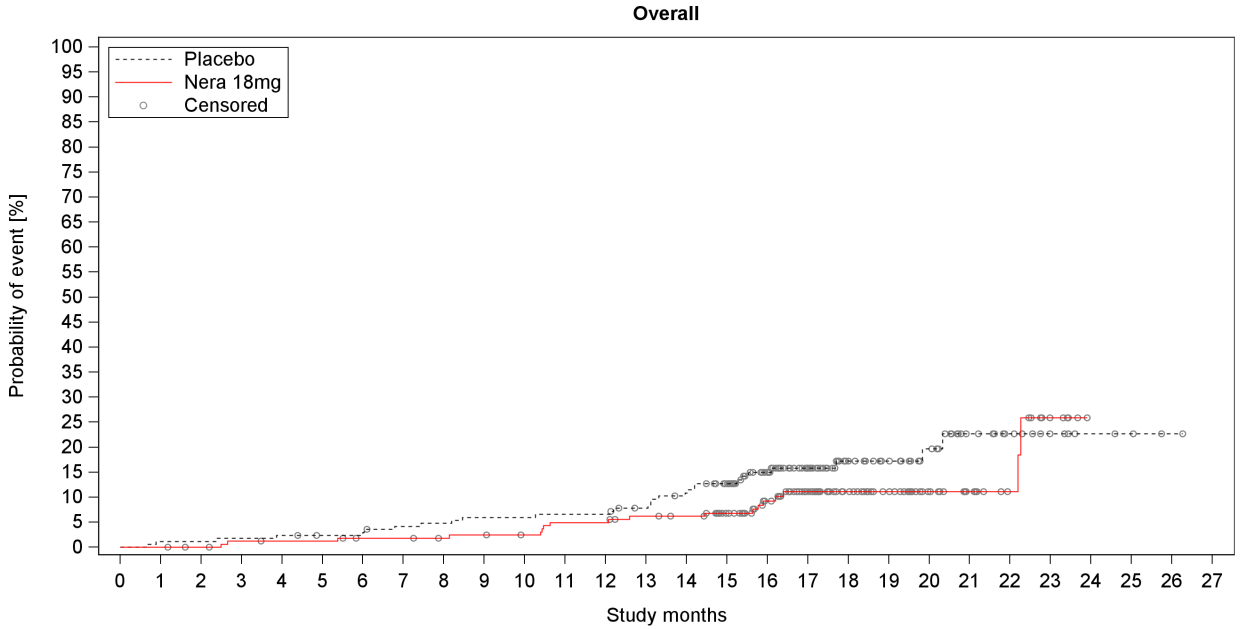

Number at risk (percentage relative to baseline)

Placebo	169	167	167	166	165	163	163	159	158	156	156	155	155	150	144	132	105	84	54	43	32	18	13	7	4	3	1	0
%	100.0	98.8	98.8	98.2	97.6	96.4	96.4	94.1	93.5	92.3	92.3	91.7	91.7	88.8	85.2	78.1	62.1	49.7	32.0	25.4	18.9	10.7	7.7	4.1	2.4	1.8	0.6	0.0
Nera 18mg	170	170	168	165	164	164	161	161	159	158	156	152	152	148	145	133	105	83	55	42	30	18	12	5	0	0	0	0
%	100.0	100.0	98.8	97.1	96.5	96.5	94.7	94.7	93.5	92.9	91.8	89.4	89.4	87.1	85.3	78.2	61.8	48.8	32.4	24.7	17.6	10.6	7.1	2.9	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	2	2	3	3	3	3	3	3	6	7	16	40	60	89	100	110	123	128	134	137	138	140	141
%	0.0	0.0	0.0	0.0	0.0	1.2	1.2	1.8	1.8	1.8	1.8	1.8	1.8	3.6	4.1	9.5	23.7	35.5	52.7	59.2	65.1	72.8	75.7	79.3	81.1	81.7	82.8	83.4
Nera 18mg	0	0	2	3	4	4	6	6	8	8	10	10	10	12	15	26	51	71	99	112	124	136	142	147	152	152	152	152
%	0.0	0.0	1.2	1.8	2.4	2.4	3.5	3.5	4.7	4.7	5.9	5.9	5.9	7.1	8.8	15.3	30.0	41.8	58.2	65.9	72.9	80.0	83.5	86.5	89.4	89.4	89.4	89.4

Study: 1305-0023

Figure I.1.1.1.1.2.1: 1 Time to death over the whole trial, Kaplan-Meier estimate - 18mg - FAS (NIN background)

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BI Trial No.: x1305p3.hta

Figure I.1.1.1.1.2.1: 1

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I.1.1.1.1.2.2 Time to first confirmed acute ILD exacerbation

Table I.1.1.1.1.2.2: 1 Cox model for time to first confirmed acute ILD exacerbation over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	18	10.7	8.02	170	14	8.2	6.14	0.70	(0.35, 1.41)	0.3182	
Age												0.5694
<65 years	65	4	6.2	4.48	64	4	6.3	4.80	0.98	(0.24, 3.96)	0.9795	
>=65 years	104	14	13.5	10.36	106	10	9.4	6.92	0.61	(0.27, 1.39)	0.2434	
Sex												0.6681
Male	114	15	13.2	10.12	108	12	11.1	8.50	0.78	(0.36, 1.69)	0.5347	
Female	55	3	5.5	3.94	62	2	3.2	2.30	0.51	(0.09, 3.08)	0.4651	
Baseline FVC percent predicted												0.5044
<=70%	95	13	13.7	10.67	97	9	9.3	6.95	0.60	(0.25, 1.40)	0.2350	
>70%	74	5	6.8	4.87	73	5	6.8	5.08	1.00	(0.29, 3.45)	0.9938	
Baseline HRCT pattern												0.5377
UIP-like	116	13	11.2	8.42	121	12	9.9	7.39	0.79	(0.36, 1.74)	0.5512	
Other fibrotic patterns	53	5	9.4	7.14	49	2	4.1	3.05	0.44	(0.09, 2.29)	0.3302	
Underlying ILD diagnosis												0.9993
iNSIP	32	0	0.0	0.00	27	5	18.5	15.45	>10	(NC, NC)	0.9885	
Unclassifiable IIP	46	8	17.4	14.04	32	3	9.4	6.77	0.44	(0.12, 1.68)	0.2294	
HP	38	3	7.9	5.79	43	2	4.7	3.52	0.53	(0.09, 3.18)	0.4835	
Autoimmune ILD	29	3	10.3	7.69	43	2	4.7	3.43	0.37	(0.06, 2.24)	0.2781	
Other ILD	24	4	16.7	12.75	25	2	8.0	5.52	0.41	(0.07, 2.31)	0.3153	
Region												0.6978
Europe	78	8	10.3	7.69	67	4	6.0	4.53	0.50	(0.15, 1.68)	0.2647	
Asia	45	7	15.6	11.52	41	5	12.2	8.88	0.63	(0.20, 2.02)	0.4386	
Canada and USA	30	2	6.7	4.98	37	4	10.8	8.03	1.75	(0.32, 9.59)	0.5181	
Rest of the World	16	1	6.3	5.11	25	1	4.0	2.98	0.71	(0.04, 11.48)	0.8070	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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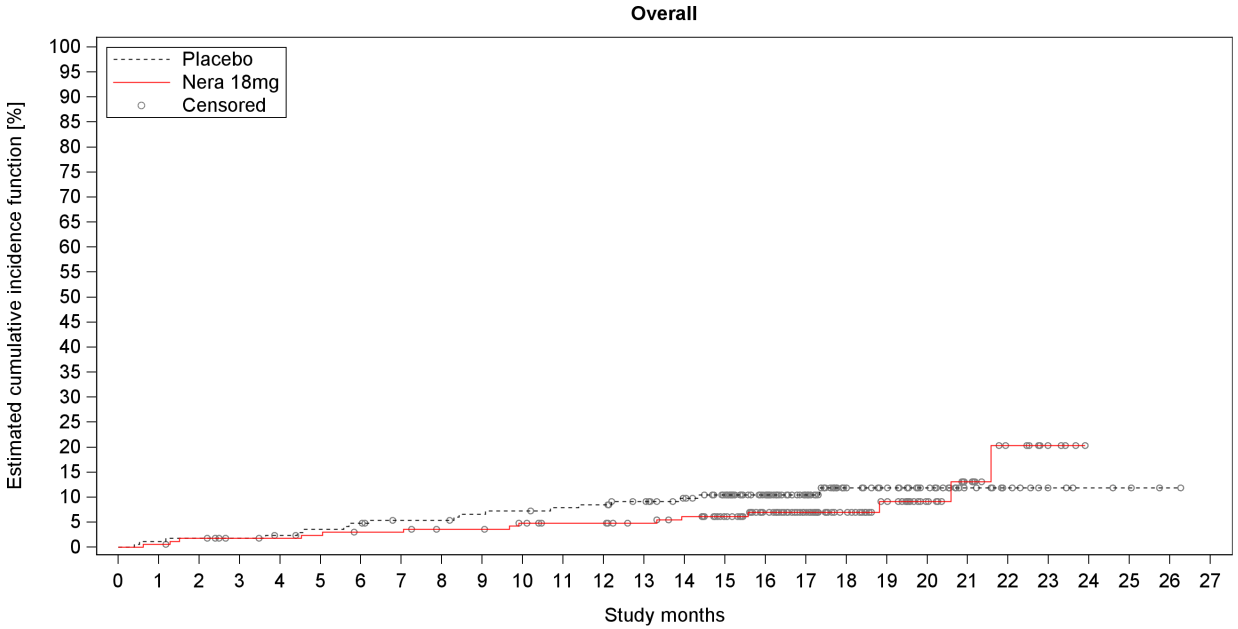

Number at risk (percentage relative to baseline)

Placebo	169	167	166	165	163	160	158	154	154	151	150	148	147	142	135	123	96	77	49	40	29	16	11	6	4	3	1	0
%	100.0	98.8	98.2	97.6	96.4	94.7	93.5	91.1	91.1	89.3	88.8	87.6	87.0	84.0	79.9	72.8	56.8	45.6	29.0	23.7	17.2	9.5	6.5	3.6	2.4	1.8	0.6	0.0
Nera 18mg	170	169	166	163	162	161	159	159	156	156	152	149	149	145	140	129	102	80	53	39	28	16	9	4	0	0	0	0
%	100.0	99.4	97.6	95.9	95.3	94.7	93.5	93.5	91.8	91.8	89.4	87.6	87.6	85.3	82.4	75.9	60.0	47.1	31.2	22.9	16.5	9.4	5.3	2.4	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	1	2	3	3	6	6	7	7	8	8	12	18	29	56	75	102	111	122	135	140	145	147	148	150	151
%	0.0	0.0	0.0	0.6	1.2	1.8	1.8	3.6	3.6	4.1	4.1	4.7	4.7	7.1	10.7	17.2	33.1	44.4	60.4	65.7	72.2	79.9	82.8	85.8	87.0	87.6	88.8	89.3
Nera 18mg	0	0	1	4	5	5	6	6	8	8	10	13	13	17	20	31	57	79	106	119	130	141	147	152	156	156	156	156
%	0.0	0.0	0.6	2.4	2.9	2.9	3.5	3.5	4.7	4.7	5.9	7.6	7.6	10.0	11.8	18.2	33.5	46.5	62.4	70.0	76.5	82.9	86.5	89.4	91.8	91.8	91.8	91.8

Study: 1305-0023

Figure I.1.1.1.1.2.2: 1 Time to first confirmed acute ILD exacerbation over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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Figure I.1.1.1.2.2: 1

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I.1.1.1.1.2.3 Time to first confirmed or suspected acute ILD exacerbation

Table I.1.1.1.1.2.3: 1 Cox model for time to first confirmed or suspected acute ILD exacerbation over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	24	14.2	10.88	170	17	10.0	7.51	0.63	(0.34, 1.18)	0.1487	
Age												0.2207
<65 years	65	5	7.7	5.62	64	6	9.4	7.32	1.18	(0.36, 3.89)	0.7863	
>=65 years	104	19	18.3	14.44	106	11	10.4	7.62	0.49	(0.23, 1.04)	0.0618	
Sex												0.9535
Male	114	19	16.7	13.03	108	13	12.0	9.23	0.65	(0.32, 1.33)	0.2405	
Female	55	5	9.1	6.69	62	4	6.5	4.68	0.63	(0.17, 2.34)	0.4858	
Baseline FVC percent predicted												0.5441
<=70%	95	18	18.9	15.03	97	12	12.4	9.39	0.56	(0.27, 1.17)	0.1202	
>70%	74	6	8.1	5.95	73	5	6.8	5.08	0.86	(0.26, 2.83)	0.8037	
Baseline HRCT pattern												0.9532
UIP-like	116	17	14.7	11.19	121	13	10.7	8.04	0.62	(0.30, 1.29)	0.2044	
Other fibrotic patterns	53	7	13.2	10.21	49	4	8.2	6.19	0.65	(0.19, 2.23)	0.4937	
Underlying ILD diagnosis												0.1744
iNSIP	32	2	6.3	4.60	27	6	22.2	18.70	3.98	(0.79, 19.95)	0.0933	
Unclassifiable IIP	46	9	19.6	15.82	32	3	9.4	6.77	0.40	(0.11, 1.51)	0.1784	
HP	38	4	10.5	7.78	43	2	4.7	3.52	0.39	(0.07, 2.13)	0.2744	
Autoimmune ILD	29	4	13.8	10.54	43	4	9.3	7.03	0.55	(0.13, 2.21)	0.3960	
Other ILD	24	5	20.8	16.23	25	2	8.0	5.52	0.32	(0.06, 1.69)	0.1798	
Region												0.7461
Europe	78	12	15.4	11.72	67	5	7.5	5.71	0.43	(0.15, 1.23)	0.1148	
Asia	45	7	15.6	11.52	41	6	14.6	10.78	0.74	(0.24, 2.21)	0.5852	
Canada and USA	30	4	13.3	10.59	37	5	13.5	10.10	1.08	(0.29, 4.06)	0.9046	
Rest of the World	16	1	6.3	5.11	25	1	4.0	2.98	0.63	(0.04, 10.16)	0.7426	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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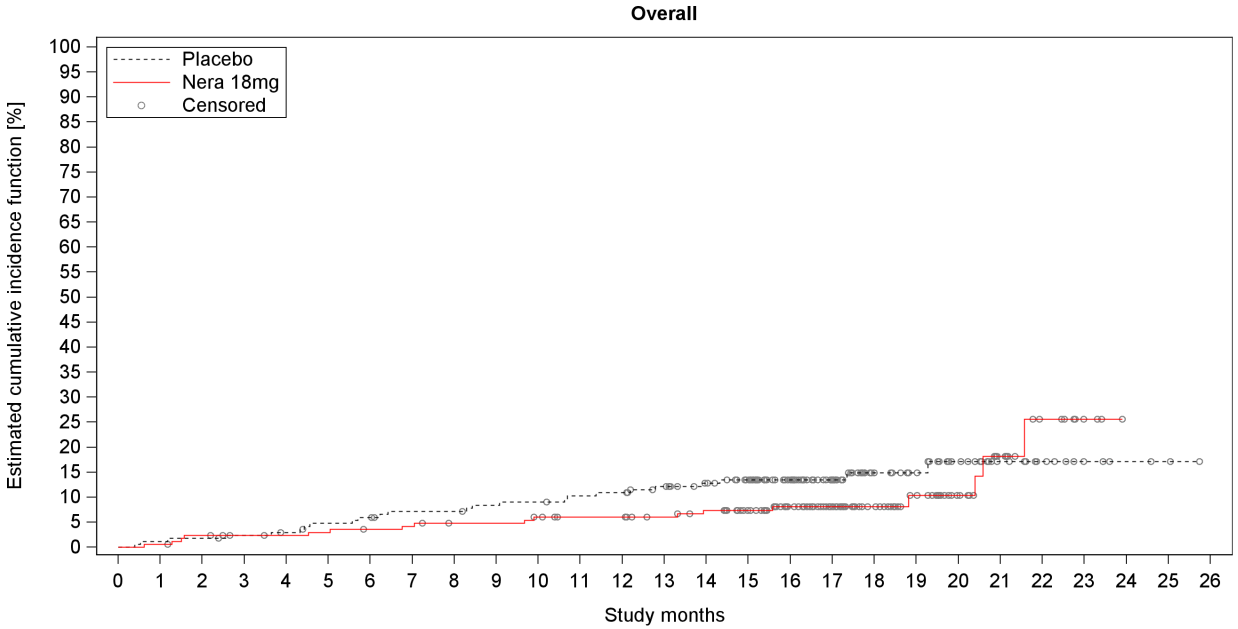

Number at risk (percentage relative to baseline)																										
Placebo	169	167	166	164	162	158	156	152	152	149	148	145	144	138	131	119	93	74	48	39	27	15	10	5	3	2	0
%	100.0	98.8	98.2	97.0	95.9	93.5	92.3	89.9	89.9	88.2	87.6	85.8	85.2	81.7	77.5	70.4	55.0	43.8	28.4	23.1	16.0	8.9	5.9	3.0	1.8	1.2	0.0
Nera 18mg	170	169	165	162	161	160	158	157	154	154	151	148	148	144	139	128	101	80	53	39	28	15	8	3	0	0	0
%	100.0	99.4	97.1	95.3	94.7	94.1	92.9	92.4	90.6	90.6	88.8	87.1	87.1	84.7	81.8	75.3	59.4	47.1	31.2	22.9	16.5	8.8	4.7	1.8	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																											
Placebo	0	0	0	1	2	3	3	5	5	6	6	7	7	11	17	28	54	73	98	107	118	130	135	140	142	143	145
%	0.0	0.0	0.0	0.6	1.2	1.8	1.8	3.0	3.0	3.6	3.6	4.1	4.1	6.5	10.1	16.6	32.0	43.2	58.0	63.3	69.8	76.9	79.9	82.8	84.0	84.6	85.8
Nera 18mg	0	0	1	4	5	5	6	6	8	8	9	12	12	16	19	30	56	77	104	117	128	139	145	150	153	153	153
%	0.0	0.0	0.6	2.4	2.9	2.9	3.5	3.5	4.7	4.7	5.3	7.1	7.1	9.4	11.2	17.6	32.9	45.3	61.2	68.8	75.3	81.8	85.3	88.2	90.0	90.0	90.0

Study: 1305-0023

Figure I.1.1.1.1.2.3: 1 Time to first confirmed or suspected acute ILD exacerbation over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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I.1.1.1.1.2.4 Time to first respiratory hospitalisation

Table I.1.1.1.1.2.4: 1 Cox model for time to first respiratory hospitalisation over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	47	27.8	22.29	170	49	28.8	23.87	0.96	(0.64,	1.44)	0.8510	
Age													0.6609
<65 years	65	14	21.5	16.65	64	12	18.8	15.54	0.82	(0.37,	1.82)	0.6289	
>=65 years	104	33	31.7	26.03	106	37	34.9	28.89	1.01	(0.63,	1.62)	0.9648	
Sex													0.8849
Male	114	36	31.6	25.72	108	37	34.3	29.08	0.99	(0.62,	1.58)	0.9732	
Female	55	11	20.0	15.53	62	12	19.4	15.37	0.93	(0.41,	2.11)	0.8533	
Baseline FVC percent predicted													0.1198
<=70%	95	30	31.6	26.35	97	27	27.8	23.35	0.75	(0.44,	1.26)	0.2743	
>70%	74	17	23.0	17.53	73	22	30.1	24.54	1.44	(0.76,	2.72)	0.2643	
Baseline HRCT pattern													0.3871
UIP-like	116	32	27.6	21.87	121	40	33.1	27.61	1.07	(0.67,	1.71)	0.7826	
Other fibrotic patterns	53	15	28.3	23.25	49	9	18.4	14.91	0.70	(0.31,	1.61)	0.4015	
Underlying ILD diagnosis													0.2419
iNSIP	32	8	25.0	19.66	27	10	37.0	32.41	1.33	(0.52,	3.40)	0.5548	
Unclassifiable IIP	46	18	39.1	32.37	32	8	25.0	19.73	0.62	(0.27,	1.43)	0.2582	
HP	38	5	13.2	10.19	43	14	32.6	28.71	2.35	(0.84,	6.59)	0.1029	
Autoimmune ILD	29	8	27.6	21.97	43	10	23.3	18.79	0.59	(0.23,	1.54)	0.2803	
Other ILD	24	8	33.3	27.53	25	7	28.0	21.95	0.97	(0.35,	2.72)	0.9581	
Region													0.9710
Europe	78	21	26.9	21.62	67	19	28.4	24.15	1.00	(0.54,	1.88)	0.9955	
Asia	45	16	35.6	28.79	41	15	36.6	30.51	0.87	(0.43,	1.76)	0.6956	
Canada and USA	30	6	20.0	14.93	37	8	21.6	16.37	0.97	(0.32,	2.89)	0.9517	
Rest of the World	16	4	25.0	22.30	25	7	28.0	24.49	1.22	(0.35,	4.22)	0.7506	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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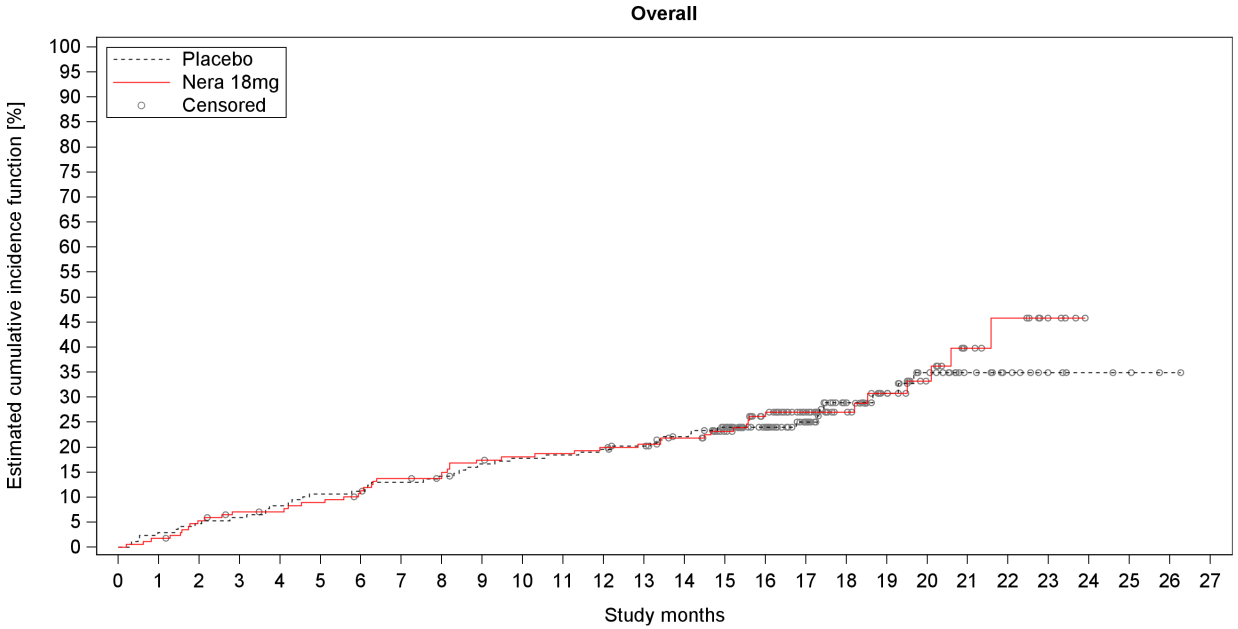

Number at risk (percentage relative to baseline)																												
Placebo	169	164	161	159	155	151	150	146	144	139	137	136	134	131	124	114	89	69	45	36	27	16	11	6	4	3	1	0
%	100.0	97.0	95.3	94.1	91.7	89.3	88.8	86.4	85.2	82.2	81.1	80.5	79.3	77.5	73.4	67.5	52.7	40.8	26.6	21.3	16.0	9.5	6.5	3.6	2.4	1.8	0.6	0.0
Nera 18mg	170	167	160	155	154	151	147	142	140	134	132	131	129	127	122	110	87	68	44	31	22	12	9	4	0	0	0	0
%	100.0	98.2	94.1	91.2	90.6	88.8	86.5	83.5	82.4	78.8	77.6	77.1	75.9	74.7	71.8	64.7	51.2	40.0	25.9	18.2	12.9	7.1	5.3	2.4	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																												
Placebo	0	0	0	0	0	0	0	1	1	2	2	2	2	4	8	15	40	59	80	88	95	106	111	116	118	119	121	122
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.6	1.2	1.2	1.2	1.2	2.4	4.7	8.9	23.7	34.9	47.3	52.1	56.2	62.7	65.7	68.6	69.8	70.4	71.6	72.2
Nera 18mg	0	0	1	3	4	4	5	5	7	7	8	8	8	9	12	22	41	59	83	94	102	110	112	117	121	121	121	121
%	0.0	0.0	0.6	1.8	2.4	2.4	2.9	2.9	4.1	4.1	4.7	4.7	4.7	5.3	7.1	12.9	24.1	34.7	48.8	55.3	60.0	64.7	65.9	68.8	71.2	71.2	71.2	71.2

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Figure I.1.1.1.1.2.4: 1 Time to first respiratory hospitalisation over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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Figure I.1.1.1.1.2.4: 1

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I.1.1.1.1.2.5 Time to first non-elective hospitalisation for any cause

Table I.1.1.1.1.2.5: 1 Cox model for time to first non-elective hospitalisation for any cause over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	58	34.3	28.69	170	66	38.8	35.05	1.11	(0.77,	1.58)	0.5790	
Age													0.8296
<65 years	65	18	27.7	21.84	64	18	28.1	24.76	1.03	(0.53,	2.01)	0.9275	
>=65 years	104	40	38.5	33.40	106	48	45.3	41.51	1.12	(0.74,	1.72)	0.5869	
Sex													0.8429
Male	114	43	37.7	32.31	108	47	43.5	39.95	1.09	(0.72,	1.66)	0.6884	
Female	55	15	27.3	21.72	62	19	30.6	26.88	1.18	(0.60,	2.33)	0.6322	
Baseline FVC percent predicted													0.0083
<=70%	95	39	41.1	36.53	97	35	36.1	32.09	0.75	(0.47,	1.19)	0.2153	
>70%	74	19	25.7	19.91	73	31	42.5	39.11	2.02	(1.14,	3.59)	0.0165	
Baseline HRCT pattern													0.7228
UIP-like	116	41	35.3	29.47	121	52	43.0	39.49	1.15	(0.76,	1.74)	0.5110	
Other fibrotic patterns	53	17	32.1	26.97	49	14	28.6	24.72	0.99	(0.49,	2.01)	0.9789	
Underlying ILD diagnosis													0.1094
iNSIP	32	10	31.3	25.61	27	13	48.1	46.69	1.52	(0.66,	3.49)	0.3289	
Unclassifiable IIP	46	22	47.8	42.80	32	10	31.3	25.52	0.59	(0.28,	1.25)	0.1690	
HP	38	6	15.8	12.50	43	16	37.2	34.10	2.38	(0.92,	6.11)	0.0722	
Autoimmune ILD	29	11	37.9	31.44	43	15	34.9	31.28	0.75	(0.34,	1.67)	0.4855	
Other ILD	24	9	37.5	31.33	25	12	48.0	45.41	1.67	(0.69,	4.01)	0.2547	
Region													0.9270
Europe	78	26	33.3	27.80	67	24	35.8	32.71	1.07	(0.61,	1.88)	0.8048	
Asia	45	22	48.9	42.75	41	23	56.1	54.47	1.03	(0.57,	1.86)	0.9106	
Canada and USA	30	6	20.0	15.30	37	11	29.7	24.32	1.39	(0.50,	3.84)	0.5225	
Rest of the World	16	4	25.0	22.30	25	8	32.0	29.10	1.47	(0.44,	4.91)	0.5332	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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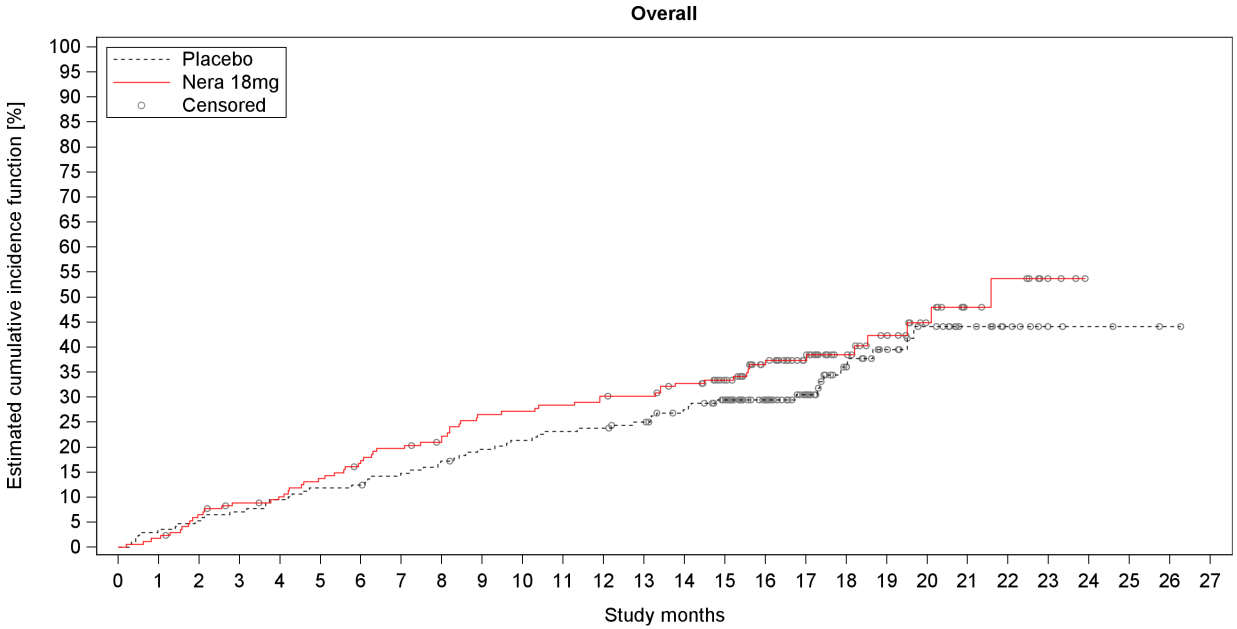

Number at risk (percentage relative to baseline)																												
Placebo	169	163	160	157	153	149	148	143	139	134	131	128	127	123	115	106	82	63	40	31	23	14	9	4	3	2	1	0
%	100.0	96.4	94.7	92.9	90.5	88.2	87.6	84.6	82.2	79.3	77.5	75.7	75.1	72.8	68.0	62.7	48.5	37.3	23.7	18.3	13.6	8.3	5.3	2.4	1.8	1.2	0.6	0.0
Nera 18mg	170	167	158	152	149	143	137	132	128	119	118	116	113	112	105	94	73	57	36	26	18	10	8	3	0	0	0	0
%	100.0	98.2	92.9	89.4	87.6	84.1	80.6	77.6	75.3	70.0	69.4	68.2	66.5	65.9	61.8	55.3	42.9	33.5	21.2	15.3	10.6	5.9	4.7	1.8	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																												
Placebo	0	0	0	0	0	0	0	1	1	2	2	2	2	4	8	14	38	56	75	82	88	97	102	107	108	109	110	111
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.6	1.2	1.2	1.2	1.2	2.4	4.7	8.3	22.5	33.1	44.4	48.5	52.1	57.4	60.4	63.3	63.9	64.5	65.1	65.7
Nera 18mg	0	0	1	3	4	4	5	5	7	7	7	7	7	8	11	21	38	53	73	81	88	95	96	101	104	104	104	104
%	0.0	0.0	0.6	1.8	2.4	2.4	2.9	2.9	4.1	4.1	4.1	4.1	4.1	4.7	6.5	12.4	22.4	31.2	42.9	47.6	51.8	55.9	56.5	59.4	61.2	61.2	61.2	61.2

Study: 1305-0023

Figure I.1.1.1.1.2.5: 1 Time to first non-elective hospitalisation for any cause over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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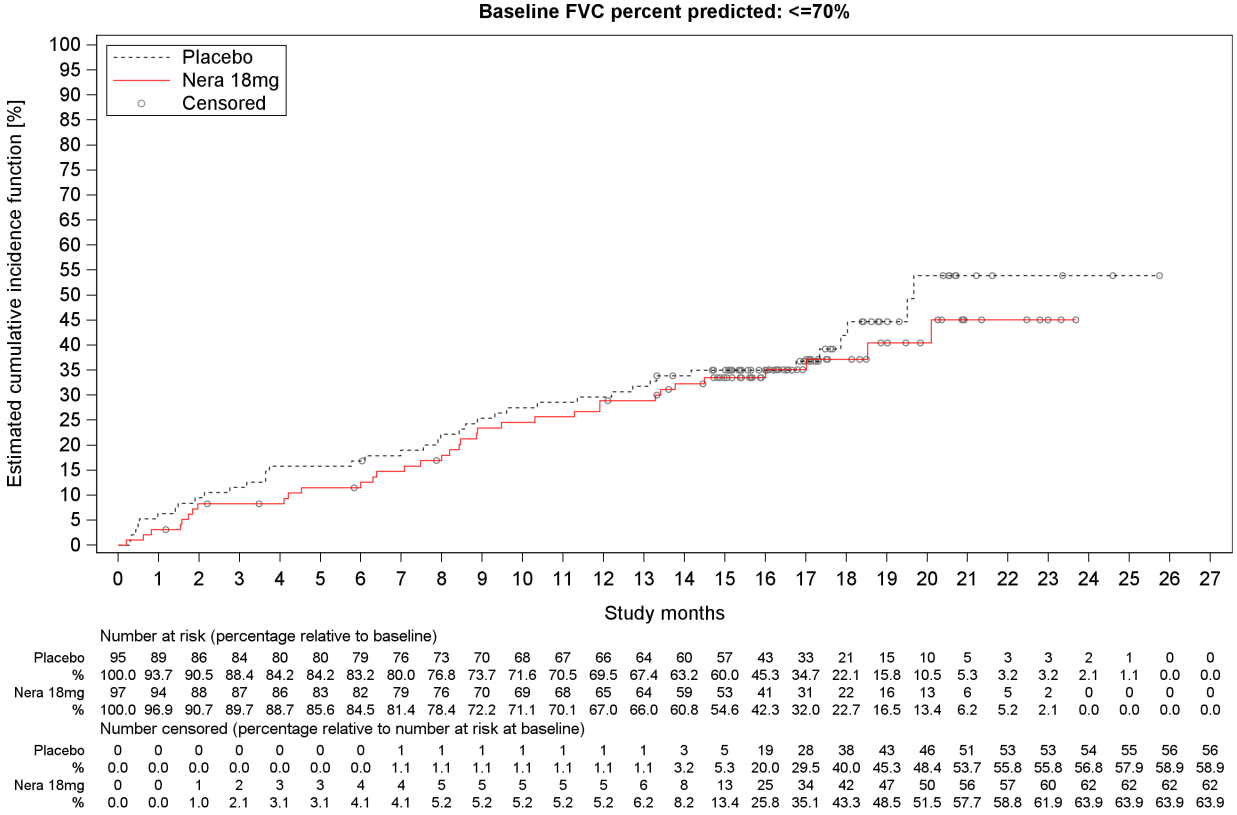

Number at risk (percentage relative to baseline)																												
Placebo	95	89	86	84	80	80	79	76	73	70	68	67	66	64	60	57	43	33	21	15	10	5	3	3	2	1	0	0
%	100.0	93.7	90.5	88.4	84.2	84.2	83.2	80.0	76.8	73.7	71.6	70.5	69.5	67.4	63.2	60.0	45.3	34.7	22.1	15.8	10.5	5.3	3.2	3.2	2.1	1.1	0.0	0.0
Nera 18mg	97	94	88	87	86	83	82	79	76	70	69	68	65	64	59	53	41	31	22	16	13	6	5	2	0	0	0	0
%	100.0	96.9	90.7	89.7	88.7	85.6	84.5	81.4	78.4	72.2	71.1	70.1	67.0	66.0	60.8	54.6	42.3	32.0	22.7	16.5	13.4	6.2	5.2	2.1	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																												
Placebo	0	0	0	0	0	0	0	1	1	1	1	1	1	1	3	5	19	28	38	43	46	51	53	53	54	55	56	56
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	1.1	1.1	1.1	1.1	3.2	5.3	20.0	29.5	40.0	45.3	48.4	53.7	55.8	55.8	56.8	57.9	58.9	58.9
Nera 18mg	0	0	1	2	3	3	4	4	5	5	5	5	5	6	8	13	25	34	42	47	50	56	57	60	62	62	62	62
%	0.0	0.0	1.0	2.1	3.1	3.1	4.1	4.1	5.2	5.2	5.2	5.2	5.2	6.2	8.2	13.4	25.8	35.1	43.3	48.5	51.5	57.7	58.8	61.9	63.9	63.9	63.9	63.9

Study: 1305-0023

Figure I.1.1.1.1.2.5: 1 Time to first non-elective hospitalisation for any cause over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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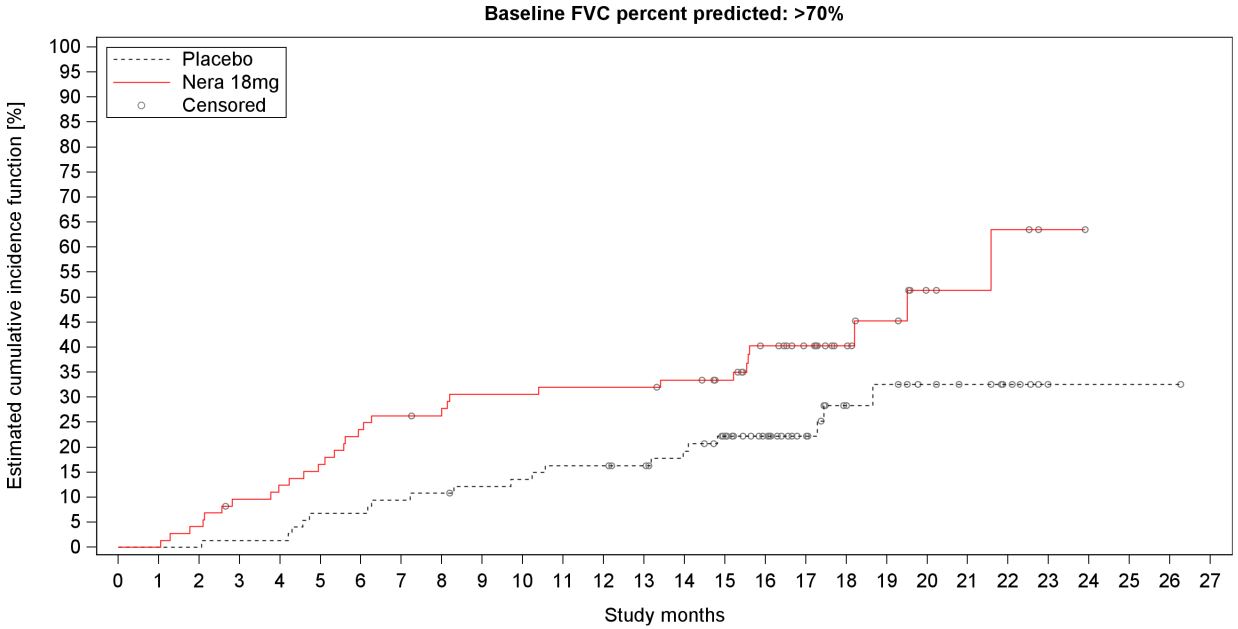

Number at risk (percentage relative to baseline)																												
Placebo	74	74	74	73	73	69	69	67	66	64	63	61	61	59	55	49	39	30	19	16	13	9	6	1	1	1	1	0
%	100.0	100.0	100.0	98.6	98.6	93.2	93.2	90.5	89.2	86.5	85.1	82.4	82.4	79.7	74.3	66.2	52.7	40.5	25.7	21.6	17.6	12.2	8.1	1.4	1.4	1.4	1.4	0.0
Nera 18mg	73	73	70	65	63	60	55	53	52	49	49	48	48	48	46	41	32	26	14	10	5	4	3	1	0	0	0	0
%	100.0	100.0	95.9	89.0	86.3	82.2	75.3	72.6	71.2	67.1	67.1	65.8	65.8	65.8	63.0	56.2	43.8	35.6	19.2	13.7	6.8	5.5	4.1	1.4	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																												
Placebo	0	0	0	0	0	0	0	0	0	1	1	1	1	3	5	9	19	28	37	39	42	46	49	54	54	54	54	55
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.4	1.4	1.4	1.4	4.1	6.8	12.2	25.7	37.8	50.0	52.7	56.8	62.2	66.2	73.0	73.0	73.0	73.0	74.3
Nera 18mg	0	0	0	1	1	1	1	1	2	2	2	2	2	2	3	8	13	19	31	34	38	39	39	41	42	42	42	42
%	0.0	0.0	0.0	1.4	1.4	1.4	1.4	1.4	2.7	2.7	2.7	2.7	2.7	2.7	4.1	11.0	17.8	26.0	42.5	46.6	52.1	53.4	53.4	56.2	57.5	57.5	57.5	57.5

Study: 1305-0023

Figure I.1.1.1.1.2.5: 1 Time to first non-elective hospitalisation for any cause over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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I.1.1.1.1.3 Time to event analyses of quality of life

I.1.1.1.1.3.1 Living with Pulmonary Fibrosis (L-PF) total scores

Table I.1.1.1.1.3.1: 1 Cox model for time to first L-PF total score deterioration (increase >= 15) over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	72	42.6	43.06	170	65	38.2	40.19	0.94	(0.67,	1.32)	0.7393	
Age													0.4934
<65 years	65	25	38.5	35.02	64	24	37.5	39.72	1.11	(0.63,	1.94)	0.7271	
>=65 years	104	47	45.2	49.05	106	41	38.7	40.46	0.86	(0.56,	1.32)	0.4973	
Sex													0.0834
Male	114	51	44.7	46.76	108	49	45.4	53.82	1.18	(0.80,	1.76)	0.4063	
Female	55	21	38.2	36.12	62	16	25.8	22.63	0.60	(0.31,	1.16)	0.1273	
Baseline FVC percent predicted													0.4974
<=70%	95	40	42.1	43.17	97	40	41.2	43.75	1.04	(0.67,	1.62)	0.8501	
>70%	74	32	43.2	42.93	73	25	34.2	35.55	0.82	(0.49,	1.39)	0.4683	
Baseline HRCT pattern													0.7641
UIP-like	116	49	42.2	42.93	121	48	39.7	40.49	0.98	(0.65,	1.46)	0.9098	
Other fibrotic patterns	53	23	43.4	43.34	49	17	34.7	39.35	0.87	(0.46,	1.63)	0.6662	
Underlying ILD diagnosis													0.0621
iNSIP	32	12	37.5	36.46	27	7	25.9	31.65	0.78	(0.30,	2.00)	0.6040	
Unclassifiable IIP	46	21	45.7	46.94	32	13	40.6	38.62	0.91	(0.45,	1.82)	0.7843	
HP	38	21	55.3	55.28	43	18	41.9	42.72	0.86	(0.45,	1.64)	0.6531	
Autoimmune ILD	29	11	37.9	38.03	43	10	23.3	22.30	0.50	(0.21,	1.19)	0.1198	
Other ILD	24	7	29.2	30.93	25	17	68.0	89.60	3.11	(1.27,	7.62)	0.0131	
Region													0.2925
Europe	78	31	39.7	40.85	67	23	34.3	36.80	0.89	(0.52,	1.53)	0.6742	
Asia	45	22	48.9	48.50	41	12	29.3	28.71	0.57	(0.28,	1.18)	0.1296	
Canada and USA	30	12	40.0	37.19	37	20	54.1	59.58	1.54	(0.75,	3.15)	0.2424	
Rest of the World	16	7	43.8	51.17	25	10	40.0	41.89	1.08	(0.40,	2.88)	0.8846	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline total score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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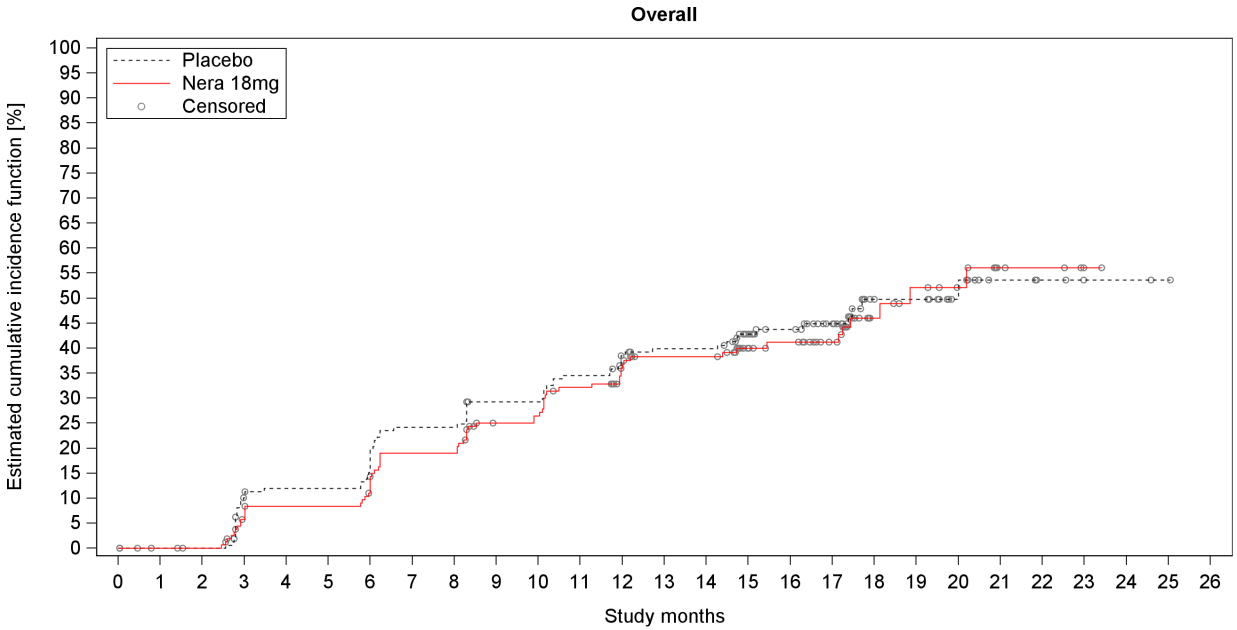

Number at risk (percentage relative to baseline)																											
Placebo	169	162	161	141	137	137	132	118	118	108	108	100	91	87	87	67	54	45	23	21	13	6	4	2	2	1	0
%	100.0	95.9	95.3	83.4	81.1	81.1	78.1	69.8	69.8	63.9	63.9	59.2	53.8	51.5	51.5	39.6	32.0	26.6	13.6	12.4	7.7	3.6	2.4	1.2	1.2	0.6	0.0
Nera 18mg	170	160	159	145	140	140	134	121	121	106	104	95	82	75	75	55	50	40	19	15	12	5	4	1	0	0	0
%	100.0	94.1	93.5	85.3	82.4	82.4	78.8	71.2	71.2	62.4	61.2	55.9	48.2	44.1	44.1	32.4	29.4	23.5	11.2	8.8	7.1	2.9	2.4	0.6	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																											
Placebo	0	7	8	12	13	13	13	13	13	15	15	15	18	20	20	36	48	56	75	77	85	91	93	95	95	96	97
%	0.0	4.1	4.7	7.1	7.7	7.7	7.7	7.7	7.7	8.9	8.9	8.9	10.7	11.8	11.8	21.3	28.4	33.1	44.4	45.6	50.3	53.8	55.0	56.2	56.2	56.8	57.4
Nera 18mg	0	10	11	16	17	17	19	20	20	26	26	27	35	39	39	57	61	71	89	91	94	100	101	104	105	105	105
%	0.0	5.9	6.5	9.4	10.0	10.0	11.2	11.8	11.8	15.3	15.3	15.9	20.6	22.9	22.9	33.5	35.9	41.8	52.4	53.5	55.3	58.8	59.4	61.2	61.8	61.8	61.8

Study: 1305-0023

Figure I.1.1.1.1.3.1: 1 Time to first L-PF total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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Figure I.1.1.1.1.3.1: 1

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Table I.1.1.1.1.3.1: 2 Cox model for time to first L-PF Impact total score deterioration (increase >= 15) over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	74	43.8	45.67	170	72	42.4	44.88	0.97	(0.70,	1.35)	0.8661	
Age													0.6263
<65 years	65	25	38.5	34.87	64	24	37.5	40.38	1.09	(0.62,	1.91)	0.7704	
>=65 years	104	49	47.1	54.24	106	48	45.3	47.54	0.91	(0.61,	1.37)	0.6675	
Sex													0.1016
Male	114	54	47.4	52.29	108	56	51.9	63.01	1.20	(0.82,	1.75)	0.3502	
Female	55	20	36.4	34.04	62	16	25.8	22.37	0.63	(0.33,	1.23)	0.1762	
Baseline FVC percent predicted													0.5350
<=70%	95	40	42.1	43.95	97	42	43.3	46.22	1.07	(0.69,	1.65)	0.7700	
>70%	74	34	45.9	47.87	73	30	41.1	43.13	0.87	(0.53,	1.42)	0.5698	
Baseline HRCT pattern													0.5572
UIP-like	116	52	44.8	47.71	121	52	43.0	43.67	0.91	(0.62,	1.35)	0.6440	
Other fibrotic patterns	53	22	41.5	41.47	49	20	40.8	48.38	1.13	(0.62,	2.08)	0.6858	
Underlying ILD diagnosis													0.2033
iNSIP	32	12	37.5	38.02	27	10	37.0	49.57	1.07	(0.46,	2.49)	0.8820	
Unclassifiable IIP	46	17	37.0	36.92	32	14	43.8	41.73	1.29	(0.63,	2.63)	0.4848	
HP	38	23	60.5	65.03	43	23	53.5	56.75	1.01	(0.56,	1.81)	0.9864	
Autoimmune ILD	29	11	37.9	38.25	43	9	20.9	19.51	0.39	(0.16,	0.96)	0.0402	
Other ILD	24	11	45.8	54.18	25	16	64.0	79.84	1.58	(0.72,	3.47)	0.2500	
Region													0.8428
Europe	78	37	47.4	51.67	67	27	40.3	43.14	0.87	(0.53,	1.44)	0.5857	
Asia	45	18	40.0	38.13	41	16	39.0	39.25	0.88	(0.44,	1.74)	0.7056	
Canada and USA	30	13	43.3	44.03	37	20	54.1	60.82	1.24	(0.61,	2.50)	0.5516	
Rest of the World	16	6	37.5	43.83	25	9	36.0	37.23	1.15	(0.40,	3.28)	0.7981	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline impact total score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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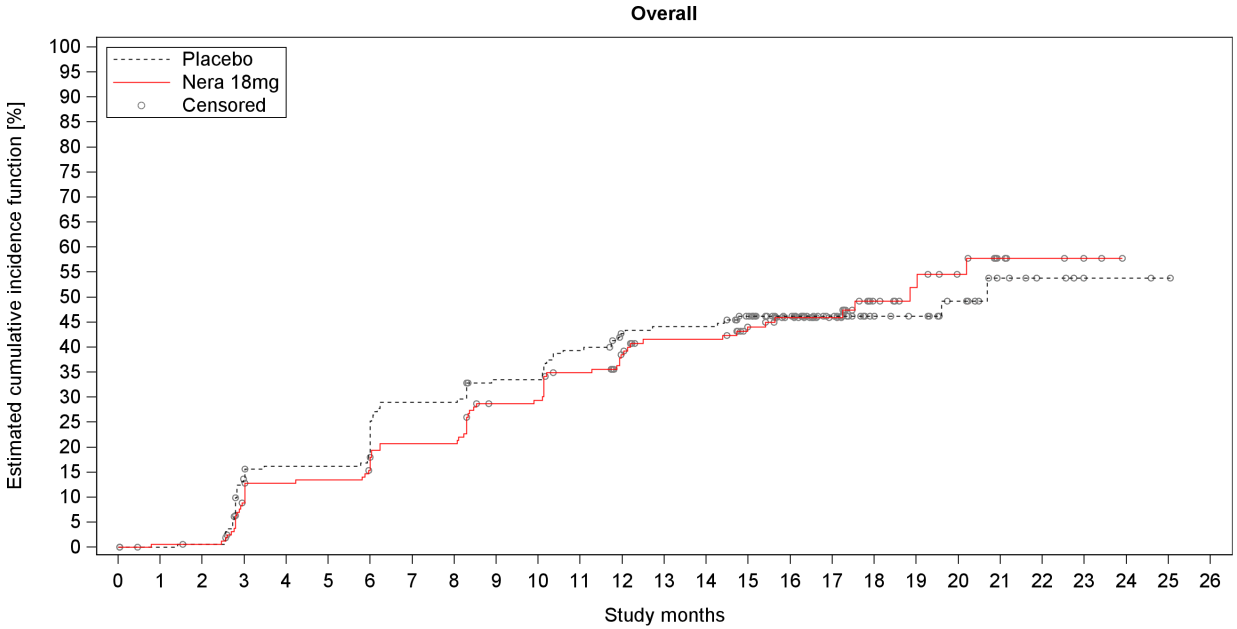

Number at risk (percentage relative to baseline)																											
Placebo	169	162	161	136	131	131	127	111	111	102	102	93	82	80	80	70	56	45	29	23	16	8	5	2	2	1	0
%	100.0	95.9	95.3	80.5	77.5	77.5	75.1	65.7	65.7	60.4	60.4	55.0	48.5	47.3	47.3	41.4	33.1	26.6	17.2	13.6	9.5	4.7	3.0	1.2	1.2	0.6	0.0
Nera 18mg	170	160	159	141	134	133	128	119	119	104	103	93	82	74	74	61	50	39	23	18	14	6	4	2	0	0	0
%	100.0	94.1	93.5	82.9	78.8	78.2	75.3	70.0	70.0	61.2	60.6	54.7	48.2	43.5	43.5	35.9	29.4	22.9	13.5	10.6	8.2	3.5	2.4	1.2	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																											
Placebo	0	7	7	11	12	12	12	12	12	14	14	14	20	20	20	27	41	52	68	74	80	87	90	93	93	94	95
%	0.0	4.1	4.1	6.5	7.1	7.1	7.1	7.1	7.1	8.3	8.3	8.3	11.8	11.8	11.8	16.0	24.3	30.8	40.2	43.8	47.3	51.5	53.3	55.0	55.0	55.6	56.2
Nera 18mg	0	9	10	15	16	16	18	19	19	22	22	24	30	34	34	44	53	64	78	82	85	92	94	96	98	98	98
%	0.0	5.3	5.9	8.8	9.4	9.4	10.6	11.2	11.2	12.9	12.9	14.1	17.6	20.0	20.0	25.9	31.2	37.6	45.9	48.2	50.0	54.1	55.3	56.5	57.6	57.6	57.6

Study: 1305-0023

Figure I.1.1.1.1.3.1: 2 Time to first L-PF Impact total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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Figure I.1.1.1.1.3.1: 2

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Table I.1.1.1.1.3.1: 3 Cox model for time to first L-PF Symptoms total score deterioration (increase >= 15) over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	81	47.9	47.82	170	74	43.5	47.61	1.02	(0.75, 1.41)	0.8807	
Age												0.8897
<65 years	65	29	44.6	41.44	64	27	42.2	47.02	1.06	(0.62, 1.79)	0.8382	
>=65 years	104	52	50.0	52.32	106	47	44.3	47.95	1.01	(0.67, 1.51)	0.9690	
Sex												0.2228
Male	114	58	50.9	52.43	108	54	50.0	61.02	1.19	(0.82, 1.74)	0.3577	
Female	55	23	41.8	39.15	62	20	32.3	29.88	0.77	(0.42, 1.40)	0.3868	
Baseline FVC percent predicted												0.5020
<=70%	95	50	52.6	56.45	97	49	50.5	58.65	1.11	(0.75, 1.65)	0.6035	
>70%	74	31	41.9	38.37	73	25	34.2	34.78	0.89	(0.52, 1.51)	0.6534	
Baseline HRCT pattern												0.6917
UIP-like	116	53	45.7	44.76	121	52	43.0	45.81	1.07	(0.73, 1.58)	0.7247	
Other fibrotic patterns	53	28	52.8	54.94	49	22	44.9	52.48	0.93	(0.53, 1.64)	0.8100	
Underlying ILD diagnosis												0.0385
iNSIP	32	13	40.6	35.62	27	10	37.0	42.03	1.10	(0.47, 2.54)	0.8280	
Unclassifiable IIP	46	25	54.3	61.10	32	13	40.6	43.11	0.83	(0.42, 1.64)	0.5953	
HP	38	24	63.2	65.89	43	21	48.8	53.91	0.88	(0.49, 1.60)	0.6818	
Autoimmune ILD	29	10	34.5	33.16	43	12	27.9	27.59	0.68	(0.29, 1.58)	0.3683	
Other ILD	24	9	37.5	35.46	25	18	72.0	94.56	3.52	(1.55, 7.96)	0.0026	
Region												0.2648
Europe	78	38	48.7	49.75	67	28	41.8	48.00	0.99	(0.61, 1.62)	0.9819	
Asia	45	23	51.1	51.48	41	13	31.7	33.24	0.65	(0.32, 1.30)	0.2194	
Canada and USA	30	12	40.0	35.02	37	21	56.8	61.67	1.78	(0.87, 3.66)	0.1158	
Rest of the World	16	8	50.0	56.90	25	12	48.0	50.11	1.04	(0.42, 2.60)	0.9249	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline symptoms total score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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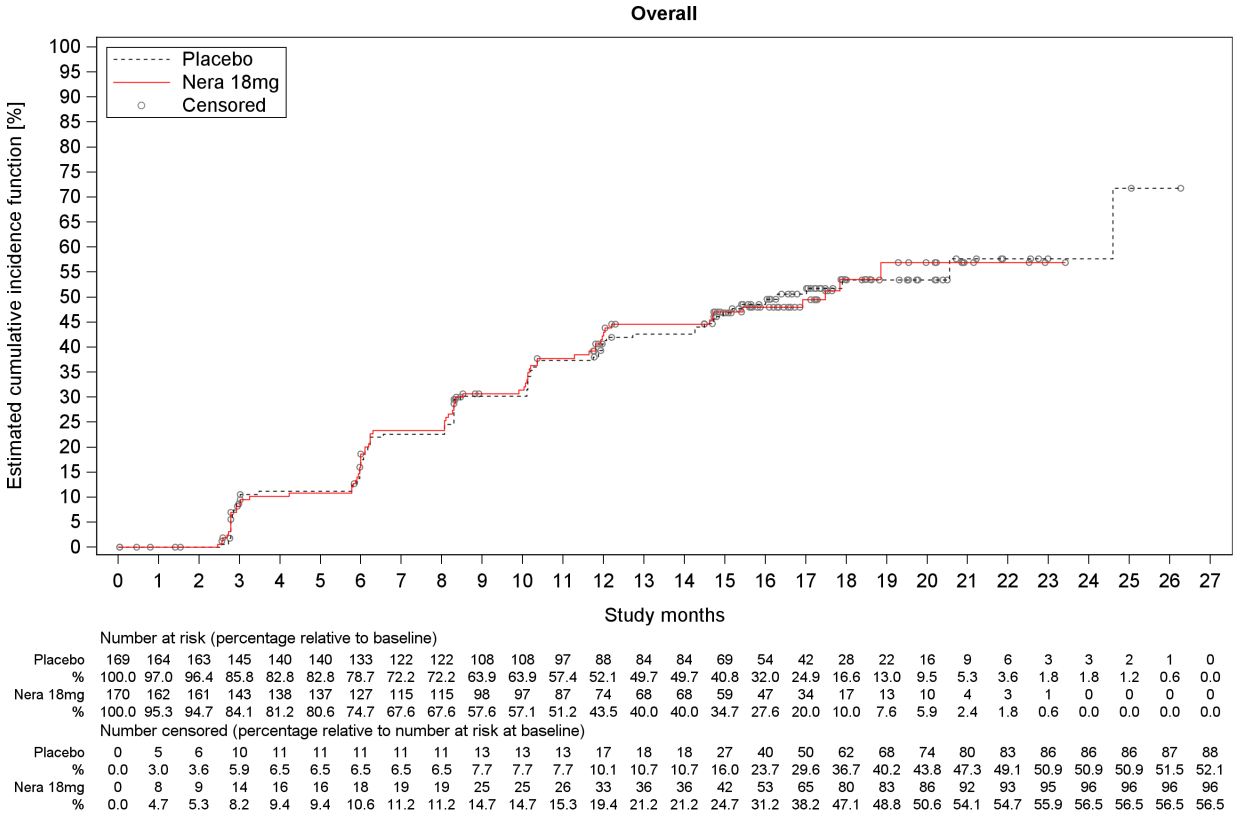

	Number at risk (percentage relative to baseline)																											
Placebo	169	164	163	145	140	140	133	122	122	108	108	97	88	84	84	69	54	42	28	22	16	9	6	3	3	2	1	0
%	100.0	97.0	96.4	85.8	82.8	82.8	78.7	72.2	72.2	63.9	63.9	57.4	52.1	49.7	49.7	40.8	32.0	24.9	16.6	13.0	9.5	5.3	3.6	1.8	1.8	1.2	0.6	0.0
Nera 18mg	170	162	161	143	138	137	127	115	115	98	97	87	74	68	68	59	47	34	17	13	10	4	3	1	0	0	0	0
%	100.0	95.3	94.7	84.1	81.2	80.6	74.7	67.6	67.6	57.6	57.1	51.2	43.5	40.0	40.0	34.7	27.6	20.0	10.0	7.6	5.9	2.4	1.8	0.6	0.0	0.0	0.0	0.0
	Number censored (percentage relative to number at risk at baseline)																											
Placebo	0	5	6	10	11	11	11	11	11	13	13	13	17	18	18	27	40	50	62	68	74	80	83	86	86	86	87	88
%	0.0	3.0	3.6	5.9	6.5	6.5	6.5	6.5	6.5	7.7	7.7	7.7	10.1	10.7	10.7	16.0	23.7	29.6	36.7	40.2	43.8	47.3	49.1	50.9	50.9	50.9	51.5	52.1
Nera 18mg	0	8	9	14	16	16	18	19	19	25	25	26	33	36	36	42	53	65	80	83	86	92	93	95	96	96	96	96
%	0.0	4.7	5.3	8.2	9.4	9.4	10.6	11.2	11.2	14.7	14.7	15.3	19.4	21.2	21.2	24.7	31.2	38.2	47.1	48.8	50.6	54.1	54.7	55.9	56.5	56.5	56.5	56.5

Study: 1305-0023

Figure I.1.1.1.1.3.1: 3 Time to first L-PF Symptoms total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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Figure I.1.1.1.1.3.1: 3

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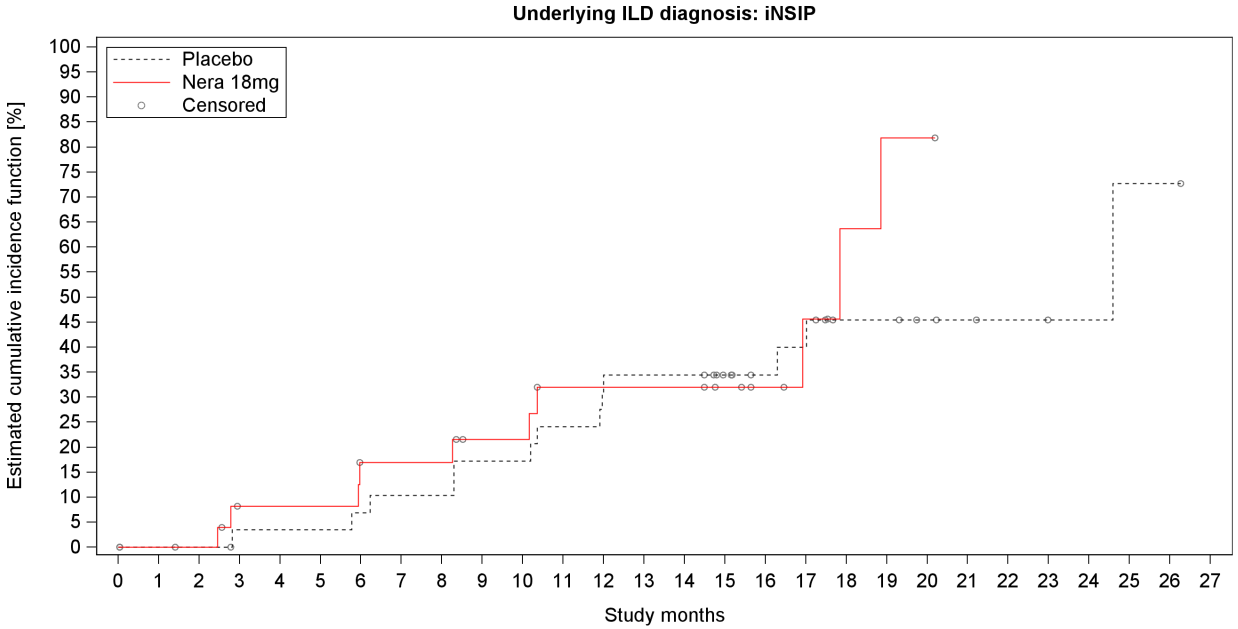

Number at risk (percentage relative to baseline)																												
Placebo	32	31	30	28	28	28	27	26	26	24	24	22	20	19	19	15	12	11	7	7	5	4	3	2	2	1	1	0
%	100.0	96.9	93.8	87.5	87.5	87.5	84.4	81.3	81.3	75.0	75.0	68.8	62.5	59.4	59.4	46.9	37.5	34.4	21.9	21.9	15.6	12.5	9.4	6.3	6.3	3.1	3.1	0.0
Nera 18mg	27	25	25	21	21	21	18	18	18	15	15	12	12	12	12	10	7	4	2	1	1	0	0	0	0	0	0	0
%	100.0	92.6	92.6	77.8	77.8	77.8	66.7	66.7	66.7	55.6	55.6	44.4	44.4	44.4	44.4	37.0	25.9	14.8	7.4	3.7	3.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																												
Placebo	0	1	2	3	3	3	3	3	3	3	3	3	3	3	3	7	10	10	13	13	15	16	17	18	18	18	18	19
%	0.0	3.1	6.3	9.4	9.4	9.4	9.4	9.4	9.4	9.4	9.4	9.4	9.4	9.4	9.4	21.9	31.3	31.3	40.6	40.6	46.9	50.0	53.1	56.3	56.3	56.3	56.3	59.4
Nera 18mg	0	2	2	4	4	4	5	5	5	7	7	8	8	8	8	10	13	15	16	16	16	17	17	17	17	17	17	17
%	0.0	7.4	7.4	14.8	14.8	14.8	18.5	18.5	18.5	25.9	25.9	29.6	29.6	29.6	29.6	37.0	48.1	55.6	59.3	59.3	59.3	63.0	63.0	63.0	63.0	63.0	63.0	63.0

Study: 1305-0023

Figure I.1.1.1.3.1: 3 Time to first L-PF Symptoms total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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Figure I.1.1.1.3.1: 3

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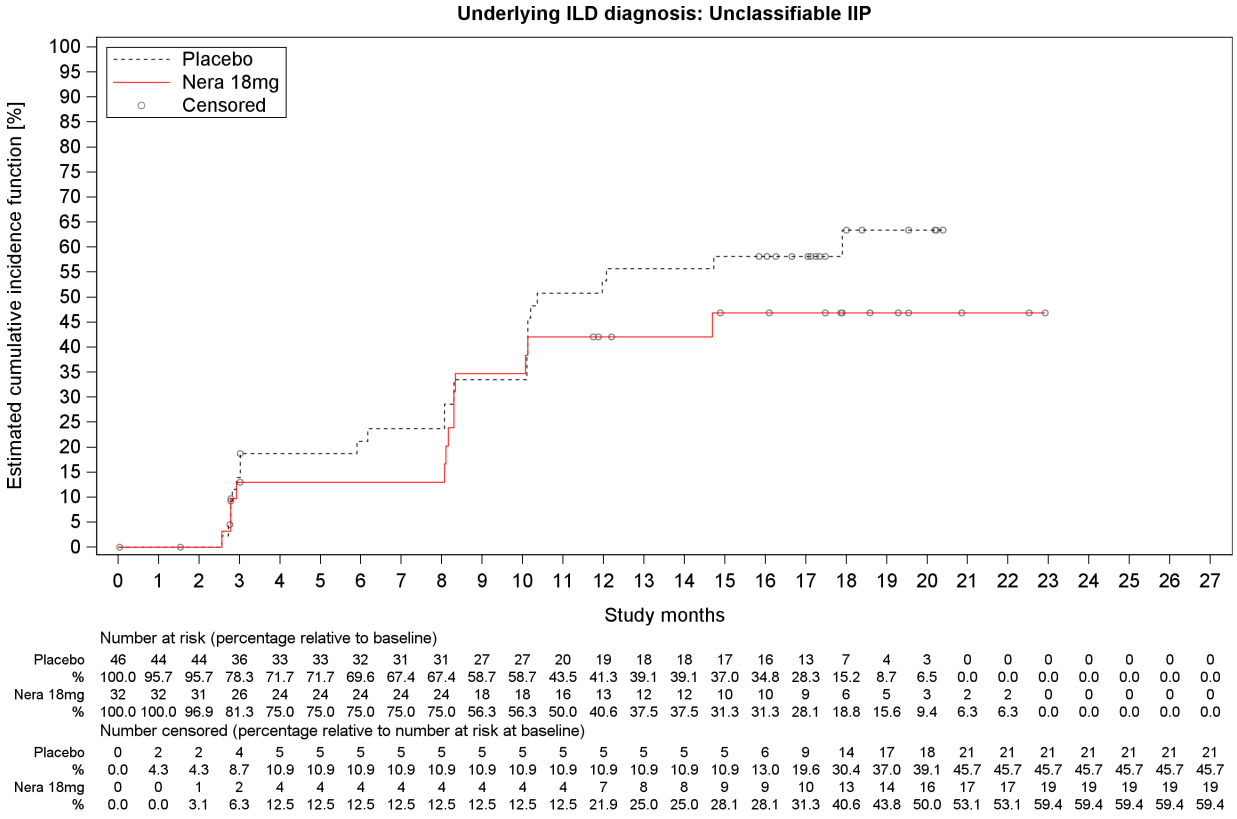

Figure I.1.1.1.1.3.1: 3 Time to first L-PF Symptoms total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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Figure I.1.1.1.1.3.1: 3

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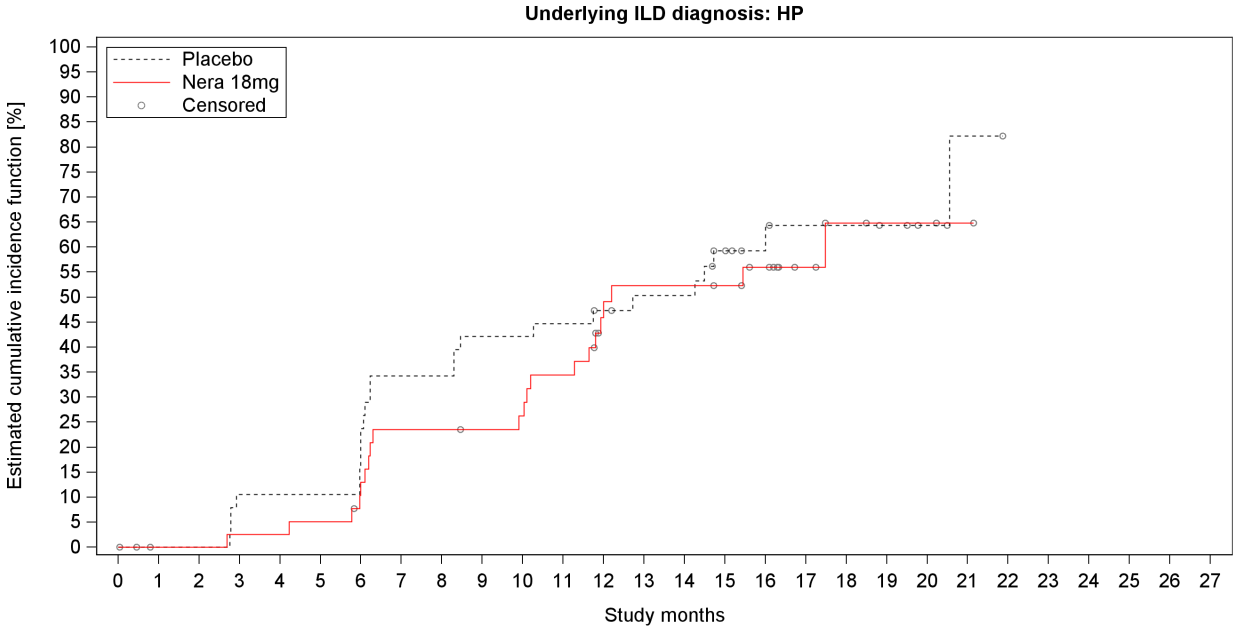

Number at risk (percentage relative to baseline)

Placebo	38	38	38	34	34	34	32	25	25	22	22	21	19	17	17	12	8	6	6	5	3	1	0	0	0	0	0	0
%	100.0	100.0	100.0	89.5	89.5	89.5	84.2	65.8	65.8	57.9	57.9	55.3	50.0	44.7	44.7	31.6	21.1	15.8	15.8	13.2	7.9	2.6	0.0	0.0	0.0	0.0	0.0	0.0
Nera 18mg	43	39	39	38	38	37	34	29	29	28	27	24	17	15	15	14	11	6	3	2	2	1	0	0	0	0	0	0
%	100.0	90.7	90.7	88.4	88.4	86.0	79.1	67.4	67.4	65.1	62.8	55.8	39.5	34.9	34.9	32.6	25.6	14.0	7.0	4.7	4.7	2.3	0.0	0.0	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	0	0	0	0	0	0	0	1	2	2	4	8	9	9	10	12	13	14	14	14	14	14	14
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.6	5.3	5.3	10.5	21.1	23.7	23.7	26.3	31.6	34.2	36.8	36.8	36.8	36.8	36.8	36.8
Nera 18mg	0	4	4	4	4	4	5	5	5	6	6	6	9	9	9	10	12	17	19	20	20	21	22	22	22	22	22	22
%	0.0	9.3	9.3	9.3	9.3	9.3	11.6	11.6	11.6	14.0	14.0	14.0	20.9	20.9	20.9	23.3	27.9	39.5	44.2	46.5	46.5	48.8	51.2	51.2	51.2	51.2	51.2	51.2

Study: 1305-0023

Figure I.1.1.1.3.1: 3 Time to first L-PF Symptoms total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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Figure I.1.1.1.3.1: 3

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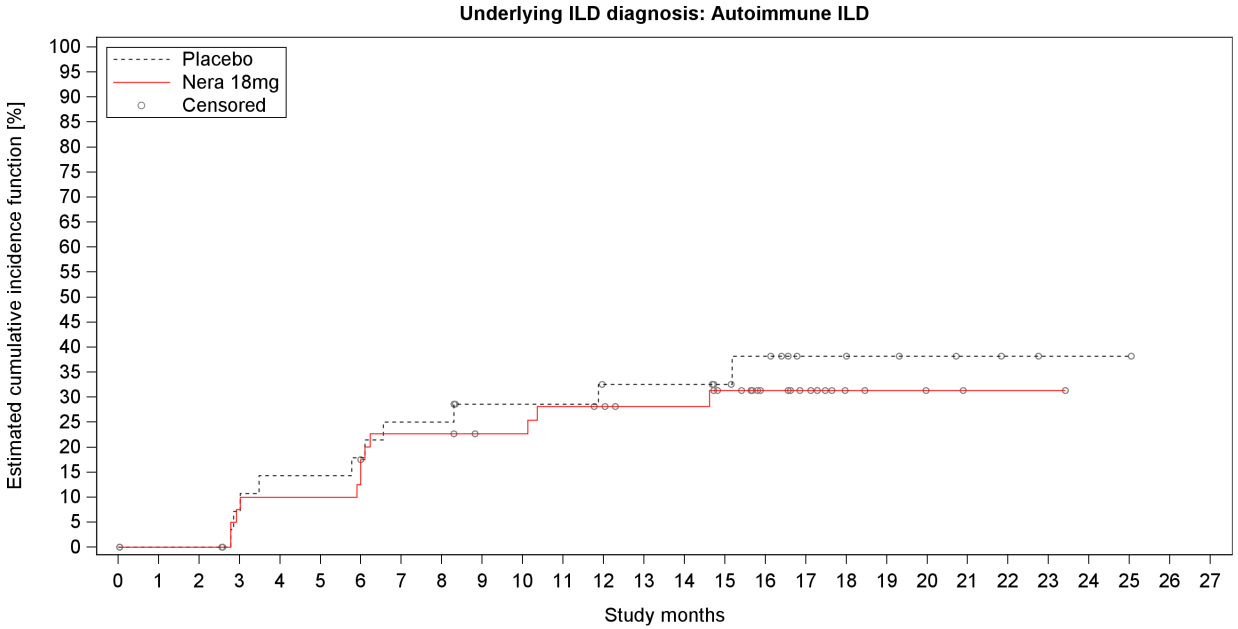

Number at risk (percentage relative to baseline)																												
Placebo	29	28	28	26	24	24	23	21	21	18	18	18	15	15	15	13	11	6	6	5	4	3	2	1	1	1	0	0
%	100.0	96.6	96.6	89.7	82.8	82.8	79.3	72.4	72.4	62.1	62.1	62.1	51.7	51.7	51.7	44.8	37.9	20.7	20.7	17.2	13.8	10.3	6.9	3.4	3.4	3.4	0.0	0.0
Nera 18mg	43	42	42	37	36	36	35	30	30	28	28	26	25	23	23	20	15	11	4	3	2	1	1	1	0	0	0	0
%	100.0	97.7	97.7	86.0	83.7	83.7	81.4	69.8	69.8	65.1	65.1	60.5	58.1	53.5	53.5	46.5	34.9	25.6	9.3	7.0	4.7	2.3	2.3	2.3	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																												
Placebo	0	1	1	1	1	1	1	1	1	3	3	3	5	5	5	7	8	13	13	14	15	16	17	18	18	18	19	19
%	0.0	3.4	3.4	3.4	3.4	3.4	3.4	3.4	3.4	10.3	10.3	10.3	17.2	17.2	17.2	24.1	27.6	44.8	44.8	48.3	51.7	55.2	58.6	62.1	62.1	62.1	65.5	65.5
Nera 18mg	0	1	1	3	3	3	3	4	4	6	6	6	7	9	9	11	16	20	27	28	29	30	30	30	31	31	31	31
%	0.0	2.3	2.3	7.0	7.0	7.0	7.0	9.3	9.3	14.0	14.0	14.0	16.3	20.9	20.9	25.6	37.2	46.5	62.8	65.1	67.4	69.8	69.8	69.8	72.1	72.1	72.1	72.1

Study: 1305-0023

Figure I.1.1.1.1.3.1: 3 Time to first L-PF Symptoms total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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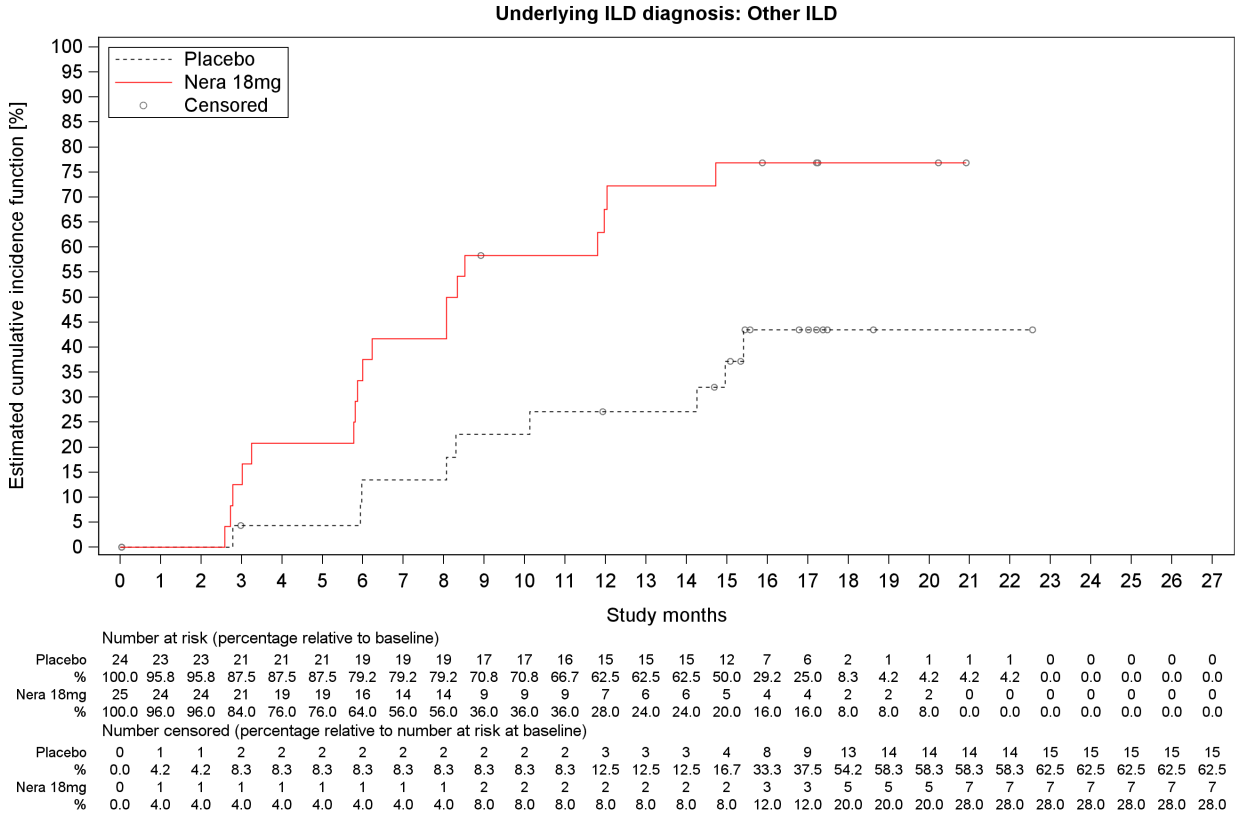

Figure I.1.1.1.1.3.1: 3 Time to first L-PF Symptoms total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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I.1.1.1.1.3.2 Living with Pulmonary Fibrosis (L-PF) domain scores

Table I.1.1.1.1.3.2: 1 Cox model for time to first L-PF Cough domain score deterioration (increase >= 15) over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	95	56.2	65.13	170	88	51.8	64.65	1.01	(0.75, 1.35)	0.9588	
Age												0.7883
<65 years	65	37	56.9	63.17	64	35	54.7	72.78	1.06	(0.66, 1.69)	0.8093	
>=65 years	104	58	55.8	66.44	106	53	50.0	60.21	0.98	(0.67, 1.42)	0.8975	
Sex												0.4964
Male	114	66	57.9	68.61	108	62	57.4	81.13	1.09	(0.77, 1.56)	0.6243	
Female	55	29	52.7	58.39	62	26	41.9	43.55	0.87	(0.51, 1.49)	0.6169	
Baseline FVC percent predicted												0.7321
<=70%	95	54	56.8	69.71	97	54	55.7	73.51	1.05	(0.72, 1.54)	0.7943	
>70%	74	41	55.4	59.94	73	34	46.6	54.27	0.95	(0.60, 1.50)	0.8193	
Baseline HRCT pattern												0.6376
UIP-like	116	65	56.0	65.67	121	60	49.6	60.93	0.96	(0.67, 1.37)	0.8200	
Other fibrotic patterns	53	30	56.6	64.00	49	28	57.1	74.38	1.12	(0.67, 1.87)	0.6761	
Underlying ILD diagnosis												0.3254
iNSIP	32	16	50.0	55.12	27	13	48.1	65.49	1.13	(0.54, 2.39)	0.7441	
Unclassifiable IIP	46	28	60.9	84.25	32	17	53.1	71.00	0.92	(0.50, 1.69)	0.7849	
HP	38	27	71.1	89.06	43	22	51.2	63.26	0.79	(0.45, 1.40)	0.4246	
Autoimmune ILD	29	11	37.9	38.44	43	18	41.9	45.91	1.04	(0.49, 2.24)	0.9135	
Other ILD	24	13	54.2	52.70	25	18	72.0	98.16	2.10	(1.02, 4.33)	0.0446	
Region												0.6623
Europe	78	42	53.8	61.83	67	36	53.7	67.29	1.08	(0.69, 1.70)	0.7261	
Asia	45	26	57.8	65.82	41	15	36.6	41.88	0.69	(0.36, 1.34)	0.2748	
Canada and USA	30	18	60.0	67.69	37	23	62.2	84.57	1.18	(0.63, 2.21)	0.6069	
Rest of the World	16	9	56.3	75.97	25	14	56.0	71.41	0.94	(0.40, 2.19)	0.8825	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline cough domain score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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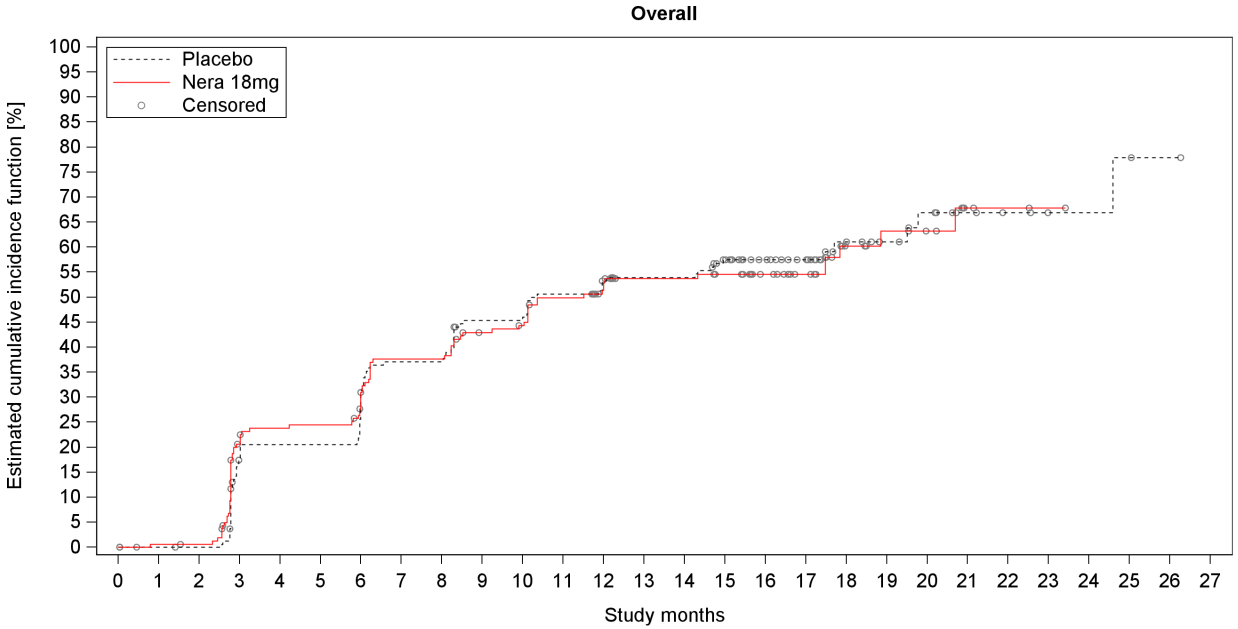

Number at risk (percentage relative to baseline)																												
Placebo	169	164	163	130	125	125	117	99	99	84	84	76	69	66	66	56	44	36	20	15	11	7	5	3	3	2	1	0
%	100.0	97.0	96.4	76.9	74.0	74.0	69.2	58.6	58.6	49.7	49.7	45.0	40.8	39.1	39.1	33.1	26.0	21.3	11.8	8.9	6.5	4.1	3.0	1.8	1.8	1.2	0.6	0.0
Nera 18mg	170	162	161	125	118	117	110	94	94	83	80	71	62	54	54	49	39	31	15	12	10	3	2	1	0	0	0	0
%	100.0	95.3	94.7	73.5	69.4	68.8	64.7	55.3	55.3	48.8	47.1	41.8	36.5	31.8	31.8	28.8	22.9	18.2	8.8	7.1	5.9	1.8	1.2	0.6	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																												
Placebo	0	5	6	11	11	11	11	11	11	13	13	13	16	18	18	23	35	43	57	62	64	68	70	72	72	72	73	74
%	0.0	3.0	3.6	6.5	6.5	6.5	6.5	6.5	6.5	7.7	7.7	7.7	9.5	10.7	10.7	13.6	20.7	25.4	33.7	36.7	37.9	40.2	41.4	42.6	42.6	42.6	43.2	43.8
Nera 18mg	0	7	8	12	14	14	16	17	17	20	21	22	29	34	34	38	48	56	69	71	73	79	80	81	82	82	82	82
%	0.0	4.1	4.7	7.1	8.2	8.2	9.4	10.0	10.0	11.8	12.4	12.9	17.1	20.0	20.0	22.4	28.2	32.9	40.6	41.8	42.9	46.5	47.1	47.6	48.2	48.2	48.2	48.2

Study: 1305-0023

Figure I.1.1.1.1.3.2: 1 Time to first L-PF Cough domain score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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Table I.1.1.1.1.3.2: 2 Cox model for time to first L-PF Dyspnea domain score deterioration (increase >= 15) over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	70	41.4	38.78	170	67	39.4	41.21	1.04	(0.74, 1.45)	0.8273	
Age												0.3523
<65 years	65	26	40.0	34.52	64	20	31.3	30.90	0.82	(0.46, 1.48)	0.5158	
>=65 years	104	44	42.3	41.83	106	47	44.3	48.03	1.16	(0.77, 1.75)	0.4851	
Sex												0.6878
Male	114	51	44.7	43.49	108	44	40.7	44.87	0.99	(0.66, 1.49)	0.9803	
Female	55	19	34.5	30.05	62	23	37.1	35.64	1.16	(0.63, 2.13)	0.6400	
Baseline FVC percent predicted												0.8182
<=70%	95	44	46.3	46.80	97	44	45.4	49.96	1.07	(0.71, 1.63)	0.7422	
>70%	74	26	35.1	30.06	73	23	31.5	30.87	0.99	(0.56, 1.74)	0.9656	
Baseline HRCT pattern												0.0235
UIP-like	116	42	36.2	32.99	121	53	43.8	46.64	1.36	(0.90, 2.04)	0.1442	
Other fibrotic patterns	53	28	52.8	52.64	49	14	28.6	28.61	0.56	(0.29, 1.06)	0.0769	
Underlying ILD diagnosis												0.6396
iNSIP	32	7	21.9	17.73	27	8	29.6	33.89	1.73	(0.62, 4.81)	0.2927	
Unclassifiable IIP	46	25	54.3	55.64	32	15	46.9	51.57	1.17	(0.61, 2.23)	0.6422	
HP	38	20	52.6	52.57	43	18	41.9	45.05	0.77	(0.40, 1.47)	0.4250	
Autoimmune ILD	29	8	27.6	23.72	43	13	30.2	29.36	0.96	(0.39, 2.33)	0.9206	
Other ILD	24	10	41.7	41.12	25	13	52.0	50.67	1.49	(0.65, 3.43)	0.3446	
Region												0.5819
Europe	78	34	43.6	42.84	67	27	40.3	45.12	1.03	(0.62, 1.72)	0.9020	
Asia	45	19	42.2	38.35	41	14	34.1	36.18	0.76	(0.38, 1.54)	0.4500	
Canada and USA	30	11	36.7	31.19	37	15	40.5	36.93	1.24	(0.57, 2.71)	0.5906	
Rest of the World	16	6	37.5	36.75	25	11	44.0	46.95	1.76	(0.64, 4.87)	0.2759	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline dyspnea domain score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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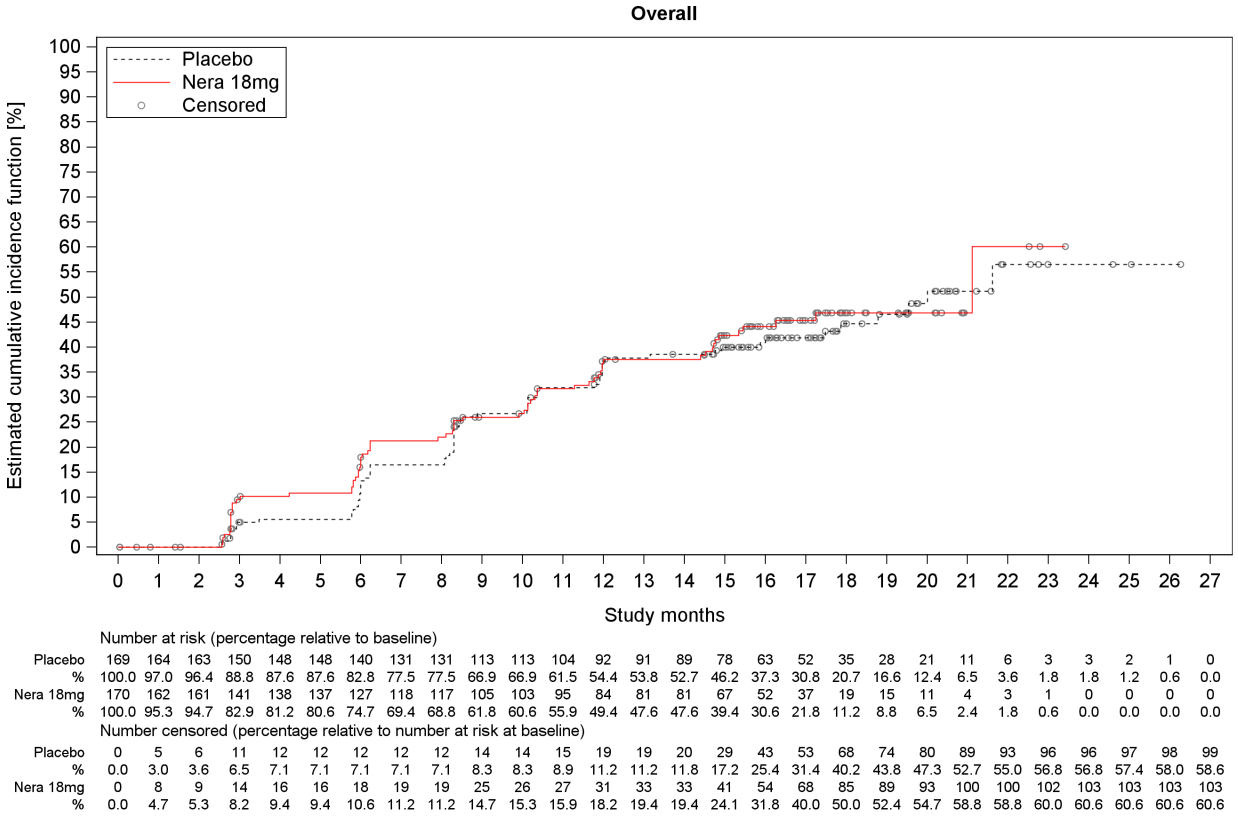

Number at risk (percentage relative to baseline)																												
Placebo	169	164	163	150	148	148	140	131	131	113	113	104	92	91	89	78	63	52	35	28	21	11	6	3	3	2	1	0
%	100.0	97.0	96.4	88.8	87.6	87.6	82.8	77.5	77.5	66.9	66.9	61.5	54.4	53.8	52.7	46.2	37.3	30.8	20.7	16.6	12.4	6.5	3.6	1.8	1.8	1.2	0.6	0.0
Nera 18mg	170	162	161	141	138	137	127	118	117	105	103	95	84	81	81	67	52	37	19	15	11	4	3	1	0	0	0	0
%	100.0	95.3	94.7	82.9	81.2	80.6	74.7	69.4	68.8	61.8	60.6	55.9	49.4	47.6	47.6	39.4	30.6	21.8	11.2	8.8	6.5	2.4	1.8	0.6	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																												
Placebo	0	5	6	11	12	12	12	12	12	14	14	15	19	19	20	29	43	53	68	74	80	89	93	96	96	97	98	99
%	0.0	3.0	3.6	6.5	7.1	7.1	7.1	7.1	7.1	8.3	8.3	8.9	11.2	11.2	11.8	17.2	25.4	31.4	40.2	43.8	47.3	52.7	55.0	56.8	56.8	57.4	58.0	58.6
Nera 18mg	0	8	9	14	16	16	18	19	19	25	26	27	31	33	33	41	54	68	85	89	93	100	100	102	103	103	103	103
%	0.0	4.7	5.3	8.2	9.4	9.4	10.6	11.2	11.2	14.7	15.3	15.9	18.2	19.4	19.4	24.1	31.8	40.0	50.0	52.4	54.7	58.8	58.8	60.0	60.6	60.6	60.6	60.6

Study: 1305-0023

Figure I.1.1.1.1.3.2: 2 Time to first L-PF Dyspnea domain score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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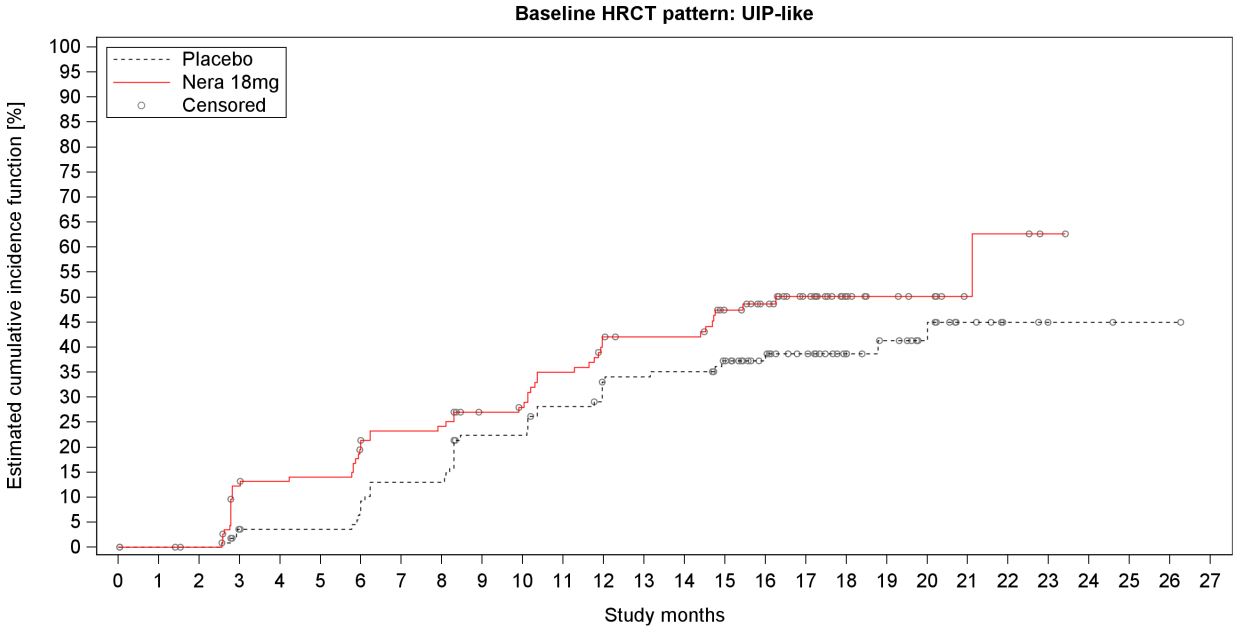

Number at risk (percentage relative to baseline)

Placebo	116	113	112	104	103	103	99	93	93	81	81	74	66	65	64	56	45	37	26	21	16	8	4	2	2	1	1	0
%	100.0	97.4	96.6	89.7	88.8	88.8	85.3	80.2	80.2	69.8	69.8	63.8	56.9	56.0	55.2	48.3	38.8	31.9	22.4	18.1	13.8	6.9	3.4	1.7	1.7	0.9	0.9	0.0
Nera 18mg	121	117	116	99	96	95	87	82	81	74	72	65	57	55	55	45	36	26	14	10	8	4	3	1	0	0	0	0
%	100.0	96.7	95.9	81.8	79.3	78.5	71.9	67.8	66.9	61.2	59.5	53.7	47.1	45.5	45.5	37.2	29.8	21.5	11.6	8.3	6.6	3.3	2.5	0.8	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	3	4	8	9	9	9	9	9	11	11	12	15	15	15	21	32	39	50	54	59	66	70	72	72	73	73	74
%	0.0	2.6	3.4	6.9	7.8	7.8	7.8	7.8	7.8	9.5	9.5	10.3	12.9	12.9	12.9	18.1	27.6	33.6	43.1	46.6	50.9	56.9	60.3	62.1	62.1	62.9	62.9	63.8
Nera 18mg	0	4	5	8	10	10	12	13	13	17	18	18	19	21	21	26	34	43	55	59	61	65	65	67	68	68	68	68
%	0.0	3.3	4.1	6.6	8.3	8.3	9.9	10.7	10.7	14.0	14.9	14.9	15.7	17.4	17.4	21.5	28.1	35.5	45.5	48.8	50.4	53.7	53.7	55.4	56.2	56.2	56.2	56.2

Study: 1305-0023

Figure I.1.1.1.3.2: 2 Time to first L-PF Dyspnea domain score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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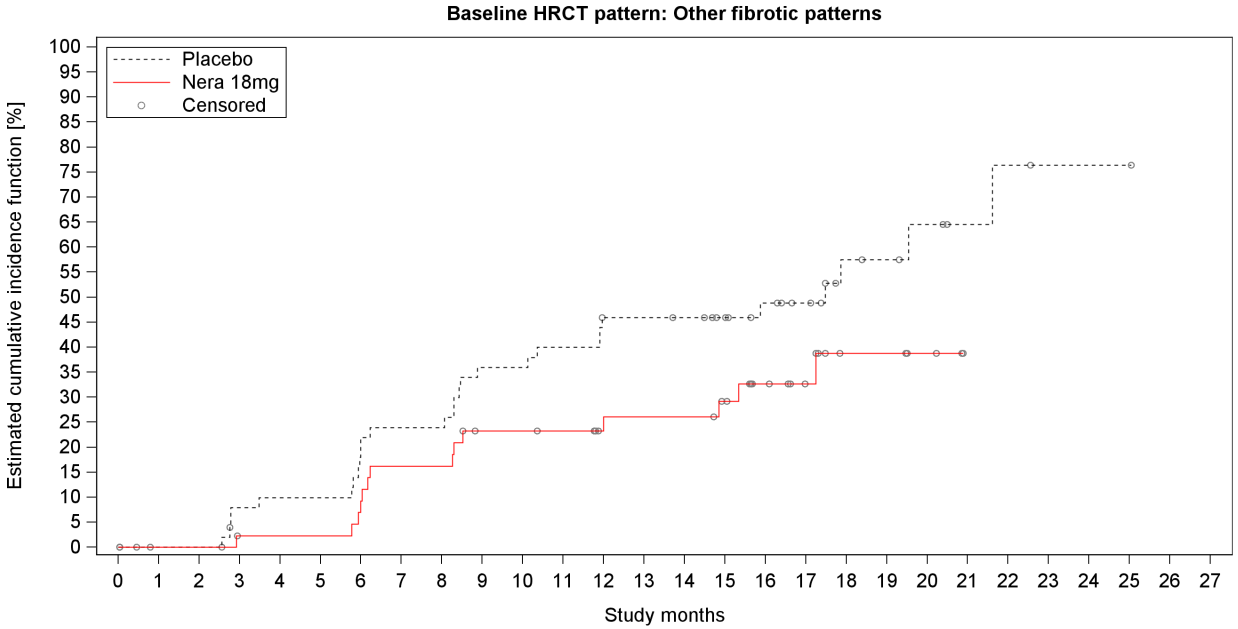

Number at risk (percentage relative to baseline)

Placebo	53	51	51	46	45	45	41	38	38	32	32	30	26	26	25	22	18	15	9	7	5	3	2	1	1	1	0	0
%	100.0	96.2	96.2	86.8	84.9	84.9	77.4	71.7	71.7	60.4	60.4	56.6	49.1	49.1	47.2	41.5	34.0	28.3	17.0	13.2	9.4	5.7	3.8	1.9	1.9	1.9	0.0	0.0
Nera 18mg	49	45	45	42	42	42	40	36	36	31	31	30	27	26	26	22	16	11	5	5	3	0	0	0	0	0	0	0
%	100.0	91.8	91.8	85.7	85.7	85.7	81.6	73.5	73.5	63.3	63.3	61.2	55.1	53.1	53.1	44.9	32.7	22.4	10.2	10.2	6.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	2	2	3	3	3	3	3	3	3	3	3	4	4	5	8	11	14	18	20	21	23	23	24	24	24	25	25
%	0.0	3.8	3.8	5.7	5.7	5.7	5.7	5.7	5.7	5.7	5.7	5.7	7.5	7.5	9.4	15.1	20.8	26.4	34.0	37.7	39.6	43.4	43.4	45.3	45.3	45.3	47.2	47.2
Nera 18mg	0	4	4	6	6	6	6	6	6	8	8	9	12	12	12	15	20	25	30	30	32	35	35	35	35	35	35	35
%	0.0	8.2	8.2	12.2	12.2	12.2	12.2	12.2	12.2	16.3	16.3	18.4	24.5	24.5	24.5	30.6	40.8	51.0	61.2	61.2	65.3	71.4	71.4	71.4	71.4	71.4	71.4	71.4

Study: 1305-0023

Figure I.1.1.1.3.2: 2 Time to first L-PF Dyspnea domain score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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Table I.1.1.1.1.3.2: 3 Cox model for time to first L-PF Fatigue domain score deterioration (increase >= 15) over the whole trial - 18mg - FAS (NIN background)

Subgroup	Placebo				Nera 18mg				Nera 18mg vs Placebo				
Category	N	n	%	Rate°	N	n	%	Rate°	Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	96	56.8	65.10	170	99	58.2	71.85	1.17	(0.88,	1.55)	0.2853	
Age													0.8207
<65 years	65	35	53.8	56.01	64	36	56.3	67.06	1.12	(0.70,	1.79)	0.6407	
>=65 years	104	61	58.7	71.80	106	63	59.4	74.90	1.20	(0.84,	1.71)	0.3218	
Sex													0.9278
Male	114	70	61.4	76.32	108	65	60.2	81.45	1.18	(0.83,	1.66)	0.3567	
Female	55	26	47.3	46.65	62	34	54.8	58.63	1.21	(0.72,	2.03)	0.4687	
Baseline FVC percent predicted													0.6603
<=70%	95	60	63.2	78.50	97	61	62.9	80.50	1.11	(0.78,	1.60)	0.5599	
>70%	74	36	48.6	50.69	73	38	52.1	61.28	1.27	(0.80,	2.01)	0.3094	
Baseline HRCT pattern													0.7469
UIP-like	116	65	56.0	64.78	121	71	58.7	71.21	1.21	(0.85,	1.70)	0.2862	
Other fibrotic patterns	53	31	58.5	65.80	49	28	57.1	73.52	1.09	(0.65,	1.82)	0.7445	
Underlying ILD diagnosis													0.3193
iNSIP	32	17	53.1	56.51	27	18	66.7	103.68	1.81	(0.92,	3.56)	0.0845	
Unclassifiable IIP	46	26	56.5	69.06	32	21	65.6	77.09	1.30	(0.73,	2.33)	0.3723	
HP	38	25	65.8	70.72	43	20	46.5	53.18	0.97	(0.53,	1.76)	0.9244	
Autoimmune ILD	29	17	58.6	69.54	43	23	53.5	63.71	0.73	(0.38,	1.38)	0.3299	
Other ILD	24	11	45.8	55.21	25	17	68.0	87.26	1.51	(0.70,	3.24)	0.2943	
Region													0.9102
Europe	78	44	56.4	64.20	67	38	56.7	76.73	1.31	(0.84,	2.02)	0.2325	
Asia	45	25	55.6	65.95	41	22	53.7	62.91	1.03	(0.57,	1.88)	0.9216	
Canada and USA	30	16	53.3	56.42	37	25	67.6	80.61	1.26	(0.67,	2.39)	0.4684	
Rest of the World	16	11	68.8	86.95	25	14	56.0	62.81	1.03	(0.46,	2.32)	0.9378	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline fatigue domain score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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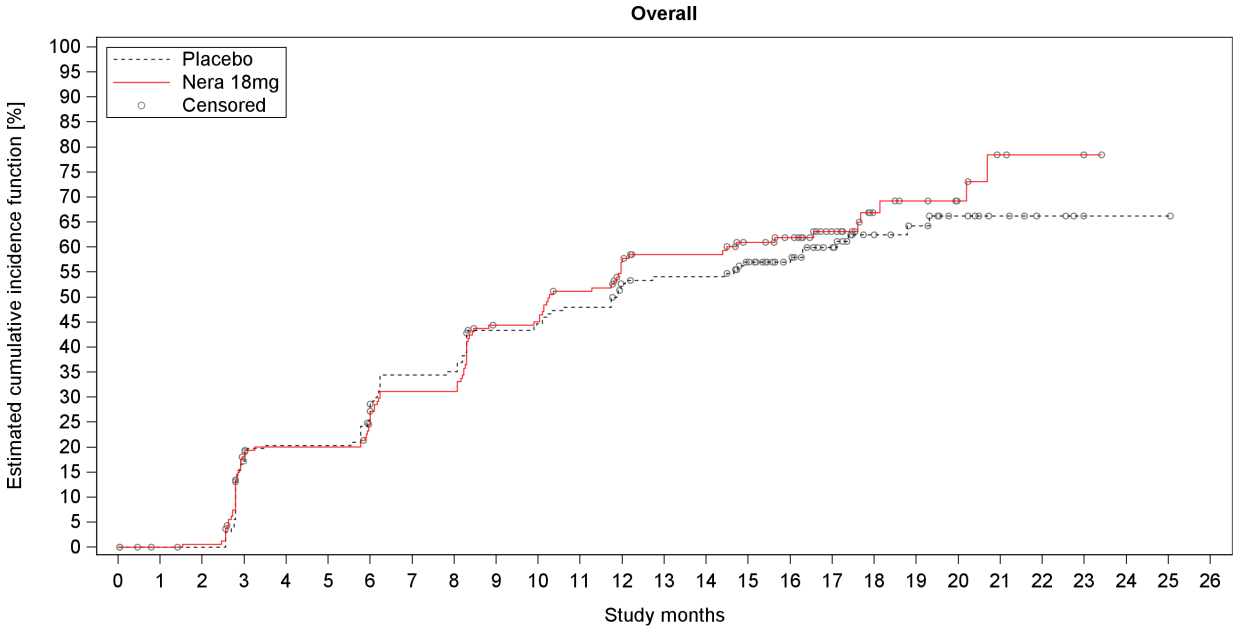

Number at risk (percentage relative to baseline)																											
Placebo	169	164	163	132	126	126	117	102	101	86	84	79	68	65	65	55	46	36	24	19	12	7	4	1	1	1	0
%	100.0	97.0	96.4	78.1	74.6	74.6	69.2	60.4	59.8	50.9	49.7	46.7	40.2	38.5	38.5	32.5	27.2	21.3	14.2	11.2	7.1	4.1	2.4	0.6	0.6	0.6	0.0
Nera 18mg	170	162	161	129	124	124	115	104	104	82	81	71	57	52	52	44	38	26	14	11	8	3	2	1	0	0	0
%	100.0	95.3	94.7	75.9	72.9	72.9	67.6	61.2	61.2	48.2	47.6	41.8	33.5	30.6	30.6	25.9	22.4	15.3	8.2	6.5	4.7	1.8	1.2	0.6	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																											
Placebo	0	5	6	9	10	10	11	12	12	14	14	14	18	19	19	25	34	41	51	55	61	66	69	72	72	72	73
%	0.0	3.0	3.6	5.3	5.9	5.9	6.5	7.1	7.1	8.3	8.3	8.3	10.7	11.2	11.2	14.8	20.1	24.3	30.2	32.5	36.1	39.1	40.8	42.6	42.6	42.6	43.2
Nera 18mg	0	8	8	12	14	14	16	17	17	19	19	20	26	29	29	34	39	50	60	62	65	68	69	70	71	71	71
%	0.0	4.7	4.7	7.1	8.2	8.2	9.4	10.0	10.0	11.2	11.2	11.8	15.3	17.1	17.1	20.0	22.9	29.4	35.3	36.5	38.2	40.0	40.6	41.2	41.8	41.8	41.8

Study: 1305-0023

Figure I.1.1.1.1.3.2: 3 Time to first L-PF Fatigue domain score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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I.1.1.1.1.3.3 Patient Global Impression of Severity (PGI-S) scores

Table I.1.1.1.1.3.3: 1 Cox model for time to first PGI-S Cough score deterioration (increase >= 1) over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	99	58.6	73.88	170	101	59.4	81.69	1.11	(0.83,	1.47)	0.4857	
Age													0.2273
<65 years	65	44	67.7	82.65	64	37	57.8	81.58	0.90	(0.58,	1.39)	0.6268	
>=65 years	104	55	52.9	68.10	106	64	60.4	81.76	1.28	(0.88,	1.85)	0.1916	
Sex													0.4511
Male	114	68	59.6	75.89	108	64	59.3	92.18	1.22	(0.86,	1.73)	0.2689	
Female	55	31	56.4	69.83	62	37	59.7	68.26	0.97	(0.60,	1.57)	0.9015	
Baseline FVC percent predicted													0.8454
<=70%	95	57	60.0	80.04	97	59	60.8	88.18	1.13	(0.78,	1.64)	0.5066	
>70%	74	42	56.8	66.89	73	42	57.5	74.04	1.07	(0.69,	1.65)	0.7562	
Baseline HRCT pattern													0.7546
UIP-like	116	69	59.5	74.41	121	72	59.5	78.44	1.07	(0.76,	1.51)	0.6870	
Other fibrotic patterns	53	30	56.6	72.70	49	29	59.2	91.06	1.18	(0.71,	1.98)	0.5197	
Underlying ILD diagnosis													0.6353
iNSIP	32	16	50.0	56.40	27	13	48.1	78.81	1.36	(0.65,	2.86)	0.4166	
Unclassifiable IIP	46	27	58.7	73.21	32	22	68.8	103.24	1.44	(0.81,	2.54)	0.2106	
HP	38	28	73.7	99.66	43	23	53.5	67.36	0.81	(0.46,	1.42)	0.4617	
Autoimmune ILD	29	13	44.8	48.14	43	24	55.8	64.70	1.25	(0.63,	2.49)	0.5218	
Other ILD	24	15	62.5	109.93	25	19	76.0	130.23	0.98	(0.49,	1.95)	0.9577	
Region													0.7038
Europe	78	49	62.8	86.00	67	41	61.2	87.35	0.96	(0.63,	1.46)	0.8590	
Asia	45	26	57.8	67.78	41	21	51.2	61.97	1.08	(0.60,	1.96)	0.8007	
Canada and USA	30	16	53.3	58.66	37	24	64.9	91.01	1.53	(0.80,	2.91)	0.1959	
Rest of the World	16	8	50.0	70.24	25	15	60.0	91.25	1.17	(0.49,	2.80)	0.7274	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline cough score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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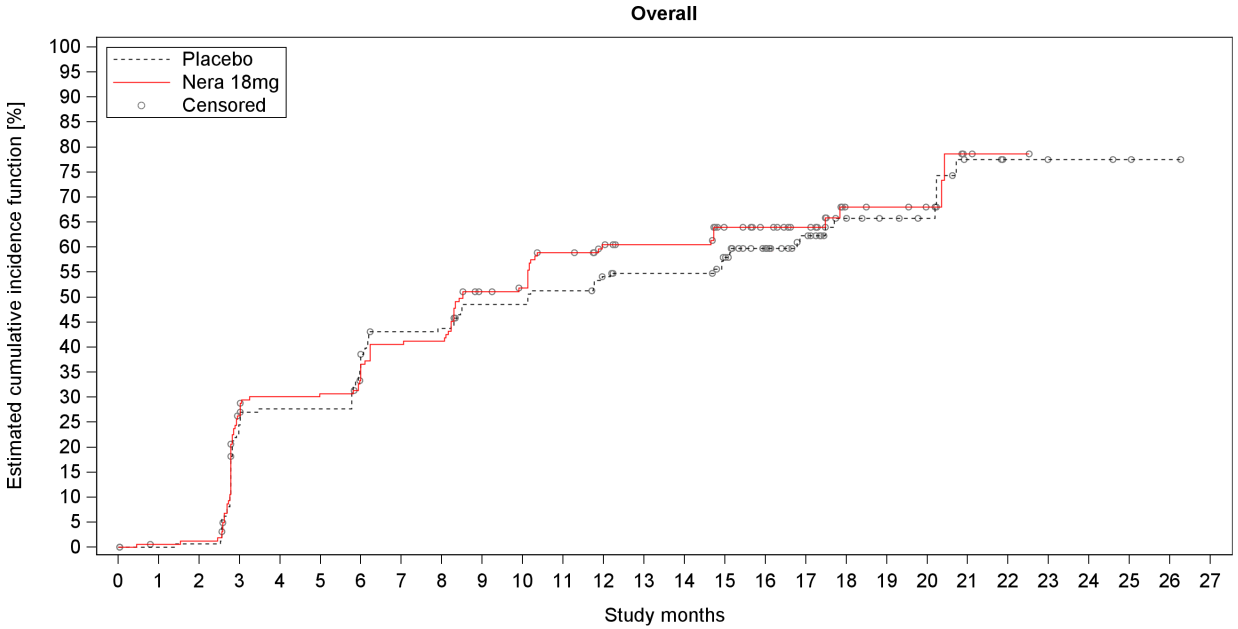

Number at risk (percentage relative to baseline)

Placebo	169	160	159	119	113	113	101	85	84	75	75	71	64	60	60	51	39	29	18	15	12	6	4	3	3	2	1	0
%	100.0	94.7	94.1	70.4	66.9	66.9	59.8	50.3	49.7	44.4	44.4	42.0	37.9	35.5	35.5	30.2	23.1	17.2	10.7	8.9	7.1	3.6	2.4	1.8	1.8	1.2	0.6	0.0
Nera 18mg	170	161	160	116	109	108	101	90	89	71	68	57	49	46	46	36	28	22	12	11	9	2	1	0	0	0	0	0
%	100.0	94.7	94.1	68.2	64.1	63.5	59.4	52.9	52.4	41.8	40.0	33.5	28.8	27.1	27.1	21.2	16.5	12.9	7.1	6.5	5.3	1.2	0.6	0.0	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	9	9	11	12	12	12	16	16	18	18	18	21	24	24	29	39	47	56	59	62	64	66	67	67	68	69	70
%	0.0	5.3	5.3	6.5	7.1	7.1	7.1	9.5	9.5	10.7	10.7	10.7	12.4	14.2	14.2	17.2	23.1	27.8	33.1	34.9	36.7	37.9	39.1	39.6	39.6	40.2	40.8	41.4
Nera 18mg	0	8	8	12	13	13	16	16	16	19	21	22	28	31	31	37	45	51	59	60	62	67	68	69	69	69	69	69
%	0.0	4.7	4.7	7.1	7.6	7.6	9.4	9.4	9.4	11.2	12.4	12.9	16.5	18.2	18.2	21.8	26.5	30.0	34.7	35.3	36.5	39.4	40.0	40.6	40.6	40.6	40.6	40.6

Study: 1305-0023

Figure I.1.1.1.1.3.3: 1 Time to first PGI-S Cough score deterioration (increase >= 1) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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Figure I.1.1.1.1.3.3: 1

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Table I.1.1.1.1.3.3: 2 Cox model for time to first PGI-S Shortness of Breath score deterioration (increase >=1) over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	94	55.6	66.07	170	87	51.2	63.16	0.94	(0.69, 1.26)	0.6580	
Age												0.4714
<65 years	65	35	53.8	58.00	64	32	50.0	62.76	0.82	(0.50, 1.32)	0.4094	
>=65 years	104	59	56.7	72.01	106	55	51.9	63.40	1.02	(0.70, 1.50)	0.9049	
Sex												0.4667
Male	114	64	56.1	66.77	108	55	50.9	63.17	1.01	(0.70, 1.47)	0.9378	
Female	55	30	54.5	64.62	62	32	51.6	63.15	0.80	(0.48, 1.34)	0.3974	
Baseline FVC percent predicted												0.5369
<=70%	95	62	65.3	83.96	97	54	55.7	69.99	0.87	(0.60, 1.26)	0.4748	
>70%	74	32	43.2	46.77	73	33	45.2	54.46	1.06	(0.65, 1.74)	0.8147	
Baseline HRCT pattern												0.9439
UIP-like	116	65	56.0	66.39	121	63	52.1	61.38	0.94	(0.66, 1.35)	0.7417	
Other fibrotic patterns	53	29	54.7	65.36	49	24	49.0	68.36	0.92	(0.54, 1.58)	0.7632	
Underlying ILD diagnosis												0.1773
iNSIP	32	19	59.4	69.31	27	13	48.1	71.09	1.21	(0.59, 2.50)	0.6035	
Unclassifiable IIP	46	25	54.3	65.04	32	21	65.6	86.46	1.24	(0.69, 2.23)	0.4734	
HP	38	26	68.4	89.25	43	17	39.5	44.92	0.65	(0.35, 1.22)	0.1839	
Autoimmune ILD	29	16	55.2	63.01	43	22	51.2	59.02	0.66	(0.34, 1.27)	0.2120	
Other ILD	24	8	33.3	36.53	25	14	56.0	69.85	1.94	(0.81, 4.65)	0.1346	
Region												0.9833
Europe	78	42	53.8	65.71	67	33	49.3	59.82	0.94	(0.59, 1.48)	0.7759	
Asia	45	23	51.1	53.68	41	20	48.8	59.99	0.87	(0.47, 1.63)	0.6706	
Canada and USA	30	20	66.7	80.33	37	21	56.8	67.07	0.95	(0.51, 1.76)	0.8622	
Rest of the World	16	9	56.3	84.81	25	13	52.0	72.55	1.09	(0.46, 2.58)	0.8532	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline shortness of breath score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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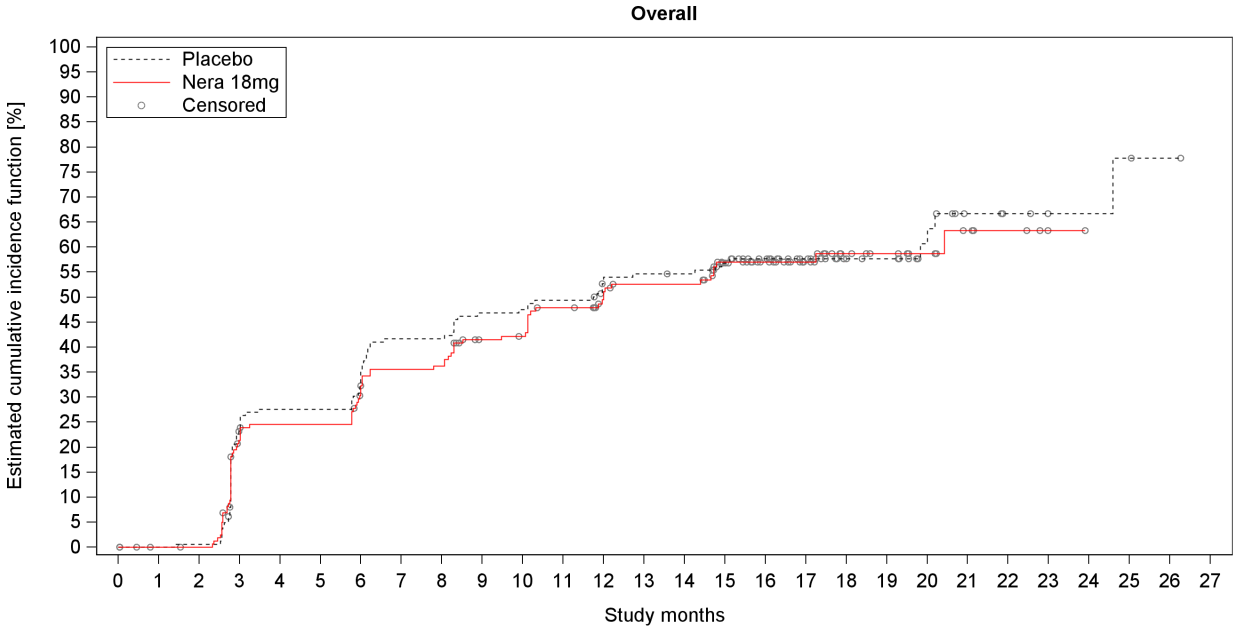

Number at risk (percentage relative to baseline)																												
Placebo	169	162	161	120	113	113	106	91	91	83	82	79	70	67	66	56	45	36	24	20	13	7	5	3	3	2	1	0
%	100.0	95.9	95.3	71.0	66.9	66.9	62.7	53.8	53.8	49.1	48.5	46.7	41.4	39.6	39.1	33.1	26.6	21.3	14.2	11.8	7.7	4.1	3.0	1.8	1.8	1.2	0.6	0.0
Nera 18mg	170	161	160	124	118	118	107	98	97	83	81	72	64	58	58	45	36	27	18	15	12	6	4	1	0	0	0	0
%	100.0	94.7	94.1	72.9	69.4	69.4	62.9	57.6	57.1	48.8	47.6	42.4	37.6	34.1	34.1	26.5	21.2	15.9	10.6	8.8	7.1	3.5	2.4	0.6	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																												
Placebo	0	7	7	12	12	12	12	12	12	12	12	12	16	16	17	24	34	43	55	59	65	69	71	73	73	73	74	75
%	0.0	4.1	4.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	9.5	9.5	10.1	14.2	20.1	25.4	32.5	34.9	38.5	40.8	42.0	43.2	43.2	43.2	43.8	44.4
Nera 18mg	0	9	10	12	13	13	15	16	16	22	23	24	30	32	32	40	49	58	66	69	72	77	79	82	83	83	83	83
%	0.0	5.3	5.9	7.1	7.6	7.6	8.8	9.4	9.4	12.9	13.5	14.1	17.6	18.8	18.8	23.5	28.8	34.1	38.8	40.6	42.4	45.3	46.5	48.2	48.8	48.8	48.8	48.8

Study: 1305-0023

Figure I.1.1.1.1.3.3: 2 Time to first PGI-S Shortness of Breath score deterioration (increase >=1) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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Figure I.1.1.1.1.3.3: 2

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I.1.1.1.1.4 Time to event analyses of supplemental oxygen use

Table I.1.1.1.1.4: 1 Cox model for time to first use of supplemental oxygen (in patients without baseline use) over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	102	27	26.5	21.38	97	24	24.7	22.24	1.04	(0.60,	1.80)	0.8981	
Age													0.9700
<65 years	44	10	22.7	17.65	41	10	24.4	20.58	1.05	(0.43,	2.54)	0.9140	
>=65 years	58	17	29.3	24.43	56	14	25.0	23.59	1.03	(0.50,	2.09)	0.9411	
Sex													0.4257
Male	66	19	28.8	23.96	61	19	31.1	30.33	1.19	(0.62,	2.27)	0.6059	
Female	36	8	22.2	17.03	36	5	13.9	11.04	0.69	(0.22,	2.15)	0.5265	
Baseline FVC percent predicted													0.7295
<=70%	49	18	36.7	31.98	46	15	32.6	30.99	0.95	(0.48,	1.90)	0.8929	
>70%	53	9	17.0	12.86	51	9	17.6	15.12	1.17	(0.46,	2.96)	0.7403	
Baseline HRCT pattern													0.1174
UIP-like	74	17	23.0	18.38	73	20	27.4	24.36	1.38	(0.72,	2.65)	0.3389	
Other fibrotic patterns	28	10	35.7	29.60	24	4	16.7	15.49	0.47	(0.15,	1.51)	0.2049	
Underlying ILD diagnosis													0.8111
iNSIP	19	4	21.1	16.73	15	1	6.7	6.54	0.32	(0.04,	2.90)	0.3103	
Unclassifiable IIP	23	8	34.8	28.01	16	3	18.8	16.10	0.98	(0.25,	3.81)	0.9731	
HP	26	7	26.9	21.82	21	7	33.3	33.35	1.46	(0.51,	4.21)	0.4857	
Autoimmune ILD	19	3	15.8	12.20	25	6	24.0	19.46	1.04	(0.26,	4.24)	0.9533	
Other ILD	15	5	33.3	29.19	20	7	35.0	31.56	1.30	(0.41,	4.15)	0.6563	
Region													0.8610
Europe	48	13	27.1	21.47	42	8	19.0	18.82	1.00	(0.41,	2.42)	0.9969	
Asia	34	9	26.5	21.83	26	7	26.9	23.01	0.85	(0.31,	2.33)	0.7577	
Canada and USA	11	2	18.2	14.20	12	2	16.7	11.82	0.64	(0.09,	4.54)	0.6510	
Rest of the World	9	3	33.3	28.84	17	7	41.2	38.73	1.61	(0.40,	6.55)	0.5063	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb). The subgroup model additionally includes the subgroup and treatment by subgroup interaction. Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined). N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk. NC=not calculable.

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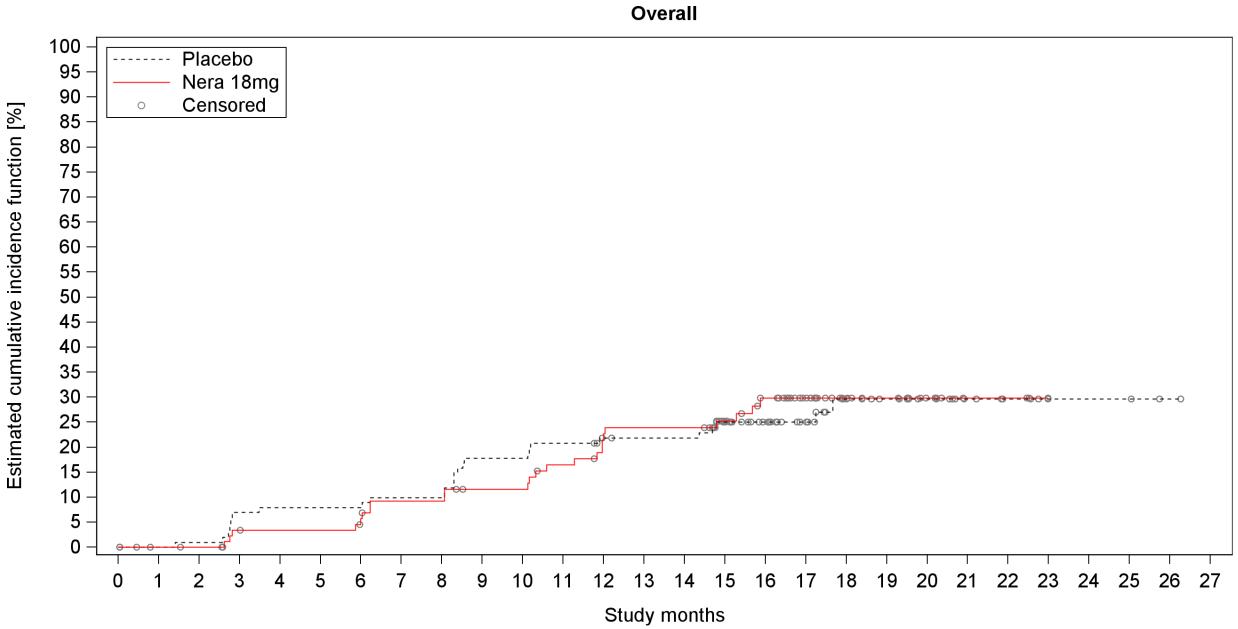

Number at risk (percentage relative to baseline)

Placebo	102	101	100	94	93	93	93	91	91	83	83	80	74	73	73	65	51	42	25	19	15	9	6	3	3	3	1	0
%	100.0	99.0	98.0	92.2	91.2	91.2	91.2	89.2	89.2	81.4	81.4	78.4	72.5	71.6	71.6	63.7	50.0	41.2	24.5	18.6	14.7	8.8	5.9	2.9	2.9	2.9	1.0	0.0
Nera 18mg	97	92	91	85	84	84	82	77	77	73	73	68	63	61	61	52	42	31	17	14	9	4	4	0	0	0	0	0
%	100.0	94.8	93.8	87.6	86.6	86.6	84.5	79.4	79.4	75.3	75.3	70.1	64.9	62.9	62.9	53.6	43.3	32.0	17.5	14.4	9.3	4.1	4.1	0.0	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	1	1	1	1	1	1	1	1	1	1	1	6	7	7	12	26	35	50	56	60	66	69	72	72	72	74	75
%	0.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	5.9	6.9	6.9	11.8	25.5	34.3	49.0	54.9	58.8	64.7	67.6	70.6	70.6	70.6	72.5	73.5
Nera 18mg	0	5	6	9	10	10	11	12	12	14	14	15	16	16	16	24	31	42	56	59	64	69	69	73	73	73	73	73
%	0.0	5.2	6.2	9.3	10.3	10.3	11.3	12.4	12.4	14.4	14.4	15.5	16.5	16.5	16.5	24.7	32.0	43.3	57.7	60.8	66.0	71.1	71.1	75.3	75.3	75.3	75.3	75.3

Study: 1305-0023

Figure I.1.1.1.1.4: 1 Time to first use of supplemental oxygen (in patients without baseline use) over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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Figure I.1.1.1.1.4: 1

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Table I.1.1.1.1.4: 2 Cox model for time to first increase of supplemental oxygen use over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	76	45.0	46.39	170	76	44.7	49.96	0.99	(0.72, 1.37)	0.9599	
Age												0.5419
<65 years	65	26	40.0	38.15	64	25	39.1	41.03	0.85	(0.49, 1.49)	0.5765	
>=65 years	104	50	48.1	52.26	106	51	48.1	55.93	1.05	(0.71, 1.56)	0.7899	
Sex												0.7447
Male	114	54	47.4	50.46	108	50	46.3	55.83	0.96	(0.65, 1.42)	0.8395	
Female	55	22	40.0	38.74	62	26	41.9	41.56	1.08	(0.60, 1.93)	0.7953	
Baseline FVC percent predicted												0.5628
<=70%	95	52	54.7	65.72	97	53	54.6	66.01	0.93	(0.63, 1.36)	0.7010	
>70%	74	24	32.4	28.34	73	23	31.5	32.02	1.14	(0.64, 2.02)	0.6609	
Baseline HRCT pattern												0.3717
UIP-like	116	46	39.7	38.66	121	55	45.5	48.79	1.10	(0.74, 1.64)	0.6323	
Other fibrotic patterns	53	30	56.6	66.93	49	21	42.9	53.31	0.81	(0.46, 1.41)	0.4495	
Underlying ILD diagnosis												0.9605
iNSIP	32	10	31.3	30.20	27	10	37.0	50.65	1.36	(0.56, 3.30)	0.4927	
Unclassifiable IIP	46	26	56.5	66.69	32	14	43.8	49.12	0.95	(0.49, 1.82)	0.8688	
HP	38	19	50.0	49.14	43	22	51.2	61.09	1.02	(0.55, 1.90)	0.9490	
Autoimmune ILD	29	9	31.0	29.51	43	20	46.5	47.59	1.12	(0.50, 2.49)	0.7882	
Other ILD	24	12	50.0	53.19	25	10	40.0	38.70	0.87	(0.38, 2.04)	0.7557	
Region												0.8702
Europe	78	35	44.9	43.23	67	26	38.8	45.28	1.06	(0.64, 1.77)	0.8147	
Asia	45	16	35.6	33.37	41	17	41.5	41.68	0.92	(0.46, 1.82)	0.8022	
Canada and USA	30	17	56.7	74.39	37	20	54.1	60.57	0.75	(0.39, 1.46)	0.3958	
Rest of the World	16	8	50.0	66.32	25	13	52.0	62.22	0.84	(0.34, 2.06)	0.6987	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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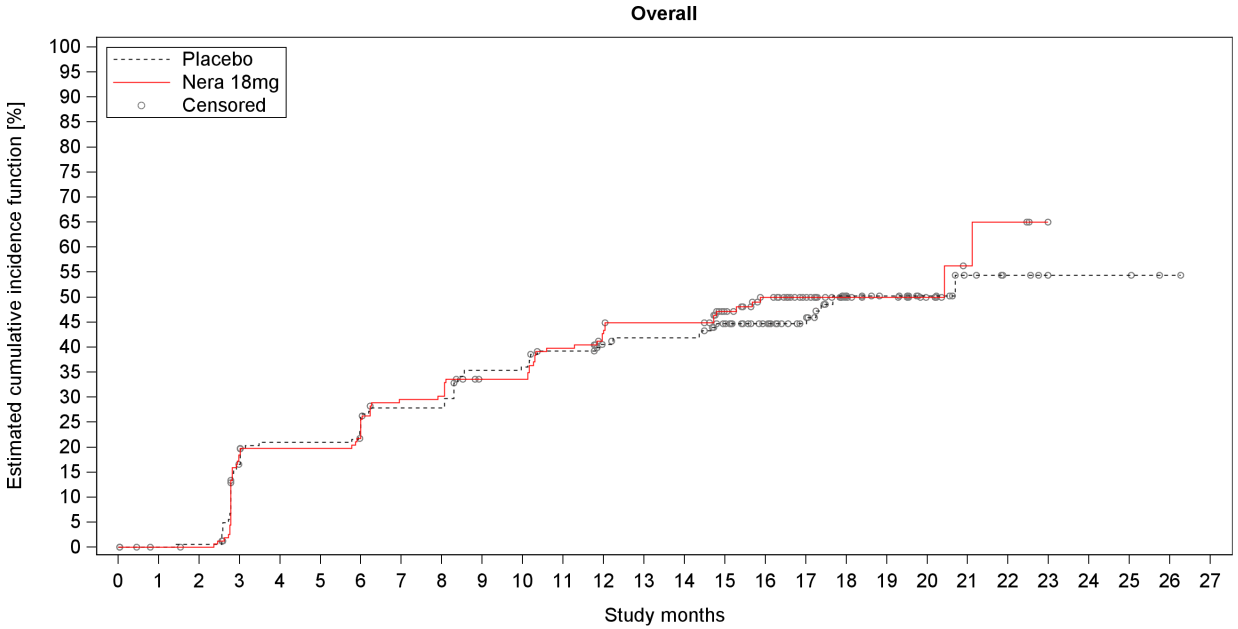

Number at risk (percentage relative to baseline)																												
Placebo	169	163	162	134	126	126	122	115	115	102	101	95	87	84	84	72	57	47	28	21	16	9	6	3	3	3	1	0
%	100.0	96.4	95.9	79.3	74.6	74.6	72.2	68.0	68.0	60.4	59.8	56.2	51.5	49.7	49.7	42.6	33.7	27.8	16.6	12.4	9.5	5.3	3.6	1.8	1.8	1.8	0.6	0.0
Nera 18mg	170	161	160	127	124	124	120	106	105	96	96	86	79	75	75	63	48	36	19	16	11	5	4	0	0	0	0	0
%	100.0	94.7	94.1	74.7	72.9	72.9	70.6	62.4	61.8	56.5	56.5	50.6	46.5	44.1	44.1	37.1	28.2	21.2	11.2	9.4	6.5	2.9	2.4	0.0	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																												
Placebo	0	6	6	8	9	9	9	9	9	10	10	11	17	18	18	26	41	51	66	73	78	84	87	90	90	90	92	93
%	0.0	3.6	3.6	4.7	5.3	5.3	5.3	5.3	5.3	5.9	5.9	6.5	10.1	10.7	10.7	15.4	24.3	30.2	39.1	43.2	46.2	49.7	51.5	53.3	53.3	53.3	54.4	55.0
Nera 18mg	0	9	10	14	15	15	16	18	18	22	22	23	26	27	27	36	48	60	77	80	85	90	90	94	94	94	94	94
%	0.0	5.3	5.9	8.2	8.8	8.8	9.4	10.6	10.6	12.9	12.9	13.5	15.3	15.9	15.9	21.2	28.2	35.3	45.3	47.1	50.0	52.9	52.9	55.3	55.3	55.3	55.3	55.3

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Figure I.1.1.1.1.4: 2 Time to first increase of supplemental oxygen use over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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I.1.1.1.2 Analyses of continuous variables

I.1.1.1.2.1 MMRM Analysis

Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Overall																	
Baseline																	
Placebo	169	167	31.8	1.4	162 (100.0%)												
Nera 18mg	170	167	33.5	1.3	162 (100.0%)												
Week 12																	
Placebo		159	32.0	1.4	157 (96.9%)	0.6	0.9	-1.2	2.4								
Nera 18mg		159	34.6	1.3	157 (96.9%)	1.3	0.9	-0.5	3.1	0.7	1.3	-1.9	3.2	0.5986			
Week 26																	
Placebo		155	35.1	1.5	153 (94.4%)	3.6	1.1	1.5	5.7								
Nera 18mg		149	34.6	1.4	146 (90.1%)	1.6	1.1	-0.6	3.7	-2.0	1.5	-5.0	1.0	0.1833			
Week 36																	
Placebo		150	33.6	1.5	148 (91.4%)	3.0	1.2	0.6	5.3								
Nera 18mg		146	34.1	1.5	144 (88.9%)	1.2	1.2	-1.1	3.6	-1.8	1.7	-5.1	1.6	0.2975			
Week 44																	
Placebo		145	34.4	1.6	143 (88.3%)	3.9	1.2	1.6	6.2								
Nera 18mg		139	36.5	1.6	136 (84.0%)	3.8	1.2	1.5	6.2	-0.1	1.7	-3.4	3.3	0.9671			
Week 52																	
Placebo		147	35.7	1.7	145 (89.5%)	5.4	1.3	2.8	8.0								
Nera 18mg		138	36.2	1.6	136 (84.0%)	4.0	1.3	1.4	6.6	-1.4	1.9	-5.1	2.3	0.4520			
Week 64																	
Placebo		126	34.4	1.7	125 (77.2%)	6.1	1.3	3.5	8.7								
Nera 18mg		120	37.1	1.8	118 (72.8%)	6.1	1.3	3.5	8.8	0.0	1.9	-3.7	3.7	0.9975			
Week 76																	
Placebo		88	32.4	2.0	87 (53.7%)												
Nera 18mg		79	37.7	2.5	77 (47.5%)												
Week 88																	
Placebo		37	36.4	3.5	36 (22.2%)												
Nera 18mg		31	45.6	4.1	31 (19.1%)												
Week 100																	
Placebo		11	27.8	5.0	11 (6.8%)												
Nera 18mg		9	43.5	6.3	9 (5.6%)												
Week 112																	
Placebo		4	21.7	5.8	4 (2.5%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Age																	
Test for homogeneity (H0)^																	
Week 12														0.1151			
Week 26														0.4985			
Week 36														0.9791			
Week 44														0.6902			
Week 52														0.3683			
Week 64														0.8760			
<65 years																	
Baseline																	
Placebo	65	65	32.2	2.2	64 (100.0%)												
Nera 18mg	64	63	32.3	2.0	61 (100.0%)												
Week 12																	
Placebo		62	30.6	2.2	62 (96.9%)	-1.0	1.5	-3.8	1.9								
Nera 18mg		61	34.4	2.2	60 (98.4%)	2.3	1.5	-0.6	5.2	3.2	2.1	-0.8	7.3	0.1203			
Week 26																	
Placebo		62	33.8	2.4	62 (96.9%)	2.2	1.7	-1.2	5.5								
Nera 18mg		58	33.6	2.5	57 (93.4%)	1.4	1.8	-2.1	4.9	-0.8	2.4	-5.6	4.0	0.7532			
Week 36																	
Placebo		61	34.2	2.5	61 (95.3%)	2.3	1.9	-1.4	5.9								
Nera 18mg		56	32.4	2.6	55 (90.2%)	0.6	1.9	-3.3	4.4	-1.7	2.7	-7.0	3.6	0.5278			
Week 44																	
Placebo		61	34.1	2.4	61 (95.3%)	2.5	1.8	-1.2	6.1								
Nera 18mg		51	33.5	2.8	50 (82.0%)	3.2	2.0	-0.7	7.1	0.7	2.7	-4.6	6.0	0.7845			
Week 52																	
Placebo		62	34.6	2.6	62 (96.9%)	2.8	2.0	-1.2	6.8								
Nera 18mg		52	34.8	2.9	51 (83.6%)	3.4	2.2	-0.9	7.6	0.6	3.0	-5.3	6.4	0.8447			
Week 64																	
Placebo		56	34.4	2.4	56 (87.5%)	5.0	2.0	1.0	9.1								
Nera 18mg		44	34.6	3.3	43 (70.5%)	4.7	2.2	0.3	9.0	-0.4	3.0	-6.3	5.6	0.9008			
Week 76																	
Placebo		37	33.8	3.3	37 (57.8%)												
Nera 18mg		34	34.9	3.8	33 (54.1%)												
Week 88																	
Placebo		15	39.9	6.0	15 (23.4%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		7	47.6	9.1	7 (11.5%)												
Week 100																	
Placebo		4	30.3	10.5	4 (6.3%)												
Nera 18mg		1	24.8	NC	1 (1.6%)												
Week 112																	
Placebo		2	22.7	11.7	2 (3.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	104	102	31.6	1.8	98 (100.0%)												
Nera 18mg	106	104	34.3	1.8	101 (100.0%)												
Week 12																	
Placebo		97	32.8	1.8	95 (96.9%)	1.6	1.2	-0.7	3.9								
Nera 18mg		98	34.8	1.6	97 (96.0%)	0.7	1.2	-1.6	3.0	-1.0	1.7	-4.2	2.3	0.5610			
Week 26																	
Placebo		93	36.0	2.0	91 (92.9%)	4.5	1.4	1.8	7.3								
Nera 18mg		91	35.2	1.8	89 (88.1%)	1.7	1.4	-1.1	4.4	-2.9	2.0	-6.8	1.0	0.1430			
Week 36																	
Placebo		89	33.3	1.9	87 (88.8%)	3.4	1.5	0.4	6.5								
Nera 18mg		90	35.2	1.8	89 (88.1%)	1.6	1.5	-1.4	4.6	-1.8	2.2	-6.1	2.5	0.4114			
Week 44																	
Placebo		84	34.6	2.2	82 (83.7%)	4.9	1.5	1.8	7.9								
Nera 18mg		88	38.2	2.0	86 (85.1%)	4.2	1.5	1.2	7.2	-0.6	2.2	-4.9	3.6	0.7671			
Week 52																	
Placebo		85	36.5	2.3	83 (84.7%)	7.3	1.7	3.9	10.6								
Nera 18mg		86	37.1	2.0	85 (84.2%)	4.4	1.7	1.1	7.7	-2.9	2.4	-7.6	1.9	0.2354			
Week 64																	
Placebo		70	34.4	2.4	69 (70.4%)	6.8	1.8	3.3	10.2								
Nera 18mg		76	38.5	2.1	75 (74.3%)	7.0	1.7	3.6	10.4	0.2	2.5	-4.6	5.1	0.9249			
Week 76																	
Placebo		51	31.4	2.6	50 (51.0%)												
Nera 18mg		45	39.7	3.2	44 (43.6%)												
Week 88																	
Placebo		22	34.0	4.3	21 (21.4%)												
Nera 18mg		24	45.0	4.6	24 (23.8%)												
Week 100																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		7	26.3	5.8	7 (7.1%)												
Nera 18mg		8	45.8	6.6	8 (7.9%)												
Week 112																	
Placebo		2	20.7	8.1	2 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Sex																	
Test for homogeneity (H0)^																	
Week 12														0.2580			
Week 26														0.9326			
Week 36														0.1553			
Week 44														0.6280			
Week 52														0.7729			
Week 64														0.2493			
Male																	
Baseline																	
Placebo	114	113	29.7	1.6	110 (100.0%)												
Nera 18mg	108	105	31.7	1.6	100 (100.0%)												
Week 12																	
Placebo		107	31.9	1.7	106 (96.4%)	2.1	1.1	-0.1	4.3								
Nera 18mg		99	33.8	1.7	97 (97.0%)	1.9	1.2	-0.4	4.2	-0.2	1.6	-3.4	2.9	0.8859			
Week 26																	
Placebo		103	34.9	1.9	102 (92.7%)	4.8	1.3	2.2	7.4								
Nera 18mg		93	34.6	1.8	90 (90.0%)	2.9	1.4	0.2	5.6	-1.9	1.9	-5.6	1.8	0.3119			
Week 36																	
Placebo		99	32.8	1.9	98 (89.1%)	3.7	1.4	0.9	6.5								
Nera 18mg		88	35.8	2.0	86 (86.0%)	4.0	1.5	1.1	7.0	0.3	2.1	-3.8	4.4	0.8683			
Week 44																	
Placebo		96	33.2	2.0	95 (86.4%)	4.8	1.4	1.9	7.6								
Nera 18mg		82	36.5	2.1	79 (79.0%)	5.5	1.5	2.5	8.5	0.7	2.1	-3.4	4.9	0.7293			
Week 52																	
Placebo		97	35.6	2.2	96 (87.3%)	7.1	1.6	4.0	10.3								
Nera 18mg		82	37.6	2.2	80 (80.0%)	6.5	1.7	3.1	9.8	-0.6	2.3	-5.2	3.9	0.7823			
Week 64																	

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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo		81	32.6	2.0	81 (73.6%)	7.1	1.6	3.9	10.3								
Nera 18mg		72	40.0	2.4	70 (70.0%)	9.1	1.7	5.8	12.5	2.0	2.4	-2.6	6.6	0.3924			
Week 76																	
Placebo		54	31.4	2.4	54 (49.1%)												
Nera 18mg		47	42.3	3.3	45 (45.0%)												
Week 88																	
Placebo		24	37.9	4.1	24 (21.8%)												
Nera 18mg		18	49.4	5.7	18 (18.0%)												
Week 100																	
Placebo		7	30.8	7.2	7 (6.4%)												
Nera 18mg		4	56.3	6.4	4 (4.0%)												
Week 112																	
Placebo		2	20.7	8.1	2 (1.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Female																	
Baseline																	
Placebo	55	54	36.2	2.6	52 (100.0%)												
Nera 18mg	62	62	36.7	2.3	62 (100.0%)												
Week 12																	
Placebo		52	32.2	2.5	51 (98.1%)	-2.5	1.6	-5.7	0.6								
Nera 18mg		60	36.0	2.2	60 (96.8%)	0.3	1.5	-2.6	3.2	2.8	2.2	-1.5	7.1	0.1945			
Week 26																	
Placebo		52	35.5	2.6	51 (98.1%)	1.1	1.9	-2.6	4.8								
Nera 18mg		56	34.7	2.4	56 (90.3%)	-0.6	1.7	-4.0	2.9	-1.6	2.5	-6.7	3.4	0.5183			
Week 36																	
Placebo		51	35.2	2.6	50 (96.2%)	1.4	2.0	-2.6	5.5								
Nera 18mg		58	31.6	2.2	58 (93.5%)	-3.2	1.9	-6.9	0.6	-4.6	2.8	-10.0	0.9	0.0985			
Week 44																	
Placebo		49	36.8	2.8	48 (92.3%)	2.1	2.1	-1.9	6.1								
Nera 18mg		57	36.5	2.7	57 (91.9%)	1.1	1.9	-2.6	4.9	-1.0	2.8	-6.5	4.5	0.7295			
Week 52																	
Placebo		50	36.0	2.9	49 (94.2%)	1.9	2.3	-2.6	6.3								
Nera 18mg		56	34.2	2.5	56 (90.3%)	0.1	2.1	-4.0	4.3	-1.8	3.1	-7.8	4.3	0.5683			
Week 64																	
Placebo		45	37.7	3.0	44 (84.6%)	4.0	2.3	-0.5	8.4								
Nera 18mg		48	32.6	2.6	48 (77.4%)	1.5	2.1	-2.7	5.7	-2.5	3.1	-8.6	3.6	0.4242			

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 76																	
Placebo		34	34.1	3.6	33 (63.5%)												
Nera 18mg		32	30.8	3.3	32 (51.6%)												
Week 88																	
Placebo		13	33.7	6.5	12 (23.1%)												
Nera 18mg		13	40.4	5.6	13 (21.0%)												
Week 100																	
Placebo		4	22.5	5.9	4 (7.7%)												
Nera 18mg		5	33.3	7.6	5 (8.1%)												
Week 112																	
Placebo		2	22.7	11.7	2 (3.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 12														0.7760			
Week 26														0.8603			
Week 36														0.8194			
Week 44														0.3356			
Week 52														0.7688			
Week 64														0.9177			
<=70%																	
Baseline																	
Placebo	95	95	35.3	1.8	91 (100.0%)												
Nera 18mg	97	95	38.4	1.7	94 (100.0%)												
Week 12																	
Placebo		87	34.5	2.0	87 (95.6%)	0.9	1.2	-1.6	3.3								
Nera 18mg		92	38.5	1.7	91 (96.8%)	1.9	1.2	-0.6	4.3	1.0	1.7	-2.4	4.4	0.5602			
Week 26																	
Placebo		85	38.8	2.1	85 (93.4%)	4.8	1.4	2.0	7.7								
Nera 18mg		85	38.8	1.8	83 (88.3%)	2.5	1.5	-0.3	5.4	-2.3	2.0	-6.3	1.7	0.2578			
Week 36																	
Placebo		82	37.8	2.1	82 (90.1%)	4.7	1.6	1.5	7.8								
Nera 18mg		85	38.6	1.9	83 (88.3%)	3.2	1.6	0.1	6.3	-1.5	2.2	-5.8	2.9	0.5129			

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n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 44																	
Placebo		80	38.2	2.1	80 (87.9%)	4.7	1.6	1.5	7.8								
Nera 18mg		79	41.2	2.0	77 (81.9%)	6.0	1.6	2.8	9.2	1.3	2.2	-3.1	5.7	0.5531			
Week 52																	
Placebo		80	41.1	2.5	80 (87.9%)	8.0	1.8	4.5	11.4								
Nera 18mg		79	41.1	2.0	77 (81.9%)	6.1	1.8	2.6	9.5	-1.9	2.5	-6.8	2.9	0.4368			
Week 64																	
Placebo		70	38.1	2.3	70 (76.9%)	8.2	1.8	4.7	11.7								
Nera 18mg		70	41.5	2.2	68 (72.3%)	8.0	1.8	4.5	11.5	-0.2	2.5	-5.1	4.7	0.9372			
Week 76																	
Placebo		45	35.5	3.0	45 (49.5%)												
Nera 18mg		44	44.0	3.4	42 (44.7%)												
Week 88																	
Placebo		19	36.9	5.0	19 (20.9%)												
Nera 18mg		19	51.4	4.6	19 (20.2%)												
Week 100																	
Placebo		5	38.5	6.5	5 (5.5%)												
Nera 18mg		5	44.6	6.9	5 (5.3%)												
Week 112																	
Placebo		3	24.7	7.0	3 (3.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	74	72	27.3	1.9	71 (100.0%)												
Nera 18mg	73	72	27.2	1.9	68 (100.0%)												
Week 12																	
Placebo		72	28.9	2.0	70 (98.6%)	0.3	1.4	-2.5	3.0								
Nera 18mg		67	29.3	2.0	66 (97.1%)	0.5	1.4	-2.3	3.4	0.3	2.0	-3.6	4.1	0.8955			
Week 26																	
Placebo		70	30.7	2.1	68 (95.8%)	2.1	1.6	-1.1	5.2								
Nera 18mg		64	29.1	2.1	63 (92.6%)	0.3	1.7	-3.0	3.6	-1.8	2.3	-6.3	2.8	0.4469			
Week 36																	
Placebo		68	28.6	2.1	66 (93.0%)	0.8	1.8	-2.7	4.3								
Nera 18mg		61	27.9	2.2	61 (89.7%)	-1.4	1.8	-5.0	2.2	-2.2	2.5	-7.2	2.8	0.3811			
Week 44																	
Placebo		65	29.7	2.4	63 (88.7%)	2.9	1.8	-0.6	6.4								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		60	30.3	2.5	59 (86.8%)	1.0	1.9	-2.7	4.6	-1.9	2.5	-7.0	3.1	0.4475			
Week 52																	
Placebo		67	29.4	2.2	65 (91.5%)	2.1	2.0	-1.7	6.0								
Nera 18mg		59	29.6	2.4	59 (86.8%)	1.3	2.0	-2.7	5.3	-0.8	2.8	-6.3	4.7	0.7683			
Week 64																	
Placebo		56	29.7	2.4	55 (77.5%)	3.5	2.0	-0.5	7.4								
Nera 18mg		50	30.9	2.8	50 (73.5%)	3.7	2.1	-0.4	7.8	0.2	2.9	-5.4	5.8	0.9456			
Week 76																	
Placebo		43	29.2	2.7	42 (59.2%)												
Nera 18mg		35	29.6	3.1	35 (51.5%)												
Week 88																	
Placebo		18	35.9	4.9	17 (23.9%)												
Nera 18mg		12	36.5	7.1	12 (17.6%)												
Week 100																	
Placebo		6	18.8	5.4	6 (8.5%)												
Nera 18mg		4	42.2	12.4	4 (5.9%)												
Week 112																	
Placebo		1	12.6	NC	1 (1.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline HRCT pattern																	
Test for homogeneity (H0)^																	
Week 12														0.9392			
Week 26														0.7420			
Week 36														0.2875			
Week 44														0.9419			
Week 52														0.7283			
Week 64														0.5267			
UIP-like																	
Baseline																	
Placebo	116	114	30.2	1.6	111 (100.0%)												
Nera 18mg	121	120	33.5	1.6	117 (100.0%)												
Week 12																	
Placebo		110	31.0	1.7	108 (97.3%)	0.9	1.1	-1.3	3.1								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg		116	35.0	1.6	115 (98.3%)	1.5	1.1	-0.6	3.6	0.6	1.5	-2.4	3.7	0.6864			
Week 26																	
Placebo		106	33.9	1.8	104 (93.7%)	3.7	1.3	1.1	6.2								
Nera 18mg		107	34.3	1.7	106 (90.6%)	1.3	1.3	-1.2	3.8	-2.4	1.8	-6.0	1.2	0.1961			
Week 36																	
Placebo		102	31.7	1.8	100 (90.1%)	2.5	1.4	-0.4	5.3								
Nera 18mg		104	34.9	1.8	104 (88.9%)	1.9	1.4	-0.9	4.7	-0.6	2.0	-4.5	3.4	0.7804			
Week 44																	
Placebo		98	33.1	2.0	96 (86.5%)	4.9	1.4	2.1	7.8								
Nera 18mg		99	37.7	2.0	98 (83.8%)	4.8	1.4	2.0	7.6	-0.2	2.0	-4.1	3.8	0.9409			
Week 52																	
Placebo		100	33.8	2.0	98 (88.3%)	5.3	1.6	2.2	8.5								
Nera 18mg		100	36.4	2.0	100 (85.5%)	4.4	1.6	1.3	7.4	-1.0	2.2	-5.4	3.4	0.6658			
Week 64																	
Placebo		88	33.9	2.1	87 (78.4%)	6.5	1.6	3.4	9.7								
Nera 18mg		85	38.0	2.2	85 (72.6%)	7.4	1.6	4.2	10.5	0.8	2.3	-3.7	5.3	0.7238			
Week 76																	
Placebo		60	30.3	2.5	59 (53.2%)												
Nera 18mg		58	38.1	2.8	58 (49.6%)												
Week 88																	
Placebo		25	35.5	4.3	24 (21.6%)												
Nera 18mg		23	46.7	4.8	23 (19.7%)												
Week 100																	
Placebo		9	29.2	6.1	9 (8.1%)												
Nera 18mg		8	40.5	6.2	8 (6.8%)												
Week 112																	
Placebo		3	25.3	6.5	3 (2.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other fibrotic patterns																	
Baseline																	
Placebo	53	53	35.3	2.4	51 (100.0%)												
Nera 18mg	49	47	33.5	2.5	45 (100.0%)												
Week 12																	
Placebo		49	34.1	2.6	49 (96.1%)	-0.0	1.6	-3.3	3.2								
Nera 18mg		43	33.6	2.5	42 (93.3%)	0.8	1.8	-2.7	4.3	0.8	2.4	-3.9	5.6	0.7257			
Week 26																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		49	37.7	2.7	49 (96.1%)	3.5	1.9	-0.3	7.2								
Nera 18mg		42	35.5	2.8	40 (88.9%)	2.2	2.1	-1.8	6.3	-1.3	2.8	-6.8	4.3	0.6540			
Week 36																	
Placebo		48	37.8	2.8	48 (94.1%)	4.0	2.1	-0.1	8.1								
Nera 18mg		42	32.2	2.7	40 (88.9%)	-0.5	2.3	-5.0	4.0	-4.5	3.1	-10.6	1.6	0.1455			
Week 44																	
Placebo		47	37.1	2.8	47 (92.2%)	1.6	2.1	-2.5	5.7								
Nera 18mg		40	33.4	2.9	38 (84.4%)	1.7	2.3	-2.8	6.2	0.1	3.1	-6.0	6.2	0.9690			
Week 52																	
Placebo		47	39.9	3.2	47 (92.2%)	5.5	2.3	0.9	10.1								
Nera 18mg		38	35.7	2.9	36 (80.0%)	3.1	2.6	-1.9	8.1	-2.4	3.5	-9.2	4.4	0.4864			
Week 64																	
Placebo		38	35.4	2.8	38 (74.5%)	5.0	2.4	0.3	9.7								
Nera 18mg		35	34.9	3.2	33 (73.3%)	3.2	2.6	-1.9	8.2	-1.8	3.5	-8.7	5.0	0.5980			
Week 76																	
Placebo		28	37.0	3.5	28 (54.9%)												
Nera 18mg		21	36.4	5.1	19 (42.2%)												
Week 88																	
Placebo		12	38.2	6.2	12 (23.5%)												
Nera 18mg		8	42.6	7.9	8 (17.8%)												
Week 100																	
Placebo		2	21.6	3.7	2 (3.9%)												
Nera 18mg		1	67.5	NC	1 (2.2%)												
Week 112																	
Placebo		1	11.0	NC	1 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Underlying ILD diagnosis																	
Test for homogeneity (H0)^																	
Week 12														0.6096			
Week 26														0.2877			
Week 36														0.9348			
Week 44														0.3929			
Week 52														0.2282			
Week 64														0.1798			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
iNSIP																	
Baseline																	
Placebo	32	32	32.3	3.4	31 (100.0%)												
Nera 18mg	27	26	32.5	3.7	24 (100.0%)												
Week 12																	
Placebo		29	29.6	3.8	29 (93.5%)	-1.3	2.1	-5.5	2.9								
Nera 18mg		22	33.5	4.5	22 (91.7%)	1.1	2.4	-3.6	5.9	2.4	3.2	-3.9	8.8	0.4522			
Week 26																	
Placebo		29	32.8	4.1	29 (93.5%)	0.8	2.5	-4.1	5.6								
Nera 18mg		23	35.1	3.9	22 (91.7%)	2.7	2.8	-2.8	8.2	1.9	3.7	-5.4	9.2	0.6072			
Week 36																	
Placebo		28	31.5	4.0	28 (90.3%)	0.9	2.7	-4.4	6.3								
Nera 18mg		21	32.8	4.1	20 (83.3%)	0.1	3.2	-6.1	6.3	-0.8	4.2	-9.0	7.4	0.8435			
Week 44																	
Placebo		28	32.9	4.0	28 (90.3%)	2.3	2.7	-3.0	7.6								
Nera 18mg		19	37.2	5.4	18 (75.0%)	6.2	3.2	-0.1	12.5	3.9	4.2	-4.3	12.2	0.3484			
Week 52																	
Placebo		27	32.3	4.2	27 (87.1%)	2.0	3.0	-3.8	7.9								
Nera 18mg		17	36.7	4.8	16 (66.7%)	6.6	3.6	-0.5	13.7	4.6	4.7	-4.6	13.8	0.3295			
Week 64																	
Placebo		23	32.2	4.6	23 (74.2%)	2.2	3.0	-3.8	8.2								
Nera 18mg		17	38.7	5.2	16 (66.7%)	8.9	3.6	1.7	16.0	6.6	4.7	-2.7	15.9	0.1628			
Week 76																	
Placebo		16	34.8	5.8	16 (51.6%)												
Nera 18mg		10	46.6	9.0	9 (37.5%)												
Week 88																	
Placebo		8	38.8	8.0	8 (25.8%)												
Nera 18mg		3	54.5	18.7	3 (12.5%)												
Week 100																	
Placebo		2	9.8	2.6	2 (6.5%)												
Nera 18mg		1	67.5	NC	1 (4.2%)												
Week 112																	
Placebo		2	20.7	8.1	2 (6.5%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Unclassifiable IIP																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Baseline																	
Placebo	46	46	31.1	2.4	44 (100.0%)												
Nera 18mg	32	32	33.0	3.1	32 (100.0%)												
Week 12																	
Placebo		44	32.4	2.7	44 (100.0%)	1.6	1.7	-1.9	5.0								
Nera 18mg		32	32.3	2.5	32 (100.0%)	-0.6	2.0	-4.7	3.4	-2.2	2.7	-7.5	3.1	0.4184			
Week 26																	
Placebo		40	35.1	3.1	40 (90.9%)	4.4	2.1	0.3	8.5								
Nera 18mg		28	31.0	2.6	28 (87.5%)	-1.9	2.5	-6.8	2.9	-6.3	3.2	-12.7	0.0	0.0514			
Week 36																	
Placebo		38	33.3	2.9	38 (86.4%)	4.1	2.3	-0.4	8.6								
Nera 18mg		27	36.0	3.2	27 (84.4%)	3.3	2.7	-2.1	8.6	-0.9	3.6	-7.9	6.2	0.8109			
Week 44																	
Placebo		36	35.5	3.5	36 (81.8%)	6.7	2.3	2.2	11.3								
Nera 18mg		27	35.4	3.4	27 (84.4%)	2.1	2.7	-3.2	7.5	-4.6	3.6	-11.7	2.4	0.1951			
Week 52																	
Placebo		38	38.0	3.7	38 (86.4%)	9.0	2.5	4.1	14.0								
Nera 18mg		28	31.2	3.1	28 (87.5%)	-1.8	3.0	-7.6	4.0	-10.8	3.9	-18.5	-3.2	0.0057	-0.69	-1.18	-0.19
Week 64																	
Placebo		31	35.1	3.4	31 (70.5%)	8.4	2.6	3.3	13.5								
Nera 18mg		23	38.4	3.9	23 (71.9%)	7.4	3.0	1.4	13.4	-1.0	4.0	-8.9	6.9	0.8033			
Week 76																	
Placebo		25	29.2	3.4	25 (56.8%)												
Nera 18mg		16	34.0	4.6	16 (50.0%)												
Week 88																	
Placebo		10	42.4	5.9	10 (22.7%)												
Nera 18mg		10	40.9	7.6	10 (31.3%)												
Week 100																	
Placebo		2	45.2	11.4	2 (4.5%)												
Nera 18mg		3	33.9	13.1	3 (9.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
HP																	
Baseline																	
Placebo	38	38	28.1	2.8	38 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg	43	43	38.3	2.9	41 (100.0%)												
Week 12																	
Placebo		37	30.6	2.5	37 (97.4%)	2.1	1.9	-1.7	5.9								
Nera 18mg		39	40.5	2.6	39 (95.1%)	2.7	1.9	-1.0	6.4	0.6	2.7	-4.7	5.8	0.8273			
Week 26																	
Placebo		38	34.5	2.9	38 (100.0%)	5.3	2.2	1.0	9.6								
Nera 18mg		35	39.2	3.5	35 (85.4%)	2.5	2.2	-1.9	6.8	-2.8	3.1	-8.9	3.3	0.3656			
Week 36																	
Placebo		37	33.8	3.0	37 (97.4%)	3.9	2.4	-0.8	8.6								
Nera 18mg		37	38.1	3.0	37 (90.2%)	2.1	2.4	-2.6	6.8	-1.8	3.4	-8.4	4.9	0.6048			
Week 44																	
Placebo		37	31.6	2.9	37 (97.4%)	3.2	2.4	-1.5	7.9								
Nera 18mg		35	41.8	3.5	35 (85.4%)	5.5	2.4	0.8	10.2	2.3	3.4	-4.3	9.0	0.4873			
Week 52																	
Placebo		36	34.2	3.5	36 (94.7%)	5.7	2.6	0.5	10.8								
Nera 18mg		34	43.6	3.2	34 (82.9%)	7.6	2.6	2.4	12.8	2.0	3.7	-5.4	9.3	0.5970			
Week 64																	
Placebo		33	34.0	3.2	33 (86.8%)	8.3	2.7	3.0	13.5								
Nera 18mg		29	42.5	3.7	29 (70.7%)	7.8	2.7	2.5	13.1	-0.4	3.8	-7.9	7.0	0.9085			
Week 76																	
Placebo		18	34.8	4.6	18 (47.4%)												
Nera 18mg		17	41.9	4.9	17 (41.5%)												
Week 88																	
Placebo		8	32.9	8.2	8 (21.1%)												
Nera 18mg		5	55.6	6.3	5 (12.2%)												
Week 100																	
Placebo		1	16.5	NC	1 (2.6%)												
Nera 18mg		1	66.8	NC	1 (2.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Autoimmune ILD																	
Baseline																	
Placebo	29	28	34.5	3.5	27 (100.0%)												
Nera 18mg	43	42	31.0	2.5	42 (100.0%)												
Week 12																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo		27	32.1	4.2	26 (96.3%)	-1.1	2.3	-5.5	3.3								
Nera 18mg		43	31.5	2.3	42 (100.0%)	0.0	1.8	-3.5	3.5	1.1	2.9	-4.5	6.8	0.6966			
Week 26																	
Placebo		27	34.3	3.8	26 (96.3%)	1.8	2.6	-3.3	6.9								
Nera 18mg		40	30.7	2.5	39 (92.9%)	-0.5	2.1	-4.6	3.6	-2.3	3.3	-8.8	4.3	0.4950			
Week 36																	
Placebo		26	32.7	3.6	25 (92.6%)	1.3	2.9	-4.3	6.9								
Nera 18mg		38	27.7	2.5	38 (90.5%)	-3.9	2.3	-8.4	0.7	-5.1	3.7	-12.4	2.1	0.1630			
Week 44																	
Placebo		23	34.2	4.4	22 (81.5%)	1.0	2.9	-4.7	6.7								
Nera 18mg		37	30.3	2.8	36 (85.7%)	-1.3	2.3	-5.9	3.3	-2.3	3.7	-9.6	5.0	0.5343			
Week 52																	
Placebo		25	35.5	4.2	24 (88.9%)	3.4	3.1	-2.8	9.6								
Nera 18mg		37	29.7	3.0	37 (88.1%)	-0.7	2.5	-5.7	4.3	-4.1	4.0	-12.0	3.9	0.3157			
Week 64																	
Placebo		21	32.1	4.1	21 (77.8%)	2.5	3.2	-3.8	8.8								
Nera 18mg		33	28.6	2.9	33 (78.6%)	0.1	2.6	-5.0	5.2	-2.4	4.1	-10.5	5.7	0.5534			
Week 76																	
Placebo		16	32.0	5.5	16 (59.3%)												
Nera 18mg		19	26.2	4.0	19 (45.2%)												
Week 88																	
Placebo		6	22.5	6.5	6 (22.2%)												
Nera 18mg		5	39.7	7.9	5 (11.9%)												
Week 100																	
Placebo		4	26.7	7.8	4 (14.8%)												
Nera 18mg		2	32.3	7.4	2 (4.8%)												
Week 112																	
Placebo		2	22.7	11.7	2 (7.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other ILD																	
Baseline																	
Placebo	24	23	35.5	3.5	22 (100.0%)												
Nera 18mg	25	24	31.1	2.8	23 (100.0%)												
Week 12																	
Placebo		22	36.3	3.0	21 (95.5%)	1.0	2.5	-4.0	5.9								
Nera 18mg		23	34.9	3.6	22 (95.7%)	3.9	2.5	-0.9	8.7	2.9	3.5	-4.0	9.9	0.4069			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 26																	
Placebo		21	40.6	3.1	20 (90.9%)	5.4	2.9	-0.4	11.1								
Nera 18mg		23	38.4	3.5	22 (95.7%)	6.9	2.8	1.4	12.5	1.5	4.1	-6.5	9.6	0.7040			
Week 36																	
Placebo		21	37.9	4.0	20 (90.9%)	4.3	3.2	-2.1	10.6								
Nera 18mg		23	37.4	4.4	22 (95.7%)	7.2	3.1	1.2	13.3	3.0	4.5	-5.8	11.8	0.5068			
Week 44																	
Placebo		21	39.5	3.8	20 (90.9%)	5.7	3.2	-0.6	11.9								
Nera 18mg		21	39.4	4.0	20 (87.0%)	10.2	3.1	4.1	16.3	4.6	4.5	-4.2	13.3	0.3072			
Week 52																	
Placebo		21	38.8	4.0	20 (90.9%)	5.2	3.5	-1.7	12.1								
Nera 18mg		22	41.8	4.2	21 (91.3%)	11.7	3.4	5.0	18.3	6.4	4.9	-3.2	16.0	0.1904			
Week 64																	
Placebo		18	39.2	4.1	17 (77.3%)	7.8	3.6	0.8	14.9								
Nera 18mg		18	40.6	4.8	17 (73.9%)	10.2	3.5	3.3	17.1	2.4	5.0	-7.5	12.3	0.6328			
Week 76																	
Placebo		13	32.9	4.1	12 (54.5%)												
Nera 18mg		17	44.4	5.5	16 (69.6%)												
Week 88																	
Placebo		5	42.8	11.3	4 (18.2%)												
Nera 18mg		8	45.6	9.4	8 (34.8%)												
Week 100																	
Placebo		2	36.1	10.9	2 (9.1%)												
Nera 18mg		2	45.4	3.5	2 (8.7%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Region																	
Test for homogeneity (H0)^																	
Week 12														0.4715			
Week 26														0.9453			
Week 36														0.7626			
Week 44														0.7372			
Week 52														0.5448			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 64														0.9213			
Europe																	
Baseline																	
Placebo	78	76	32.4	2.1	75 (100.0%)												
Nera 18mg	67	65	34.4	2.1	63 (100.0%)												
Week 12																	
Placebo		75	34.1	2.1	73 (97.3%)	2.4	1.3	-0.2	5.1								
Nera 18mg		62	35.3	1.9	61 (96.8%)	1.5	1.5	-1.4	4.4	-0.9	2.0	-4.8	3.0	0.6508			
Week 26																	
Placebo		73	37.9	2.4	71 (94.7%)	5.7	1.6	2.6	8.8								
Nera 18mg		56	37.6	2.4	54 (85.7%)	3.7	1.8	0.2	7.2	-2.0	2.4	-6.6	2.6	0.3933			
Week 36																	
Placebo		68	35.3	2.3	66 (88.0%)	4.2	1.8	0.7	7.6								
Nera 18mg		55	36.8	2.4	54 (85.7%)	3.2	2.0	-0.6	7.0	-1.0	2.6	-6.1	4.2	0.7121			
Week 44																	
Placebo		67	34.4	2.4	65 (86.7%)	3.7	1.8	0.2	7.1								
Nera 18mg		53	37.2	2.4	51 (81.0%)	4.4	2.0	0.5	8.2	0.7	2.6	-4.5	5.9	0.7913			
Week 52																	
Placebo		69	36.0	2.4	67 (89.3%)	5.4	1.9	1.6	9.2								
Nera 18mg		53	38.4	2.5	52 (82.5%)	4.6	2.2	0.3	8.9	-0.8	2.9	-6.5	4.9	0.7760			
Week 64																	
Placebo		62	36.7	2.4	61 (81.3%)	7.2	1.9	3.4	11.0								
Nera 18mg		51	41.0	2.7	50 (79.4%)	7.1	2.2	2.8	11.3	-0.2	2.9	-5.9	5.6	0.9578			
Week 76																	
Placebo		38	32.5	2.9	37 (49.3%)												
Nera 18mg		29	44.7	4.1	28 (44.4%)												
Week 88																	
Placebo		15	35.5	5.9	14 (18.7%)												
Nera 18mg		8	46.8	7.4	8 (12.7%)												
Week 100																	
Placebo		3	16.8	5.3	3 (4.0%)												
Nera 18mg		2	47.3	1.5	2 (3.2%)												
Week 112																	
Placebo		1	11.0	NC	1 (1.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Asia																	
Baseline																	
Placebo	45	45	30.6	2.8	43 (100.0%)												
Nera 18mg	41	41	34.0	3.0	39 (100.0%)												
Week 12																	
Placebo		42	28.3	2.9	42 (97.7%)	-2.0	1.8	-5.5	1.5								
Nera 18mg		39	34.4	3.2	39 (100.0%)	0.6	1.8	-3.0	4.3	2.6	2.6	-2.4	7.7	0.3045			
Week 26																	
Placebo		42	31.5	3.0	42 (97.7%)	1.5	2.0	-2.5	5.5								
Nera 18mg		36	31.4	2.9	36 (92.3%)	-2.2	2.2	-6.5	2.1	-3.7	3.0	-9.6	2.2	0.2166			
Week 36																	
Placebo		41	32.1	3.2	41 (95.3%)	2.6	2.3	-1.9	7.1								
Nera 18mg		34	32.5	3.2	34 (87.2%)	-1.0	2.5	-5.8	3.9	-3.6	3.3	-10.1	3.0	0.2854			
Week 44																	
Placebo		37	35.4	3.6	37 (86.0%)	5.4	2.3	0.9	10.0								
Nera 18mg		31	37.4	3.9	31 (79.5%)	2.4	2.5	-2.5	7.2	-3.1	3.4	-9.7	3.6	0.3621			
Week 52																	
Placebo		39	34.2	3.6	39 (90.7%)	4.9	2.5	-0.1	9.8								
Nera 18mg		32	34.8	3.6	32 (82.1%)	2.9	2.7	-2.5	8.2	-2.0	3.7	-9.3	5.3	0.5898			
Week 64																	
Placebo		33	31.6	3.7	33 (76.7%)	5.2	2.6	0.2	10.3								
Nera 18mg		26	33.5	3.9	26 (66.7%)	3.5	2.8	-2.0	9.0	-1.7	3.8	-9.2	5.8	0.6516			
Week 76																	
Placebo		25	29.1	4.3	25 (58.1%)												
Nera 18mg		19	32.2	4.9	19 (48.7%)												
Week 88																	
Placebo		13	34.0	6.6	13 (30.2%)												
Nera 18mg		9	43.7	10.2	9 (23.1%)												
Week 100																	
Placebo		5	33.4	8.9	5 (11.6%)												
Nera 18mg		4	30.1	8.9	4 (10.3%)												
Week 112																	
Placebo		1	34.3	NC	1 (2.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	
Baseline																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo	30	30	30.1	2.9	30 (100.0%)												
Nera 18mg	37	36	29.8	2.3	36 (100.0%)												
Week 12																	
Placebo		28	29.8	2.9	28 (93.3%)	-1.6	2.2	-5.9	2.7								
Nera 18mg		35	32.9	2.7	34 (94.4%)	2.7	2.0	-1.2	6.5	4.3	2.9	-1.4	10.0	0.1417			
Week 26																	
Placebo		26	32.7	2.8	26 (86.7%)	1.1	2.6	-3.9	6.2								
Nera 18mg		34	32.7	2.7	33 (91.7%)	3.0	2.3	-1.5	7.5	1.9	3.4	-4.9	8.6	0.5833			
Week 36																	
Placebo		27	31.3	2.8	27 (90.0%)	0.7	2.8	-4.8	6.3								
Nera 18mg		34	32.0	2.7	33 (91.7%)	2.5	2.5	-2.5	7.4	1.7	3.8	-5.7	9.1	0.6484			
Week 44																	
Placebo		27	32.4	3.4	27 (90.0%)	2.5	2.8	-3.0	8.0								
Nera 18mg		33	34.7	3.3	32 (88.9%)	6.2	2.5	1.2	11.2	3.7	3.8	-3.7	11.1	0.3236			
Week 52																	
Placebo		26	33.2	3.8	26 (86.7%)	3.0	3.1	-3.1	9.1								
Nera 18mg		33	35.0	3.3	32 (88.9%)	6.3	2.8	0.7	11.8	3.3	4.2	-4.9	11.5	0.4321			
Week 64																	
Placebo		20	33.4	3.8	20 (66.7%)	5.1	3.2	-1.3	11.4								
Nera 18mg		27	36.0	3.4	26 (72.2%)	9.5	2.9	3.9	15.2	4.4	4.3	-4.0	12.9	0.3026			
Week 76																	
Placebo		17	37.4	4.9	17 (56.7%)												
Nera 18mg		20	39.0	4.6	19 (52.8%)												
Week 88																	
Placebo		8	43.0	5.2	8 (26.7%)												
Nera 18mg		11	45.0	6.1	11 (30.6%)												
Week 100																	
Placebo		3	29.5	8.9	3 (10.0%)												
Nera 18mg		3	58.8	8.4	3 (8.3%)												
Week 112																	
Placebo		2	20.7	8.1	2 (6.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Rest of the World																	
Baseline																	
Placebo	16	16	35.5	4.2	14 (100.0%)												
Nera 18mg	25	25	35.9	4.0	24 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in L-PF total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 12																	
Placebo		14	35.6	4.8	14 (100.0%)	3.5	3.1	-2.6	9.5								
Nera 18mg		23	36.0	3.2	23 (95.8%)	-0.3	2.4	-5.0	4.4	-3.8	3.9	-11.4	3.9	0.3319			
Week 26																	
Placebo		14	36.1	4.8	14 (100.0%)	3.9	3.6	-3.1	10.9								
Nera 18mg		23	35.3	4.2	23 (95.8%)	0.3	2.8	-5.1	5.7	-3.6	4.5	-12.4	5.3	0.4295			
Week 36																	
Placebo		14	34.5	4.7	14 (100.0%)	2.3	3.9	-5.4	10.0								
Nera 18mg		23	33.6	4.2	23 (95.8%)	-2.0	3.0	-7.9	4.0	-4.3	5.0	-14.0	5.5	0.3924			
Week 44																	
Placebo		14	35.4	5.2	14 (100.0%)	3.4	3.9	-4.3	11.1								
Nera 18mg		22	36.1	4.5	22 (91.7%)	1.3	3.0	-4.7	7.3	-2.1	4.9	-11.8	7.6	0.6720			
Week 52																	
Placebo		13	43.7	6.4	13 (92.9%)	12.0	4.4	3.4	20.5								
Nera 18mg		20	34.8	4.4	20 (83.3%)	1.1	3.4	-5.7	7.9	-10.9	5.6	-21.8	0.1	0.0513			
Week 64																	
Placebo		11	31.4	4.8	11 (78.6%)	5.0	4.4	-3.8	13.7								
Nera 18mg		16	32.4	5.5	16 (66.7%)	3.0	3.5	-4.0	9.9	-2.0	5.7	-13.2	9.2	0.7237			
Week 76																	
Placebo		8	31.9	5.6	8 (57.1%)												
Nera 18mg		11	26.3	6.0	11 (45.8%)												
Week 88																	
Placebo		1	28.6	NC	1 (7.1%)												
Nera 18mg		3	50.3	11.0	3 (12.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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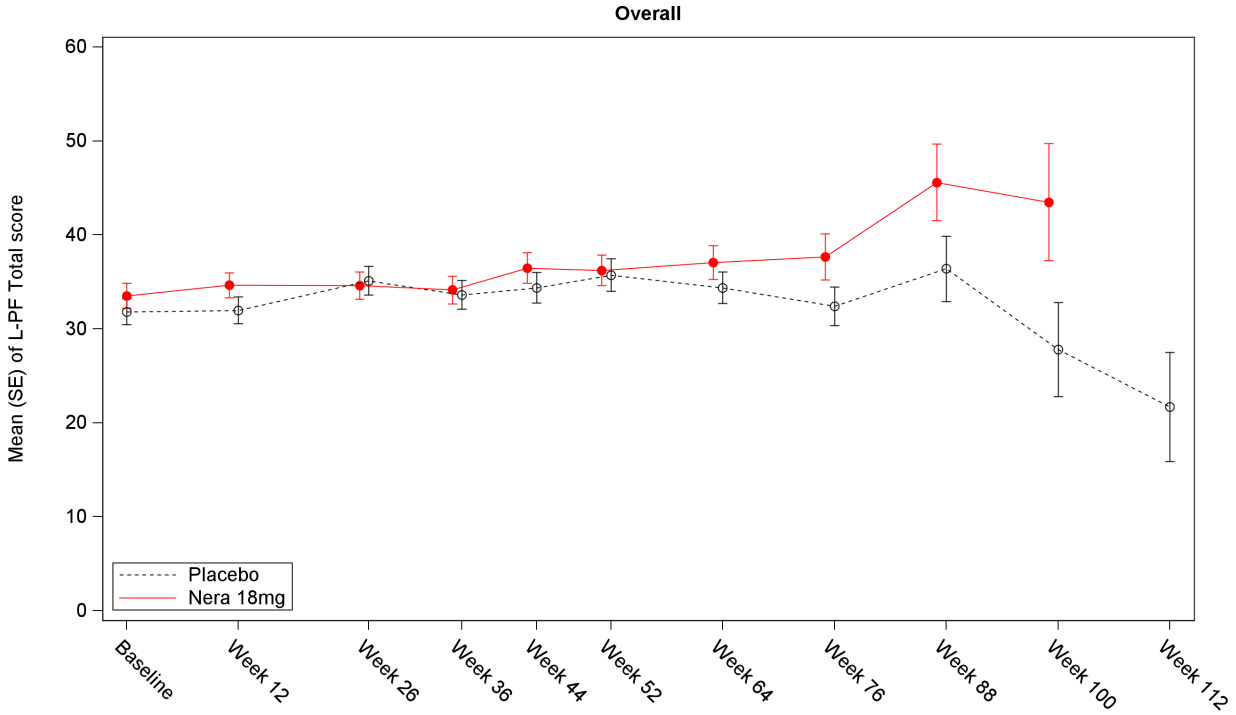

Number of patients

Placebo	167	159	155	150	145	147	126	88	37	11	4
Nera 18mg	167	159	149	146	139	138	120	79	31	9	0

Study: 1305-0023. Number of patients refers to the number of patients with observed data at visit.

Figure I.1.1.1.2.1: 1 Mean (SE) of L-PF total score
over the whole trial - 18mg - FAS (NIN background)

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Overall																	
Baseline																	
Placebo	169	167	35.4	1.5	162 (100.0%)												
Nera 18mg	170	167	38.0	1.6	162 (100.0%)												
Week 12																	
Placebo		160	35.4	1.6	158 (97.5%)	0.3	1.1	-1.9	2.5								
Nera 18mg		160	38.1	1.5	158 (97.5%)	0.4	1.1	-1.8	2.6	0.1	1.6	-3.0	3.2	0.9491			
Week 26																	
Placebo		155	38.5	1.6	153 (94.4%)	3.1	1.2	0.7	5.4								
Nera 18mg		149	37.9	1.6	146 (90.1%)	0.5	1.2	-1.8	2.9	-2.5	1.7	-5.9	0.8	0.1330			
Week 36																	
Placebo		150	36.4	1.6	148 (91.4%)	2.0	1.4	-0.7	4.7								
Nera 18mg		146	37.4	1.7	144 (88.9%)	0.1	1.4	-2.6	2.8	-1.9	1.9	-5.7	1.9	0.3347			
Week 44																	
Placebo		146	37.4	1.8	144 (88.9%)	3.5	1.3	0.9	6.1								
Nera 18mg		140	40.8	1.8	137 (84.6%)	3.5	1.4	0.8	6.1	-0.0	1.9	-3.8	3.7	0.9910			
Week 52																	
Placebo		147	38.8	1.9	145 (89.5%)	4.8	1.5	1.9	7.6								
Nera 18mg		139	39.7	1.8	137 (84.6%)	3.2	1.5	0.3	6.1	-1.5	2.1	-5.6	2.5	0.4566			
Week 64																	
Placebo		126	37.3	1.8	125 (77.2%)	5.3	1.5	2.4	8.3								
Nera 18mg		121	41.1	2.0	119 (73.5%)	5.9	1.5	2.9	8.9	0.6	2.1	-3.6	4.8	0.7754			
Week 76																	
Placebo		88	34.9	2.2	87 (53.7%)												
Nera 18mg		80	40.8	2.7	78 (48.1%)												
Week 88																	
Placebo		37	38.4	3.8	36 (22.2%)												
Nera 18mg		31	50.7	4.5	31 (19.1%)												
Week 100																	
Placebo		11	30.3	5.6	11 (6.8%)												
Nera 18mg		9	46.6	7.7	9 (5.6%)												
Week 112																	
Placebo		4	21.1	6.4	4 (2.5%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Impact total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Age																	
Test for homogeneity (H0)^																	
Week 12														0.1303			
Week 26														0.3449			
Week 36														0.5365			
Week 44														0.7054			
Week 52														0.4357			
Week 64														0.7408			
<65 years																	
Baseline																	
Placebo	65	65	36.0	2.5	64 (100.0%)												
Nera 18mg	64	63	37.2	2.4	61 (100.0%)												
Week 12																	
Placebo		63	34.0	2.5	63 (98.4%)	-1.7	1.7	-5.1	1.8								
Nera 18mg		61	38.3	2.6	60 (98.4%)	1.4	1.8	-2.1	4.9	3.0	2.5	-1.9	8.0	0.2248			
Week 26																	
Placebo		62	36.9	2.6	62 (96.9%)	1.3	1.9	-2.4	5.0								
Nera 18mg		58	37.5	2.7	57 (93.4%)	0.7	1.9	-3.1	4.5	-0.6	2.7	-5.9	4.7	0.8265			
Week 36																	
Placebo		61	35.7	2.7	61 (95.3%)	-0.3	2.1	-4.5	3.9								
Nera 18mg		56	35.8	2.9	55 (90.2%)	-0.7	2.2	-5.1	3.7	-0.4	3.1	-6.5	5.6	0.8888			
Week 44																	
Placebo		61	37.6	2.7	61 (95.3%)	2.0	2.1	-2.1	6.0								
Nera 18mg		52	38.6	3.2	51 (83.6%)	2.8	2.2	-1.5	7.1	0.9	3.0	-5.1	6.8	0.7776			
Week 52																	
Placebo		62	37.3	2.8	62 (96.9%)	1.3	2.3	-3.2	5.7								
Nera 18mg		52	37.8	3.1	51 (83.6%)	1.5	2.4	-3.2	6.3	0.3	3.3	-6.2	6.8	0.9291			
Week 64																	
Placebo		56	36.9	2.7	56 (87.5%)	3.6	2.3	-1.0	8.1								
Nera 18mg		45	37.7	3.6	44 (72.1%)	3.3	2.5	-1.7	8.2	-0.3	3.4	-7.0	6.4	0.9233			
Week 76																	
Placebo		37	36.3	3.5	37 (57.8%)												
Nera 18mg		34	37.7	4.2	33 (54.1%)												
Week 88																	
Placebo		15	41.4	6.5	15 (23.4%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Impact total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		7	51.4	9.5	7 (11.5%)												
Week 100																	
Placebo		4	32.4	11.6	4 (6.3%)												
Nera 18mg		1	27.4	NC	1 (1.6%)												
Week 112																	
Placebo		2	22.0	12.5	2 (3.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	104	102	35.0	1.9	98 (100.0%)												
Nera 18mg	106	104	38.5	2.1	101 (100.0%)												
Week 12																	
Placebo		97	36.3	2.0	95 (96.9%)	1.6	1.4	-1.2	4.4								
Nera 18mg		99	38.0	1.8	98 (97.0%)	-0.2	1.4	-3.0	2.5	-1.8	2.0	-5.8	2.1	0.3660			
Week 26																	
Placebo		93	39.5	2.1	91 (92.9%)	4.2	1.5	1.2	7.3								
Nera 18mg		91	38.2	1.9	89 (88.1%)	0.4	1.5	-2.6	3.4	-3.9	2.2	-8.1	0.4	0.0768			
Week 36																	
Placebo		89	36.8	2.1	87 (88.8%)	3.5	1.8	0.1	7.0								
Nera 18mg		90	38.4	2.1	89 (88.1%)	0.7	1.8	-2.8	4.1	-2.9	2.5	-7.8	2.0	0.2488			
Week 44																	
Placebo		85	37.2	2.3	83 (84.7%)	4.5	1.7	1.1	7.9								
Nera 18mg		88	42.1	2.3	86 (85.1%)	3.9	1.7	0.5	7.2	-0.6	2.5	-5.4	4.2	0.8012			
Week 52																	
Placebo		85	39.8	2.5	83 (84.7%)	7.2	1.9	3.5	10.9								
Nera 18mg		87	40.9	2.2	86 (85.1%)	4.2	1.9	0.5	7.9	-3.0	2.7	-8.3	2.2	0.2600			
Week 64																	
Placebo		70	37.5	2.5	69 (70.4%)	6.4	2.0	2.5	10.3								
Nera 18mg		76	43.1	2.3	75 (74.3%)	7.5	1.9	3.7	11.3	1.1	2.8	-4.3	6.6	0.6855			
Week 76																	
Placebo		51	33.9	2.9	50 (51.0%)												
Nera 18mg		46	43.0	3.4	45 (44.6%)												
Week 88																	
Placebo		22	36.4	4.7	21 (21.4%)												
Nera 18mg		24	50.5	5.2	24 (23.8%)												
Week 100																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Impact total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		7	29.1	6.6	7 (7.1%)												
Nera 18mg		8	49.0	8.3	8 (7.9%)												
Week 112																	
Placebo		2	20.2	9.5	2 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Sex																	
Test for homogeneity (H0)^																	
Week 12														0.2513			
Week 26														0.5646			
Week 36														0.2605			
Week 44														0.8517			
Week 52														0.8085			
Week 64														0.4423			
Male																	
Baseline																	
Placebo	114	113	33.1	1.8	110 (100.0%)												
Nera 18mg	108	105	36.6	2.0	100 (100.0%)												
Week 12																	
Placebo		107	35.4	1.9	106 (96.4%)	2.0	1.3	-0.7	4.6								
Nera 18mg		99	37.8	1.9	97 (97.0%)	0.9	1.4	-1.8	3.7	-1.1	1.9	-4.9	2.8	0.5842			
Week 26																	
Placebo		103	38.8	2.0	102 (92.7%)	4.6	1.4	1.8	7.5								
Nera 18mg		93	38.1	2.0	90 (90.0%)	1.6	1.5	-1.4	4.6	-3.0	2.1	-7.2	1.1	0.1466			
Week 36																	
Placebo		99	36.0	2.0	98 (89.1%)	2.9	1.7	-0.3	6.2								
Nera 18mg		88	39.7	2.3	86 (86.0%)	3.0	1.7	-0.4	6.5	0.1	2.4	-4.6	4.8	0.9652			
Week 44																	
Placebo		96	37.0	2.2	95 (86.4%)	4.7	1.6	1.5	8.0								
Nera 18mg		83	41.1	2.4	80 (80.0%)	4.6	1.7	1.2	8.0	-0.1	2.4	-4.8	4.6	0.9588			
Week 52																	
Placebo		97	39.4	2.4	96 (87.3%)	7.1	1.8	3.6	10.6								
Nera 18mg		83	41.5	2.4	81 (81.0%)	5.5	1.9	1.9	9.2	-1.5	2.6	-6.6	3.5	0.5536			
Week 64																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Impact total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		81	35.8	2.2	81 (73.6%)	6.5	1.8	2.9	10.1								
Nera 18mg		73	44.4	2.7	71 (71.0%)	8.7	1.9	4.9	12.5	2.2	2.7	-3.0	7.5	0.4060			
Week 76																	
Placebo		54	34.3	2.7	54 (49.1%)												
Nera 18mg		47	46.1	3.6	45 (45.0%)												
Week 88																	
Placebo		24	40.4	4.5	24 (21.8%)												
Nera 18mg		18	55.9	6.3	18 (18.0%)												
Week 100																	
Placebo		7	34.2	8.3	7 (6.4%)												
Nera 18mg		4	65.2	8.2	4 (4.0%)												
Week 112																	
Placebo		2	20.2	9.5	2 (1.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Female																	
Baseline																	
Placebo	55	54	40.2	2.8	52 (100.0%)												
Nera 18mg	62	62	40.5	2.7	62 (100.0%)												
Week 12																	
Placebo		53	35.4	2.7	52 (100.0%)	-3.2	1.9	-7.0	0.6								
Nera 18mg		61	38.7	2.4	61 (98.4%)	-0.5	1.8	-4.0	3.0	2.7	2.6	-2.5	7.8	0.3068			
Week 26																	
Placebo		52	38.0	2.8	51 (98.1%)	-0.1	2.1	-4.2	3.9								
Nera 18mg		56	37.6	2.6	56 (90.3%)	-1.2	1.9	-5.0	2.6	-1.0	2.8	-6.6	4.5	0.7158			
Week 36																	
Placebo		51	37.2	2.8	50 (96.2%)	0.1	2.3	-4.5	4.7								
Nera 18mg		58	33.9	2.5	58 (93.5%)	-4.3	2.2	-8.6	-0.0	-4.4	3.2	-10.7	1.9	0.1693			
Week 44																	
Placebo		50	38.1	2.9	49 (94.2%)	0.9	2.3	-3.6	5.4								
Nera 18mg		57	40.3	3.0	57 (91.9%)	1.5	2.1	-2.7	5.7	0.6	3.1	-5.6	6.8	0.8451			
Week 52																	
Placebo		50	37.6	2.9	49 (94.2%)	0.0	2.5	-4.9	4.9								
Nera 18mg		56	37.2	2.7	56 (90.3%)	-0.5	2.3	-5.0	4.1	-0.5	3.4	-7.2	6.2	0.8851			
Week 64																	
Placebo		45	39.9	3.2	44 (84.6%)	2.7	2.6	-2.3	7.7								
Nera 18mg		48	36.1	2.8	48 (77.4%)	1.5	2.4	-3.2	6.3	-1.2	3.5	-8.1	5.7	0.7386			

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 76																	
Placebo		34	35.9	3.8	33 (63.5%)												
Nera 18mg		33	33.1	3.7	33 (53.2%)												
Week 88																	
Placebo		13	34.7	7.1	12 (23.1%)												
Nera 18mg		13	43.5	5.9	13 (21.0%)												
Week 100																	
Placebo		4	23.5	5.0	4 (7.7%)												
Nera 18mg		5	31.7	6.8	5 (8.1%)												
Week 112																	
Placebo		2	22.0	12.5	2 (3.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 12														0.8136			
Week 26														0.6665			
Week 36														0.6304			
Week 44														0.1726			
Week 52														0.7771			
Week 64														0.9057			
<=70%																	
Baseline																	
Placebo	95	95	39.4	2.1	91 (100.0%)												
Nera 18mg	97	95	44.5	2.0	94 (100.0%)												
Week 12																	
Placebo		88	37.7	2.2	88 (96.7%)	0.1	1.5	-2.8	3.1								
Nera 18mg		92	42.4	1.8	91 (96.8%)	0.6	1.5	-2.4	3.5	0.4	2.1	-3.7	4.5	0.8382			
Week 26																	
Placebo		85	42.7	2.2	85 (93.4%)	4.6	1.6	1.5	7.7								
Nera 18mg		85	42.8	2.0	83 (88.3%)	1.4	1.6	-1.8	4.6	-3.2	2.2	-7.6	1.2	0.1558			
Week 36																	
Placebo		82	40.8	2.2	82 (90.1%)	3.7	1.8	0.1	7.2								
Nera 18mg		85	43.0	2.1	83 (88.3%)	2.6	1.8	-1.0	6.2	-1.1	2.6	-6.1	4.0	0.6809			

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n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Impact total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 44																	
Placebo		81	41.3	2.4	81 (89.0%)	4.2	1.8	0.7	7.7								
Nera 18mg		80	47.2	2.2	78 (83.0%)	6.5	1.8	2.9	10.0	2.3	2.5	-2.7	7.2	0.3702			
Week 52																	
Placebo		80	44.3	2.7	80 (87.9%)	7.2	1.9	3.4	11.0								
Nera 18mg		80	46.2	2.2	78 (83.0%)	6.2	2.0	2.3	10.1	-1.0	2.7	-6.4	4.4	0.7120			
Week 64																	
Placebo		70	41.1	2.4	70 (76.9%)	7.4	2.0	3.5	11.4								
Nera 18mg		70	46.5	2.4	68 (72.3%)	7.8	2.0	3.8	11.8	0.4	2.8	-5.2	6.0	0.8904			
Week 76																	
Placebo		45	38.8	3.2	45 (49.5%)												
Nera 18mg		44	47.9	3.6	42 (44.7%)												
Week 88																	
Placebo		19	38.1	5.4	19 (20.9%)												
Nera 18mg		19	57.3	4.9	19 (20.2%)												
Week 100																	
Placebo		5	42.1	7.5	5 (5.5%)												
Nera 18mg		5	49.8	9.3	5 (5.3%)												
Week 112																	
Placebo		3	24.6	7.7	3 (3.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	74	72	30.0	2.1	71 (100.0%)												
Nera 18mg	73	72	29.5	2.2	68 (100.0%)												
Week 12																	
Placebo		72	32.5	2.1	70 (98.6%)	0.5	1.7	-2.8	3.8								
Nera 18mg		68	32.3	2.4	67 (98.5%)	0.2	1.7	-3.2	3.6	-0.3	2.4	-5.0	4.4	0.8931			
Week 26																	
Placebo		70	33.4	2.3	68 (95.8%)	1.1	1.8	-2.4	4.7								
Nera 18mg		64	31.4	2.3	63 (92.6%)	-0.6	1.9	-4.3	3.0	-1.7	2.6	-6.8	3.3	0.4979			
Week 36																	
Placebo		68	31.0	2.3	66 (93.0%)	-0.1	2.1	-4.2	3.9								
Nera 18mg		61	29.6	2.5	61 (89.7%)	-3.1	2.1	-7.2	1.1	-2.9	2.9	-8.7	2.8	0.3173			
Week 44																	
Placebo		65	32.5	2.5	63 (88.7%)	2.5	2.0	-1.5	6.5								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Impact total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		60	32.3	2.8	59 (86.8%)	-0.4	2.1	-4.5	3.7	-2.9	2.9	-8.5	2.7	0.3046			
Week 52																	
Placebo		67	32.2	2.4	65 (91.5%)	1.5	2.2	-2.8	5.8								
Nera 18mg		59	31.0	2.6	59 (86.8%)	-0.6	2.3	-5.1	3.8	-2.2	3.1	-8.3	3.9	0.4821			
Week 64																	
Placebo		56	32.4	2.7	55 (77.5%)	2.7	2.3	-1.8	7.1								
Nera 18mg		51	33.6	3.1	51 (75.0%)	3.6	2.4	-1.1	8.2	0.9	3.2	-5.5	7.3	0.7803			
Week 76																	
Placebo		43	30.9	2.9	42 (59.2%)												
Nera 18mg		36	32.1	3.4	36 (52.9%)												
Week 88																	
Placebo		18	38.8	5.6	17 (23.9%)												
Nera 18mg		12	40.2	7.9	12 (17.6%)												
Week 100																	
Placebo		6	20.4	6.0	6 (8.5%)												
Nera 18mg		4	42.6	14.1	4 (5.9%)												
Week 112																	
Placebo		1	10.7	NC	1 (1.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline HRCT pattern																	
Test for homogeneity (H0)^																	
Week 12														0.9224			
Week 26														0.7571			
Week 36														0.2303			
Week 44														0.9102			
Week 52														0.9213			
Week 64														0.4540			
UIP-like																	
Baseline																	
Placebo	116	114	33.6	1.9	111 (100.0%)												
Nera 18mg	121	120	38.2	1.9	117 (100.0%)												
Week 12																	
Placebo		110	34.2	1.9	108 (97.3%)	0.5	1.3	-2.2	3.1								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Impact total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg		117	38.4	1.8	116 (99.1%)	0.5	1.3	-2.1	3.0	0.0	1.9	-3.7	3.7	0.9978			
Week 26																	
Placebo		106	37.1	2.0	104 (93.7%)	3.0	1.4	0.1	5.8								
Nera 18mg		107	37.4	1.8	106 (90.6%)	0.1	1.4	-2.7	2.8	-2.9	2.0	-6.9	1.1	0.1539			
Week 36																	
Placebo		102	34.0	1.9	100 (90.1%)	1.2	1.7	-2.1	4.4								
Nera 18mg		104	38.1	2.0	104 (88.9%)	0.9	1.6	-2.3	4.0	-0.3	2.3	-4.9	4.3	0.8919			
Week 44																	
Placebo		98	36.1	2.1	96 (86.5%)	4.5	1.6	1.3	7.7								
Nera 18mg		100	42.0	2.2	99 (84.6%)	4.3	1.6	1.2	7.5	-0.2	2.3	-4.7	4.3	0.9413			
Week 52																	
Placebo		100	36.6	2.2	98 (88.3%)	4.7	1.8	1.2	8.2								
Nera 18mg		100	39.7	2.2	100 (85.5%)	3.3	1.7	-0.1	6.8	-1.4	2.5	-6.3	3.5	0.5752			
Week 64																	
Placebo		88	36.3	2.3	87 (78.4%)	5.5	1.8	1.9	9.1								
Nera 18mg		86	41.7	2.4	86 (73.5%)	7.2	1.8	3.6	10.7	1.7	2.6	-3.4	6.7	0.5164			
Week 76																	
Placebo		60	31.8	2.7	59 (53.2%)												
Nera 18mg		59	41.5	3.1	59 (50.4%)												
Week 88																	
Placebo		25	36.8	4.6	24 (21.6%)												
Nera 18mg		23	51.2	5.2	23 (19.7%)												
Week 100																	
Placebo		9	31.7	6.8	9 (8.1%)												
Nera 18mg		8	42.3	7.2	8 (6.8%)												
Week 112																	
Placebo		3	25.0	7.3	3 (2.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other fibrotic patterns																	
Baseline																	
Placebo	53	53	39.2	2.6	51 (100.0%)												
Nera 18mg	49	47	37.5	2.9	45 (100.0%)												
Week 12																	
Placebo		50	38.0	2.8	50 (98.0%)	-0.1	2.0	-4.0	3.8								
Nera 18mg		43	37.2	2.6	42 (93.3%)	0.2	2.1	-3.9	4.4	0.3	2.9	-5.4	6.0	0.9060			
Week 26																	

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n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Impact total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		49	41.5	2.7	49 (96.1%)	3.4	2.1	-0.8	7.5								
Nera 18mg		42	39.2	3.0	40 (88.9%)	1.6	2.3	-2.9	6.1	-1.7	3.1	-7.8	4.4	0.5751			
Week 36																	
Placebo		48	41.5	3.0	48 (94.1%)	3.7	2.4	-1.0	8.5								
Nera 18mg		42	35.6	3.1	40 (88.9%)	-1.7	2.6	-6.8	3.4	-5.4	3.5	-12.4	1.5	0.1270			
Week 44																	
Placebo		48	40.0	3.1	48 (94.1%)	1.2	2.3	-3.4	5.8								
Nera 18mg		40	37.9	3.3	38 (84.4%)	1.5	2.6	-3.5	6.6	0.3	3.5	-6.5	7.1	0.9307			
Week 52																	
Placebo		47	43.4	3.5	47 (92.2%)	4.7	2.6	-0.3	9.8								
Nera 18mg		39	40.0	3.1	37 (82.2%)	2.9	2.8	-2.7	8.4	-1.9	3.8	-9.4	5.7	0.6281			
Week 64																	
Placebo		38	39.4	3.1	38 (74.5%)	4.7	2.7	-0.6	10.0								
Nera 18mg		35	39.5	3.7	33 (73.3%)	2.8	2.9	-2.9	8.6	-1.9	3.9	-9.6	5.9	0.6355			
Week 76																	
Placebo		28	41.6	3.6	28 (54.9%)												
Nera 18mg		21	38.7	5.5	19 (42.2%)												
Week 88																	
Placebo		12	41.9	7.0	12 (23.5%)												
Nera 18mg		8	49.1	9.1	8 (17.8%)												
Week 100																	
Placebo		2	23.8	4.8	2 (3.9%)												
Nera 18mg		1	81.0	NC	1 (2.2%)												
Week 112																	
Placebo		1	9.5	NC	1 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Underlying ILD diagnosis																	
Test for homogeneity (H0)^																	
Week 12														0.5289			
Week 26														0.4014			
Week 36														0.6791			
Week 44														0.5680			
Week 52														0.2622			
Week 64														0.2666			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Impact total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
iNSIP																	
Baseline																	
Placebo	32	32	35.7	4.0	31 (100.0%)												
Nera 18mg	27	26	35.8	4.3	24 (100.0%)												
Week 12																	
Placebo		29	32.5	4.2	29 (93.5%)	-1.7	2.6	-6.8	3.3								
Nera 18mg		22	36.7	4.7	22 (91.7%)	0.6	2.9	-5.2	6.4	2.3	3.9	-5.3	10.0	0.5515			
Week 26																	
Placebo		29	36.2	4.5	29 (93.5%)	0.7	2.7	-4.7	6.0								
Nera 18mg		23	38.3	4.0	22 (91.7%)	1.5	3.1	-4.6	7.5	0.8	4.1	-7.3	8.9	0.8481			
Week 36																	
Placebo		28	33.0	4.4	28 (90.3%)	-1.1	3.1	-7.2	5.1								
Nera 18mg		21	37.0	4.6	20 (83.3%)	-0.8	3.6	-7.9	6.4	0.3	4.8	-9.1	9.8	0.9457			
Week 44																	
Placebo		28	35.3	4.1	28 (90.3%)	1.1	3.0	-4.8	7.1								
Nera 18mg		19	40.3	5.7	18 (75.0%)	4.0	3.6	-3.1	11.1	2.8	4.7	-6.4	12.1	0.5463			
Week 52																	
Placebo		27	34.3	4.5	27 (87.1%)	0.7	3.3	-5.8	7.2								
Nera 18mg		17	41.5	5.3	16 (66.7%)	5.3	4.0	-2.5	13.2	4.6	5.2	-5.6	14.8	0.3762			
Week 64																	
Placebo		23	34.3	5.2	23 (74.2%)	1.1	3.5	-5.7	7.9								
Nera 18mg		17	43.8	6.0	16 (66.7%)	7.7	4.1	-0.4	15.8	6.6	5.4	-4.0	17.2	0.2235			
Week 76																	
Placebo		16	35.7	5.8	16 (51.6%)												
Nera 18mg		10	49.8	9.0	9 (37.5%)												
Week 88																	
Placebo		8	39.3	8.2	8 (25.8%)												
Nera 18mg		3	58.7	17.7	3 (12.5%)												
Week 100																	
Placebo		2	8.3	3.6	2 (6.5%)												
Nera 18mg		1	81.0	NC	1 (4.2%)												
Week 112																	
Placebo		2	20.2	9.5	2 (6.5%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Unclassifiable IIP																	

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n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Impact total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Baseline																	
Placebo	46	46	34.2	2.8	44 (100.0%)												
Nera 18mg	32	32	38.4	3.8	32 (100.0%)												
Week 12																	
Placebo		44	34.1	2.9	44 (100.0%)	-0.3	2.1	-4.5	3.8								
Nera 18mg		32	34.7	3.1	32 (100.0%)	-3.1	2.5	-7.9	1.8	-2.7	3.3	-9.2	3.7	0.4000			
Week 26																	
Placebo		40	38.6	3.4	40 (90.9%)	3.9	2.3	-0.6	8.5								
Nera 18mg		28	33.7	2.9	28 (87.5%)	-3.7	2.7	-9.1	1.7	-7.6	3.6	-14.7	-0.6	0.0333	-0.52	-1.01	-0.04
Week 36																	
Placebo		38	35.7	3.1	38 (86.4%)	3.0	2.7	-2.2	8.2								
Nera 18mg		27	36.5	3.7	27 (84.4%)	-0.4	3.1	-6.6	5.8	-3.4	4.1	-11.6	4.7	0.4062			
Week 44																	
Placebo		36	38.3	3.7	36 (81.8%)	5.8	2.6	0.6	10.9								
Nera 18mg		27	37.8	4.0	27 (84.4%)	0.2	3.0	-5.8	6.2	-5.6	4.0	-13.5	2.3	0.1656			
Week 52																	
Placebo		38	42.1	4.1	38 (86.4%)	9.5	2.8	4.0	15.0								
Nera 18mg		28	33.6	3.6	28 (87.5%)	-3.8	3.3	-10.3	2.6	-13.3	4.3	-21.8	-4.9	0.0022	-0.76	-1.26	-0.26
Week 64																	
Placebo		31	37.4	3.7	31 (70.5%)	7.4	3.0	1.6	13.2								
Nera 18mg		23	41.7	4.6	23 (71.9%)	6.5	3.5	-0.3	13.3	-0.9	4.6	-9.9	8.1	0.8467			
Week 76																	
Placebo		25	30.8	3.8	25 (56.8%)												
Nera 18mg		17	36.3	5.2	17 (53.1%)												
Week 88																	
Placebo		10	46.4	7.1	10 (22.7%)												
Nera 18mg		10	44.2	7.8	10 (31.3%)												
Week 100																	
Placebo		2	54.8	9.5	2 (4.5%)												
Nera 18mg		3	31.4	12.1	3 (9.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
HP																	
Baseline																	
Placebo	38	38	32.2	3.2	38 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Impact total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg	43	43	43.0	3.3	41 (100.0%)												
Week 12																	
Placebo		37	35.1	2.7	37 (97.4%)	2.2	2.3	-2.3	6.7								
Nera 18mg		39	44.6	3.1	39 (95.1%)	2.7	2.2	-1.8	7.1	0.5	3.2	-5.9	6.8	0.8885			
Week 26																	
Placebo		38	37.2	2.9	38 (100.0%)	3.5	2.4	-1.3	8.2								
Nera 18mg		35	42.2	3.9	35 (85.4%)	1.3	2.4	-3.5	6.0	-2.2	3.4	-8.9	4.5	0.5214			
Week 36																	
Placebo		37	37.1	3.2	37 (97.4%)	2.6	2.8	-2.8	8.1								
Nera 18mg		37	42.4	3.4	37 (90.2%)	2.5	2.7	-2.9	7.9	-0.2	3.9	-7.8	7.5	0.9646			
Week 44																	
Placebo		37	35.1	3.2	37 (97.4%)	2.3	2.7	-2.9	7.6								
Nera 18mg		35	46.5	3.9	35 (85.4%)	6.2	2.7	0.9	11.5	3.9	3.8	-3.6	11.3	0.3047			
Week 52																	
Placebo		36	37.7	3.8	36 (94.7%)	4.6	2.9	-1.1	10.3								
Nera 18mg		35	47.2	3.4	35 (85.4%)	7.8	2.9	2.1	13.5	3.2	4.1	-4.9	11.3	0.4366			
Week 64																	
Placebo		33	36.9	3.4	33 (86.8%)	6.8	3.0	0.8	12.7								
Nera 18mg		29	46.8	4.0	29 (70.7%)	8.2	3.1	2.1	14.3	1.4	4.3	-7.1	9.9	0.7412			
Week 76																	
Placebo		18	36.8	5.0	18 (47.4%)												
Nera 18mg		17	45.0	5.4	17 (41.5%)												
Week 88																	
Placebo		8	33.9	8.6	8 (21.1%)												
Nera 18mg		5	65.5	7.3	5 (12.2%)												
Week 100																	
Placebo		1	20.2	NC	1 (2.6%)												
Nera 18mg		1	76.2	NC	1 (2.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Autoimmune ILD																	
Baseline																	
Placebo	29	28	38.6	3.9	27 (100.0%)												
Nera 18mg	43	42	35.4	3.1	42 (100.0%)												
Week 12																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Impact total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo		28	36.9	4.5	27 (100.0%)	-0.3	2.7	-5.6	5.0								
Nera 18mg		43	35.1	2.7	42 (100.0%)	-0.9	2.2	-5.1	3.4	-0.6	3.4	-7.4	6.2	0.8625			
Week 26																	
Placebo		27	37.7	4.1	26 (96.3%)	1.7	2.9	-4.0	7.3								
Nera 18mg		40	34.3	2.8	39 (92.9%)	-1.1	2.3	-5.7	3.4	-2.8	3.7	-10.0	4.4	0.4477			
Week 36																	
Placebo		26	36.1	3.9	25 (92.6%)	1.4	3.3	-5.0	7.9								
Nera 18mg		38	30.8	3.0	38 (90.5%)	-4.8	2.7	-10.1	0.5	-6.2	4.2	-14.6	2.1	0.1419			
Week 44																	
Placebo		24	36.5	4.8	23 (85.2%)	2.0	3.2	-4.3	8.4								
Nera 18mg		37	34.6	3.1	36 (85.7%)	-1.1	2.6	-6.2	4.1	-3.1	4.2	-11.3	5.1	0.4537			
Week 52																	
Placebo		25	38.3	4.4	24 (88.9%)	3.1	3.5	-3.7	10.0								
Nera 18mg		37	32.9	3.3	37 (88.1%)	-1.4	2.8	-6.9	4.2	-4.5	4.5	-13.3	4.3	0.3133			
Week 64																	
Placebo		21	35.8	4.5	21 (77.8%)	2.9	3.6	-4.3	10.1								
Nera 18mg		33	33.3	3.4	33 (78.6%)	0.8	2.9	-5.0	6.6	-2.1	4.7	-11.3	7.1	0.6519			
Week 76																	
Placebo		16	34.5	6.0	16 (59.3%)												
Nera 18mg		19	28.2	4.4	19 (45.2%)												
Week 88																	
Placebo		6	23.0	7.9	6 (22.2%)												
Nera 18mg		5	42.6	8.8	5 (11.9%)												
Week 100																	
Placebo		4	27.7	7.5	4 (14.8%)												
Nera 18mg		2	32.1	4.8	2 (4.8%)												
Week 112																	
Placebo		2	22.0	12.5	2 (7.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other ILD																	
Baseline																	
Placebo	24	23	38.6	3.7	22 (100.0%)												
Nera 18mg	25	24	35.9	3.5	23 (100.0%)												
Week 12																	
Placebo		22	40.5	3.2	21 (95.5%)	1.9	3.0	-4.0	7.9								
Nera 18mg		24	38.7	3.8	23 (100.0%)	3.3	2.9	-2.4	9.0	1.4	4.2	-6.9	9.7	0.7463			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Impact total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 26																	
Placebo		21	44.9	3.2	20 (90.9%)	6.0	3.2	-0.4	12.4								
Nera 18mg		23	42.5	3.9	22 (95.7%)	6.5	3.1	0.4	12.6	0.5	4.5	-8.3	9.4	0.9095			
Week 36																	
Placebo		21	41.3	4.2	20 (90.9%)	4.2	3.7	-3.1	11.5								
Nera 18mg		23	41.5	4.8	22 (95.7%)	6.6	3.6	-0.4	13.6	2.4	5.1	-7.7	12.5	0.6395			
Week 44																	
Placebo		21	43.7	4.1	20 (90.9%)	6.3	3.6	-0.7	13.4								
Nera 18mg		22	46.2	4.4	21 (91.3%)	10.7	3.5	3.8	17.5	4.3	5.0	-5.5	14.2	0.3858			
Week 52																	
Placebo		21	40.6	4.2	20 (90.9%)	3.5	3.9	-4.1	11.1								
Nera 18mg		22	45.8	4.8	21 (91.3%)	11.0	3.8	3.6	18.4	7.5	5.4	-3.2	18.1	0.1678			
Week 64																	
Placebo		18	43.1	4.2	17 (77.3%)	7.8	4.1	-0.2	15.8								
Nera 18mg		19	42.7	5.3	18 (78.3%)	9.3	3.9	1.5	17.1	1.5	5.7	-9.7	12.7	0.7911			
Week 76																	
Placebo		13	39.8	4.8	12 (54.5%)												
Nera 18mg		17	49.6	6.1	16 (69.6%)												
Week 88																	
Placebo		5	46.7	11.0	4 (18.2%)												
Nera 18mg		8	51.6	10.8	8 (34.8%)												
Week 100																	
Placebo		2	38.1	9.5	2 (9.1%)												
Nera 18mg		2	51.8	6.5	2 (8.7%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Region																	
Test for homogeneity (H0)^																	
Week 12														0.6478			
Week 26														0.9939			
Week 36														0.5716			
Week 44														0.7265			
Week 52														0.5080			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 64														0.8587			
Europe																	
Baseline																	
Placebo	78	76	35.8	2.2	75 (100.0%)												
Nera 18mg	67	65	39.6	2.4	63 (100.0%)												
Week 12																	
Placebo		76	37.6	2.2	74 (98.7%)	2.2	1.6	-1.0	5.4								
Nera 18mg		62	39.5	2.2	61 (96.8%)	0.9	1.8	-2.6	4.4	-1.3	2.4	-6.0	3.4	0.5881			
Week 26																	
Placebo		73	41.2	2.5	71 (94.7%)	5.3	1.7	1.9	8.7								
Nera 18mg		56	41.6	2.6	54 (85.7%)	3.0	1.9	-0.9	6.8	-2.4	2.6	-7.5	2.7	0.3577			
Week 36																	
Placebo		68	37.8	2.4	66 (88.0%)	3.3	2.0	-0.7	7.3								
Nera 18mg		55	40.9	2.7	54 (85.7%)	2.7	2.2	-1.7	7.1	-0.6	3.0	-6.6	5.3	0.8353			
Week 44																	
Placebo		67	37.5	2.5	65 (86.7%)	3.4	2.0	-0.5	7.3								
Nera 18mg		54	42.5	2.7	52 (82.5%)	4.1	2.2	-0.3	8.4	0.7	3.0	-5.1	6.5	0.8114			
Week 52																	
Placebo		69	38.9	2.7	67 (89.3%)	4.8	2.1	0.6	9.0								
Nera 18mg		54	42.3	2.8	53 (84.1%)	4.0	2.4	-0.7	8.8	-0.8	3.2	-7.1	5.6	0.8130			
Week 64																	
Placebo		62	39.7	2.6	61 (81.3%)	6.6	2.2	2.3	10.9								
Nera 18mg		52	45.0	3.1	51 (81.0%)	6.7	2.4	1.9	11.5	0.1	3.3	-6.4	6.5	0.9825			
Week 76																	
Placebo		38	35.5	3.1	37 (49.3%)												
Nera 18mg		30	47.9	4.2	29 (46.0%)												
Week 88																	
Placebo		15	38.3	6.2	14 (18.7%)												
Nera 18mg		8	52.7	8.7	8 (12.7%)												
Week 100																	
Placebo		3	17.5	6.9	3 (4.0%)												
Nera 18mg		2	51.3	7.1	2 (3.2%)												
Week 112																	
Placebo		1	9.5	NC	1 (1.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Asia																	
Baseline																	
Placebo	45	45	35.6	3.3	43 (100.0%)												
Nera 18mg	41	41	37.3	3.5	39 (100.0%)												
Week 12																	
Placebo		42	32.7	3.3	42 (97.7%)	-2.3	2.1	-6.5	2.0								
Nera 18mg		39	36.5	3.7	39 (100.0%)	-0.7	2.2	-5.1	3.6	1.5	3.1	-4.6	7.6	0.6265			
Week 26																	
Placebo		42	35.4	3.4	42 (97.7%)	0.8	2.3	-3.6	5.3								
Nera 18mg		36	34.0	3.1	36 (92.3%)	-3.2	2.4	-8.0	1.5	-4.1	3.3	-10.6	2.4	0.2185			
Week 36																	
Placebo		41	34.6	3.7	41 (95.3%)	0.7	2.6	-4.4	5.8								
Nera 18mg		34	34.8	3.7	34 (87.2%)	-2.0	2.8	-7.6	3.5	-2.7	3.8	-10.3	4.8	0.4733			
Week 44																	
Placebo		38	38.2	3.9	38 (88.4%)	4.8	2.6	-0.2	9.9								
Nera 18mg		31	40.6	4.4	31 (79.5%)	2.4	2.8	-3.1	7.9	-2.4	3.8	-9.8	5.1	0.5306			
Week 52																	
Placebo		39	37.1	3.9	39 (90.7%)	3.5	2.8	-2.0	9.0								
Nera 18mg		32	38.3	4.1	32 (82.1%)	2.9	3.0	-3.1	8.9	-0.6	4.1	-8.7	7.6	0.8914			
Week 64																	
Placebo		33	34.4	4.0	33 (76.7%)	3.9	2.9	-1.8	9.6								
Nera 18mg		26	37.6	4.2	26 (66.7%)	4.5	3.2	-1.8	10.7	0.5	4.3	-7.9	9.0	0.9009			
Week 76																	
Placebo		25	30.8	4.8	25 (58.1%)												
Nera 18mg		19	34.8	5.5	19 (48.7%)												
Week 88																	
Placebo		13	35.6	7.4	13 (30.2%)												
Nera 18mg		9	46.7	10.7	9 (23.1%)												
Week 100																	
Placebo		5	35.7	9.4	5 (11.6%)												
Nera 18mg		4	28.6	7.8	4 (10.3%)												
Week 112																	
Placebo		1	34.5	NC	1 (2.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	
Baseline																	

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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	95% CI upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	95% CI upper	p-value	Hedges'g value	95% CI lower	95% CI upper
Placebo	30	30	32.5	3.4	30 (100.0%)												
Nera 18mg	37	36	34.3	3.0	36 (100.0%)												
Week 12																	
Placebo		28	31.9	3.4	28 (93.3%)	-2.5	2.6	-7.7	2.6								
Nera 18mg		36	37.4	3.3	35 (97.2%)	2.7	2.3	-1.9	7.3	5.2	3.5	-1.6	12.1	0.1351			
Week 26																	
Placebo		26	36.5	3.0	26 (86.7%)	0.8	2.8	-4.7	6.4								
Nera 18mg		34	36.9	3.1	33 (91.7%)	2.8	2.5	-2.1	7.8	2.0	3.8	-5.4	9.4	0.5997			
Week 36																	
Placebo		27	35.0	3.0	27 (90.0%)	0.4	3.2	-6.0	6.7								
Nera 18mg		34	35.5	3.2	33 (91.7%)	1.6	2.9	-4.1	7.4	1.3	4.3	-7.2	9.7	0.7722			
Week 44																	
Placebo		27	35.7	3.7	27 (90.0%)	1.9	3.1	-4.3	8.1								
Nera 18mg		33	39.2	3.9	32 (88.9%)	6.3	2.9	0.7	11.9	4.4	4.2	-3.9	12.7	0.2957			
Week 52																	
Placebo		26	37.6	4.5	26 (86.7%)	3.7	3.5	-3.2	10.5								
Nera 18mg		33	38.3	3.7	32 (88.9%)	5.2	3.1	-1.0	11.3	1.5	4.6	-7.6	10.6	0.7424			
Week 64																	
Placebo		20	36.1	4.1	20 (66.7%)	4.2	3.7	-3.0	11.4								
Nera 18mg		27	40.0	3.9	26 (72.2%)	9.2	3.3	2.8	15.6	5.0	4.9	-4.6	14.6	0.3086			
Week 76																	
Placebo		17	40.8	5.3	17 (56.7%)												
Nera 18mg		20	41.6	5.2	19 (52.8%)												
Week 88																	
Placebo		8	44.8	6.1	8 (26.7%)												
Nera 18mg		11	50.0	6.2	11 (30.6%)												
Week 100																	
Placebo		3	34.1	11.1	3 (10.0%)												
Nera 18mg		3	67.5	11.2	3 (8.3%)												
Week 112																	
Placebo		2	20.2	9.5	2 (6.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Rest of the World																	
Baseline																	
Placebo	16	16	38.1	4.7	14 (100.0%)												
Nera 18mg	25	25	40.5	4.8	24 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Table I.1.1.1.2.1: 2 Adjusted mean (SE) of absolute change from baseline in L-PF Impact total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 12																	
Placebo		14	38.4	4.9	14 (100.0%)	3.6	3.7	-3.7	10.9								
Nera 18mg		23	38.1	3.3	23 (95.8%)	-2.6	2.9	-8.2	3.1	-6.2	4.7	-15.4	3.1	0.1896			
Week 26																	
Placebo		14	37.2	4.3	14 (100.0%)	2.4	3.9	-5.3	10.1								
Nera 18mg		23	36.6	4.4	23 (95.8%)	-2.8	3.0	-8.8	3.2	-5.2	5.0	-15.0	4.6	0.2971			
Week 36																	
Placebo		14	37.4	4.8	14 (100.0%)	2.5	4.5	-6.4	11.3								
Nera 18mg		23	35.5	4.7	23 (95.8%)	-4.8	3.5	-11.7	2.1	-7.3	5.7	-18.5	4.0	0.2043			
Week 44																	
Placebo		14	38.0	5.7	14 (100.0%)	3.5	4.4	-5.1	12.1								
Nera 18mg		22	39.2	5.0	22 (91.7%)	-0.6	3.4	-7.4	6.2	-4.1	5.6	-15.1	6.9	0.4641			
Week 52																	
Placebo		13	45.4	6.6	13 (92.9%)	10.8	4.9	1.2	20.3								
Nera 18mg		20	37.6	4.7	20 (83.3%)	-1.1	3.8	-8.6	6.4	-11.9	6.2	-24.0	0.3	0.0555			
Week 64																	
Placebo		11	33.9	6.0	11 (78.6%)	4.9	5.0	-5.1	14.8								
Nera 18mg		16	36.0	6.2	16 (66.7%)	1.9	4.0	-6.0	9.9	-2.9	6.4	-15.6	9.8	0.6527			
Week 76																	
Placebo		8	32.6	5.2	8 (57.1%)												
Nera 18mg		11	30.0	7.0	11 (45.8%)												
Week 88																	
Placebo		1	26.2	NC	1 (7.1%)												
Nera 18mg		3	59.9	15.9	3 (12.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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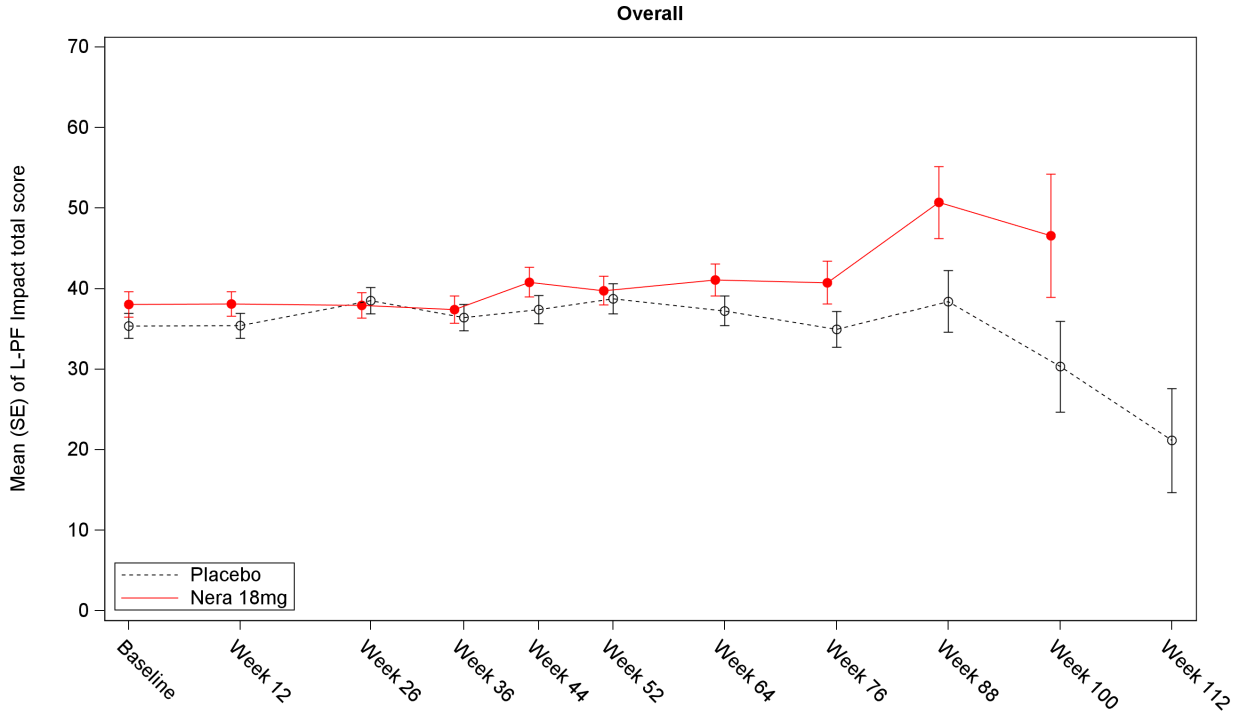

Number of patients

Placebo	167	160	155	150	146	147	126	88	37	11	4
Nera 18mg	167	160	149	146	140	139	121	80	31	9	0

Study: 1305-0023. Number of patients refers to the number of patients with observed data at visit.

Figure I.1.1.1.2.1: 2 Mean (SE) of L-PF Impact total score over the whole trial - 18mg - FAS (NIN background)

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Boehringer Ingelheim
BI Trial No.: x1305p3.hta

Figure I.1.1.1.2.1: 2

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Overall																	
Baseline																	
Placebo	169	169	28.3	1.3	164 (100.0%)												
Nera 18mg	170	169	28.8	1.2	164 (100.0%)												
Week 12																	
Placebo		161	28.6	1.4	161 (98.2%)	0.8	0.9	-1.0	2.5								
Nera 18mg		163	31.2	1.3	162 (98.8%)	2.4	0.9	0.7	4.2	1.7	1.3	-0.8	4.2	0.1891			
Week 26																	
Placebo		156	31.6	1.5	156 (95.1%)	4.0	1.1	1.8	6.1								
Nera 18mg		153	31.5	1.4	152 (92.7%)	3.0	1.1	0.8	5.2	-1.0	1.6	-4.1	2.1	0.5239			
Week 36																	
Placebo		151	30.8	1.5	151 (92.1%)	3.9	1.1	1.6	6.2								
Nera 18mg		146	30.9	1.4	146 (89.0%)	2.6	1.2	0.3	4.9	-1.3	1.6	-4.5	1.9	0.4195			
Week 44																	
Placebo		146	31.2	1.6	146 (89.0%)	4.2	1.2	1.9	6.6								
Nera 18mg		139	32.4	1.6	138 (84.1%)	4.4	1.2	2.1	6.8	0.2	1.7	-3.1	3.5	0.9019			
Week 52																	
Placebo		148	32.7	1.7	148 (90.2%)	5.8	1.3	3.3	8.3								
Nera 18mg		138	32.7	1.6	138 (84.1%)	5.1	1.3	2.6	7.7	-0.7	1.8	-4.3	3.0	0.7248			
Week 64																	
Placebo		128	31.5	1.6	128 (78.0%)	6.8	1.3	4.2	9.3								
Nera 18mg		122	32.9	1.7	122 (74.4%)	6.6	1.3	4.0	9.2	-0.2	1.8	-3.8	3.4	0.9141			
Week 76																	
Placebo		88	29.9	2.0	88 (53.7%)												
Nera 18mg		79	34.7	2.3	79 (48.2%)												
Week 88																	
Placebo		38	33.8	3.3	38 (23.2%)												
Nera 18mg		31	40.5	3.9	31 (18.9%)												
Week 100																	
Placebo		11	25.3	4.7	11 (6.7%)												
Nera 18mg		9	40.4	5.3	9 (5.5%)												
Week 112																	
Placebo		4	22.3	5.2	4 (2.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Age																	
Test for homogeneity (H0)^																	
Week 12														0.3083			
Week 26														0.8653			
Week 36														0.3930			
Week 44														0.8672			
Week 52														0.5111			
Week 64														0.9354			
<65 years																	
Baseline																	
Placebo	65	65	28.4	2.1	64 (100.0%)												
Nera 18mg	64	64	27.2	1.9	62 (100.0%)												
Week 12																	
Placebo		63	27.8	2.2	63 (98.4%)	-0.1	1.4	-3.0	2.7								
Nera 18mg		61	30.5	2.0	61 (98.4%)	3.2	1.5	0.3	6.1	3.3	2.0	-0.7	7.3	0.1072			
Week 26																	
Placebo		62	30.6	2.3	62 (96.9%)	3.0	1.7	-0.5	6.4								
Nera 18mg		58	29.7	2.3	58 (93.5%)	2.3	1.8	-1.2	5.8	-0.7	2.5	-5.6	4.3	0.7884			
Week 36																	
Placebo		62	32.4	2.4	62 (96.9%)	4.8	1.8	1.3	8.4								
Nera 18mg		56	29.0	2.5	56 (90.3%)	1.8	1.9	-1.9	5.5	-3.0	2.6	-8.2	2.1	0.2477			
Week 44																	
Placebo		61	30.6	2.3	61 (95.3%)	2.9	1.9	-0.7	6.6								
Nera 18mg		51	29.2	2.7	51 (82.3%)	3.4	2.0	-0.5	7.3	0.5	2.7	-4.8	5.9	0.8512			
Week 52																	
Placebo		62	32.0	2.5	62 (96.9%)	4.3	2.0	0.3	8.2								
Nera 18mg		52	31.8	2.8	52 (83.9%)	5.1	2.2	0.9	9.3	0.8	3.0	-5.0	6.6	0.7785			
Week 64																	
Placebo		57	31.9	2.3	57 (89.1%)	6.4	2.0	2.5	10.3								
Nera 18mg		45	30.6	3.1	45 (72.6%)	6.0	2.2	1.8	10.3	-0.4	2.9	-6.1	5.4	0.9032			
Week 76																	
Placebo		37	31.3	3.2	37 (57.8%)												
Nera 18mg		34	32.2	3.5	34 (54.8%)												
Week 88																	
Placebo		15	38.4	5.5	15 (23.4%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		7	43.8	9.0	7 (11.3%)												
Week 100																	
Placebo		4	28.2	9.8	4 (6.3%)												
Nera 18mg		1	22.3	NC	1 (1.6%)												
Week 112																	
Placebo		2	23.3	10.8	2 (3.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	104	104	28.2	1.7	100 (100.0%)												
Nera 18mg	106	105	29.9	1.6	102 (100.0%)												
Week 12																	
Placebo		98	29.1	1.8	98 (98.0%)	1.4	1.2	-0.9	3.6								
Nera 18mg		102	31.6	1.6	101 (99.0%)	2.0	1.1	-0.2	4.2	0.6	1.6	-2.5	3.8	0.6921			
Week 26																	
Placebo		94	32.3	2.0	94 (94.0%)	4.6	1.4	1.8	7.4								
Nera 18mg		95	32.5	1.7	94 (92.2%)	3.4	1.4	0.6	6.2	-1.2	2.0	-5.2	2.7	0.5429			
Week 36																	
Placebo		89	29.7	1.9	89 (89.0%)	3.2	1.5	0.3	6.1								
Nera 18mg		90	32.1	1.7	90 (88.2%)	3.0	1.5	0.1	6.0	-0.2	2.1	-4.3	4.0	0.9421			
Week 44																	
Placebo		85	31.7	2.2	85 (85.0%)	5.1	1.5	2.1	8.2								
Nera 18mg		88	34.3	1.9	87 (85.3%)	5.1	1.5	2.0	8.1	-0.1	2.2	-4.4	4.2	0.9729			
Week 52																	
Placebo		86	33.2	2.3	86 (86.0%)	6.9	1.7	3.5	10.2								
Nera 18mg		86	33.2	1.9	86 (84.3%)	5.2	1.7	1.9	8.5	-1.7	2.4	-6.3	3.0	0.4842			
Week 64																	
Placebo		71	31.2	2.3	71 (71.0%)	7.0	1.7	3.6	10.3								
Nera 18mg		77	34.3	2.0	77 (75.5%)	6.9	1.7	3.6	10.2	-0.1	2.4	-4.7	4.6	0.9832			
Week 76																	
Placebo		51	28.9	2.6	51 (51.0%)												
Nera 18mg		45	36.6	3.1	45 (44.1%)												
Week 88																	
Placebo		23	30.9	4.1	23 (23.0%)												
Nera 18mg		24	39.5	4.4	24 (23.5%)												
Week 100																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		7	23.6	5.3	7 (7.0%)												
Nera 18mg		8	42.7	5.5	8 (7.8%)												
Week 112																	
Placebo		2	21.2	6.6	2 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Sex																	
Test for homogeneity (H0)^																	
Week 12														0.5119			
Week 26														0.5032			
Week 36														0.0826			
Week 44														0.1986			
Week 52														0.3180			
Week 64														0.0902			
Male																	
Baseline																	
Placebo	114	114	26.4	1.5	111 (100.0%)												
Nera 18mg	108	107	26.5	1.4	102 (100.0%)												
Week 12																	
Placebo		109	28.2	1.7	109 (98.2%)	2.0	1.1	-0.2	4.1								
Nera 18mg		102	30.0	1.5	101 (99.0%)	3.2	1.1	0.9	5.4	1.2	1.6	-1.9	4.3	0.4419			
Week 26																	
Placebo		104	30.9	1.8	104 (93.7%)	4.7	1.3	2.1	7.4								
Nera 18mg		95	31.4	1.7	94 (92.2%)	4.7	1.4	2.0	7.5	-0.0	1.9	-3.8	3.8	0.9880			
Week 36																	
Placebo		100	29.5	1.8	100 (90.1%)	4.2	1.4	1.5	7.0								
Nera 18mg		88	32.0	1.9	88 (86.3%)	5.2	1.5	2.4	8.1	1.0	2.0	-2.9	5.0	0.6060			
Week 44																	
Placebo		97	29.5	1.9	97 (87.4%)	4.4	1.5	1.6	7.3								
Nera 18mg		82	32.3	1.9	81 (79.4%)	6.5	1.6	3.4	9.5	2.0	2.1	-2.2	6.2	0.3445			
Week 52																	
Placebo		97	31.8	2.0	97 (87.4%)	6.8	1.6	3.6	9.9								
Nera 18mg		82	33.7	2.1	82 (80.4%)	7.8	1.7	4.5	11.1	1.0	2.3	-3.5	5.5	0.6604			
Week 64																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		82	29.3	1.9	82 (73.9%)	7.2	1.6	4.1	10.3								
Nera 18mg		74	35.4	2.2	74 (72.5%)	9.6	1.7	6.3	12.9	2.4	2.3	-2.1	6.9	0.2870			
Week 76																	
Placebo		54	28.4	2.4	54 (48.6%)												
Nera 18mg		47	38.5	3.2	47 (46.1%)												
Week 88																	
Placebo		25	34.5	3.8	25 (22.5%)												
Nera 18mg		18	42.8	5.4	18 (17.6%)												
Week 100																	
Placebo		7	27.4	6.4	7 (6.3%)												
Nera 18mg		4	47.4	4.9	4 (3.9%)												
Week 112																	
Placebo		2	21.2	6.6	2 (1.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Female																	
Baseline																	
Placebo	55	55	32.1	2.5	53 (100.0%)												
Nera 18mg	62	62	32.8	2.1	62 (100.0%)												
Week 12																	
Placebo		52	29.3	2.5	52 (98.1%)	-1.7	1.6	-4.8	1.4								
Nera 18mg		61	33.1	2.2	61 (98.4%)	1.2	1.5	-1.6	4.1	3.0	2.1	-1.3	7.2	0.1698			
Week 26																	
Placebo		52	33.1	2.6	52 (98.1%)	2.4	1.9	-1.4	6.1								
Nera 18mg		58	31.6	2.3	58 (93.5%)	0.2	1.8	-3.4	3.7	-2.2	2.6	-7.3	2.9	0.3985			
Week 36																	
Placebo		51	33.3	2.7	51 (96.2%)	3.2	2.0	-0.7	7.1								
Nera 18mg		58	29.3	2.1	58 (93.5%)	-1.7	1.9	-5.3	2.0	-4.8	2.7	-10.1	0.5	0.0742			
Week 44																	
Placebo		49	34.7	2.9	49 (92.5%)	3.7	2.1	-0.3	7.8								
Nera 18mg		57	32.6	2.7	57 (91.9%)	1.2	1.9	-2.6	5.0	-2.5	2.8	-8.1	3.0	0.3681			
Week 52																	
Placebo		51	34.4	3.0	51 (96.2%)	3.8	2.2	-0.6	8.2								
Nera 18mg		56	31.2	2.4	56 (90.3%)	1.0	2.1	-3.1	5.1	-2.8	3.0	-8.8	3.2	0.3571			
Week 64																	
Placebo		46	35.3	3.0	46 (86.8%)	5.8	2.2	1.5	10.1								
Nera 18mg		48	29.2	2.5	48 (77.4%)	1.8	2.1	-2.3	5.9	-4.0	3.0	-9.9	1.9	0.1851			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 76																	
Placebo		34	32.3	3.6	34 (64.2%)												
Nera 18mg		32	29.1	3.1	32 (51.6%)												
Week 88																	
Placebo		13	32.6	6.5	13 (24.5%)												
Nera 18mg		13	37.3	5.6	13 (21.0%)												
Week 100																	
Placebo		4	21.5	6.9	4 (7.5%)												
Nera 18mg		5	34.8	8.4	5 (8.1%)												
Week 112																	
Placebo		2	23.3	10.8	2 (3.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 12														0.7171			
Week 26														0.7528			
Week 36														0.9422			
Week 44														0.5586			
Week 52														0.4485			
Week 64														0.9136			
<=70%																	
Baseline																	
Placebo	95	95	31.1	1.8	91 (100.0%)												
Nera 18mg	97	97	31.9	1.6	96 (100.0%)												
Week 12																	
Placebo		88	31.6	2.0	88 (96.7%)	1.8	1.2	-0.6	4.2								
Nera 18mg		96	34.5	1.6	96 (100.0%)	3.8	1.2	1.5	6.1	2.0	1.7	-1.3	5.3	0.2386			
Week 26																	
Placebo		85	34.8	2.1	85 (93.4%)	5.2	1.5	2.3	8.1								
Nera 18mg		88	34.7	1.8	88 (91.7%)	4.6	1.5	1.7	7.4	-0.7	2.1	-4.7	3.4	0.7496			
Week 36																	
Placebo		83	34.5	2.1	83 (91.2%)	5.9	1.5	2.8	8.9								
Nera 18mg		85	34.3	1.9	85 (88.5%)	4.5	1.5	1.5	7.5	-1.3	2.2	-5.6	2.9	0.5315			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 44																	
Placebo		80	34.6	2.1	80 (87.9%)	5.3	1.6	2.1	8.5								
Nera 18mg		79	35.6	2.1	79 (82.3%)	6.3	1.6	3.2	9.4	1.0	2.3	-3.5	5.4	0.6639			
Week 52																	
Placebo		80	37.8	2.4	80 (87.9%)	8.8	1.7	5.4	12.3								
Nera 18mg		79	36.0	2.0	79 (82.3%)	6.8	1.7	3.4	10.2	-2.1	2.4	-6.8	2.7	0.4000			
Week 64																	
Placebo		70	35.1	2.3	70 (76.9%)	9.0	1.7	5.6	12.4								
Nera 18mg		70	36.5	2.2	70 (72.9%)	8.8	1.7	5.4	12.2	-0.2	2.4	-5.0	4.6	0.9420			
Week 76																	
Placebo		45	32.3	3.0	45 (49.5%)												
Nera 18mg		44	40.2	3.3	44 (45.8%)												
Week 88																	
Placebo		20	34.6	4.7	20 (22.0%)												
Nera 18mg		19	45.4	4.5	19 (19.8%)												
Week 100																	
Placebo		5	34.9	6.5	5 (5.5%)												
Nera 18mg		5	39.4	5.1	5 (5.2%)												
Week 112																	
Placebo		3	24.8	6.4	3 (3.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	74	74	24.6	1.9	73 (100.0%)												
Nera 18mg	73	72	24.8	1.8	68 (100.0%)												
Week 12																	
Placebo		73	25.0	1.9	73 (100.0%)	-0.5	1.3	-3.1	2.1								
Nera 18mg		67	26.4	1.8	66 (97.1%)	0.6	1.4	-2.2	3.3	1.1	1.9	-2.7	4.8	0.5863			
Week 26																	
Placebo		71	27.8	2.0	71 (97.3%)	2.4	1.6	-0.8	5.7								
Nera 18mg		65	27.1	2.1	64 (94.1%)	0.8	1.7	-2.6	4.2	-1.6	2.4	-6.3	3.0	0.4847			
Week 36																	
Placebo		68	26.3	2.0	68 (93.2%)	1.4	1.7	-1.9	4.8								
Nera 18mg		61	26.2	2.0	61 (89.7%)	-0.1	1.8	-3.7	3.4	-1.6	2.5	-6.4	3.3	0.5202			
Week 44																	
Placebo		66	27.2	2.4	66 (90.4%)	2.9	1.8	-0.6	6.4								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		60	28.3	2.4	59 (86.8%)	1.9	1.9	-1.8	5.6	-1.0	2.6	-6.1	4.0	0.6917			
Week 52																	
Placebo		68	26.6	2.2	68 (93.2%)	2.1	1.9	-1.6	5.9								
Nera 18mg		59	28.3	2.4	59 (86.8%)	2.8	2.0	-1.1	6.8	0.7	2.8	-4.7	6.2	0.7892			
Week 64																	
Placebo		58	27.2	2.2	58 (79.5%)	4.0	1.9	0.3	7.8								
Nera 18mg		52	28.2	2.6	52 (76.5%)	3.5	2.0	-0.5	7.4	-0.6	2.8	-6.0	4.9	0.8348			
Week 76																	
Placebo		43	27.4	2.7	43 (58.9%)												
Nera 18mg		35	27.8	2.9	35 (51.5%)												
Week 88																	
Placebo		18	33.0	4.8	18 (24.7%)												
Nera 18mg		12	32.7	6.6	12 (17.6%)												
Week 100																	
Placebo		6	17.2	4.9	6 (8.2%)												
Nera 18mg		4	41.7	11.3	4 (5.9%)												
Week 112																	
Placebo		1	14.6	NC	1 (1.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline HRCT pattern																	
Test for homogeneity (H0)^																	
Week 12														0.8314			
Week 26														0.7073			
Week 36														0.4788			
Week 44														0.9527			
Week 52														0.6703			
Week 64														0.6302			
UIP-like																	
Baseline																	
Placebo	116	116	26.9	1.5	113 (100.0%)												
Nera 18mg	121	120	28.8	1.5	117 (100.0%)												
Week 12																	
Placebo		111	27.6	1.7	111 (98.2%)	0.9	1.1	-1.2	3.1								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg		117	31.7	1.5	116 (99.1%)	2.8	1.1	0.7	4.9	1.8	1.5	-1.1	4.8	0.2246			
Week 26																	
Placebo		107	30.5	1.8	107 (94.7%)	4.1	1.3	1.4	6.7								
Nera 18mg		110	31.4	1.6	109 (93.2%)	2.7	1.3	0.1	5.3	-1.4	1.9	-5.1	2.3	0.4606			
Week 36																	
Placebo		103	29.2	1.8	103 (91.2%)	3.6	1.4	0.9	6.4								
Nera 18mg		104	31.8	1.7	104 (88.9%)	3.1	1.4	0.4	5.8	-0.5	2.0	-4.4	3.3	0.7807			
Week 44																	
Placebo		99	30.2	2.0	99 (87.6%)	5.1	1.4	2.2	7.9								
Nera 18mg		99	33.8	1.9	98 (83.8%)	5.4	1.4	2.6	8.2	0.3	2.0	-3.7	4.3	0.8907			
Week 52																	
Placebo		100	30.9	2.0	100 (88.5%)	5.6	1.6	2.5	8.7								
Nera 18mg		100	33.1	1.9	100 (85.5%)	5.5	1.6	2.4	8.5	-0.1	2.2	-4.5	4.2	0.9554			
Week 64																	
Placebo		90	31.5	2.0	90 (79.6%)	7.3	1.6	4.2	10.3								
Nera 18mg		87	34.0	2.1	87 (74.4%)	7.7	1.6	4.6	10.7	0.4	2.2	-3.9	4.7	0.8589			
Week 76																	
Placebo		60	28.7	2.4	60 (53.1%)												
Nera 18mg		58	34.9	2.6	58 (49.6%)												
Week 88																	
Placebo		26	33.5	4.1	26 (23.0%)												
Nera 18mg		23	42.1	4.6	23 (19.7%)												
Week 100																	
Placebo		9	26.6	5.7	9 (8.0%)												
Nera 18mg		8	38.7	5.7	8 (6.8%)												
Week 112																	
Placebo		3	25.5	5.8	3 (2.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other fibrotic patterns																	
Baseline																	
Placebo	53	53	31.4	2.4	51 (100.0%)												
Nera 18mg	49	49	28.9	2.3	47 (100.0%)												
Week 12																	
Placebo		50	30.8	2.5	50 (98.0%)	0.4	1.6	-2.8	3.6								
Nera 18mg		46	30.0	2.3	46 (97.9%)	1.6	1.7	-1.7	4.9	1.3	2.3	-3.3	5.8	0.5910			
Week 26																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		49	33.9	2.8	49 (96.1%)	3.8	2.0	-0.1	7.7								
Nera 18mg		43	31.5	2.7	43 (91.5%)	3.7	2.1	-0.4	7.8	-0.1	2.9	-5.7	5.5	0.9742			
Week 36																	
Placebo		48	34.1	2.8	48 (94.1%)	4.4	2.0	0.4	8.5								
Nera 18mg		42	28.8	2.7	42 (89.4%)	1.3	2.2	-2.9	5.6	-3.1	3.0	-9.0	2.8	0.3021			
Week 44																	
Placebo		47	33.3	2.7	47 (92.2%)	2.3	2.1	-1.9	6.5								
Nera 18mg		40	29.0	2.7	40 (85.1%)	2.4	2.3	-2.1	6.8	0.1	3.1	-6.0	6.2	0.9846			
Week 52																	
Placebo		48	36.3	3.1	48 (94.1%)	6.2	2.3	1.7	10.7								
Nera 18mg		38	31.5	2.7	38 (80.9%)	4.3	2.5	-0.6	9.2	-1.9	3.4	-8.5	4.8	0.5849			
Week 64																	
Placebo		38	31.4	2.7	38 (74.5%)	5.5	2.3	0.9	10.0								
Nera 18mg		35	30.3	2.9	35 (74.5%)	3.9	2.5	-0.9	8.8	-1.6	3.4	-8.2	5.1	0.6457			
Week 76																	
Placebo		28	32.4	3.7	28 (54.9%)												
Nera 18mg		21	34.2	5.0	21 (44.7%)												
Week 88																	
Placebo		12	34.5	6.0	12 (23.5%)												
Nera 18mg		8	36.0	7.4	8 (17.0%)												
Week 100																	
Placebo		2	19.4	2.6	2 (3.9%)												
Nera 18mg		1	54.1	NC	1 (2.1%)												
Week 112																	
Placebo		1	12.5	NC	1 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Underlying ILD diagnosis																	
Test for homogeneity (H0)^																	
Week 12														0.6046			
Week 26														0.1761			
Week 36														0.9230			
Week 44														0.2310			
Week 52														0.1730			
Week 64														0.1209			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
iNSIP																	
Baseline																	
Placebo	32	32	28.9	3.2	31 (100.0%)												
Nera 18mg	27	27	28.9	3.3	25 (100.0%)												
Week 12																	
Placebo		29	26.8	3.8	29 (93.5%)	-1.0	2.1	-5.1	3.1								
Nera 18mg		24	30.6	4.2	24 (96.0%)	2.6	2.3	-1.9	7.2	3.6	3.1	-2.6	9.8	0.2490			
Week 26																	
Placebo		29	29.5	3.9	29 (93.5%)	0.9	2.5	-4.1	5.9								
Nera 18mg		23	31.9	4.1	23 (92.0%)	5.1	2.8	-0.5	10.7	4.2	3.8	-3.3	11.7	0.2751			
Week 36																	
Placebo		28	30.0	3.9	28 (90.3%)	2.9	2.6	-2.3	8.1								
Nera 18mg		21	28.6	4.1	21 (84.0%)	2.0	3.0	-3.9	7.9	-0.9	4.0	-8.8	7.0	0.8203			
Week 44																	
Placebo		28	30.5	4.0	28 (90.3%)	3.2	2.7	-2.1	8.6								
Nera 18mg		19	34.1	5.4	19 (76.0%)	8.9	3.2	2.7	15.2	5.7	4.2	-2.6	13.9	0.1770			
Week 52																	
Placebo		27	30.4	4.1	27 (87.1%)	3.2	3.0	-2.6	9.1								
Nera 18mg		17	31.9	4.9	17 (68.0%)	9.0	3.5	2.0	16.0	5.8	4.6	-3.4	14.9	0.2152			
Week 64																	
Placebo		23	30.2	4.1	23 (74.2%)	3.2	3.0	-2.7	9.0								
Nera 18mg		17	33.5	4.7	17 (68.0%)	10.4	3.4	3.7	17.2	7.3	4.5	-1.7	16.2	0.1105			
Week 76																	
Placebo		16	33.9	6.3	16 (51.6%)												
Nera 18mg		10	43.4	9.2	10 (40.0%)												
Week 88																	
Placebo		9	35.5	7.5	9 (29.0%)												
Nera 18mg		3	50.2	19.9	3 (12.0%)												
Week 100																	
Placebo		2	11.2	1.6	2 (6.5%)												
Nera 18mg		1	54.1	NC	1 (4.0%)												
Week 112																	
Placebo		2	21.2	6.6	2 (6.5%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Unclassifiable IIP																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Baseline																	
Placebo	46	46	28.0	2.4	44 (100.0%)												
Nera 18mg	32	32	27.6	2.7	32 (100.0%)												
Week 12																	
Placebo		44	30.8	2.7	44 (100.0%)	3.2	1.7	-0.2	6.6								
Nera 18mg		32	29.9	2.4	32 (100.0%)	2.0	2.0	-2.0	6.0	-1.2	2.7	-6.5	4.0	0.6513			
Week 26																	
Placebo		40	31.5	2.9	40 (90.9%)	4.6	2.1	0.4	8.9								
Nera 18mg		28	28.4	2.5	28 (87.5%)	0.0	2.6	-5.0	5.0	-4.6	3.3	-11.2	1.9	0.1655			
Week 36																	
Placebo		38	30.8	2.9	38 (86.4%)	5.0	2.2	0.6	9.4								
Nera 18mg		27	35.5	2.9	27 (84.4%)	7.1	2.7	1.9	12.4	2.2	3.5	-4.7	9.0	0.5359			
Week 44																	
Placebo		37	33.2	3.3	37 (84.1%)	7.7	2.3	3.2	12.3								
Nera 18mg		27	32.9	3.1	27 (84.4%)	4.3	2.7	-1.1	9.7	-3.5	3.6	-10.5	3.6	0.3381			
Week 52																	
Placebo		38	33.9	3.5	38 (86.4%)	8.3	2.5	3.3	13.2								
Nera 18mg		28	28.8	2.9	28 (87.5%)	0.4	3.0	-5.4	6.2	-7.9	3.9	-15.5	-0.2	0.0434	-0.50	-0.99	-0.01
Week 64																	
Placebo		32	32.6	3.2	32 (72.7%)	9.0	2.5	4.1	14.0								
Nera 18mg		23	35.1	3.8	23 (71.9%)	8.4	3.0	2.6	14.2	-0.6	3.9	-8.3	7.0	0.8715			
Week 76																	
Placebo		25	27.6	3.2	25 (56.8%)												
Nera 18mg		16	32.8	4.1	16 (50.0%)												
Week 88																	
Placebo		10	38.4	5.4	10 (22.7%)												
Nera 18mg		10	37.6	7.6	10 (31.3%)												
Week 100																	
Placebo		2	35.6	13.3	2 (4.5%)												
Nera 18mg		3	36.5	14.1	3 (9.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
HP																	
Baseline																	
Placebo	38	38	23.9	2.6	38 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg	43	43	33.7	2.8	41 (100.0%)												
Week 12																	
Placebo		38	26.4	2.4	38 (100.0%)	1.8	1.9	-1.9	5.5								
Nera 18mg		41	36.0	2.4	41 (100.0%)	3.0	1.8	-0.6	6.5	1.2	2.6	-4.0	6.3	0.6494			
Week 26																	
Placebo		38	31.8	3.0	38 (100.0%)	6.8	2.3	2.4	11.2								
Nera 18mg		38	36.4	3.2	38 (92.7%)	4.3	2.2	-0.1	8.7	-2.5	3.2	-8.8	3.7	0.4266			
Week 36																	
Placebo		38	30.2	2.9	38 (100.0%)	5.1	2.3	0.5	9.6								
Nera 18mg		37	33.8	2.7	37 (90.2%)	2.3	2.3	-2.3	6.8	-2.8	3.3	-9.3	3.7	0.3971			
Week 44																	
Placebo		37	28.0	2.7	37 (97.4%)	3.6	2.4	-1.1	8.3								
Nera 18mg		35	37.1	3.3	35 (85.4%)	5.6	2.4	0.8	10.3	1.9	3.4	-4.8	8.6	0.5700			
Week 52																	
Placebo		37	30.7	3.3	37 (97.4%)	6.0	2.6	0.9	11.1								
Nera 18mg		34	39.7	3.1	34 (82.9%)	8.2	2.6	3.0	13.4	2.2	3.7	-5.1	9.5	0.5601			
Week 64																	
Placebo		33	31.1	3.2	33 (86.8%)	9.3	2.6	4.2	14.4								
Nera 18mg		30	39.0	3.5	30 (73.2%)	8.2	2.6	3.0	13.3	-1.1	3.7	-8.4	6.1	0.7636			
Week 76																	
Placebo		18	32.7	4.5	18 (47.4%)												
Nera 18mg		17	38.9	4.8	17 (41.5%)												
Week 88																	
Placebo		8	31.9	8.0	8 (21.1%)												
Nera 18mg		5	45.7	5.4	5 (12.2%)												
Week 100																	
Placebo		1	12.7	NC	1 (2.6%)												
Nera 18mg		1	57.4	NC	1 (2.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Autoimmune ILD																	
Baseline																	
Placebo	29	29	30.3	3.4	28 (100.0%)												
Nera 18mg	43	42	26.7	2.2	42 (100.0%)												
Week 12																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo		27	28.1	4.0	27 (96.4%)	-1.7	2.2	-6.0	2.6								
Nera 18mg		43	28.0	2.1	42 (100.0%)	0.9	1.8	-2.6	4.4	2.6	2.8	-2.9	8.2	0.3556			
Week 26																	
Placebo		27	31.0	3.7	27 (96.4%)	1.9	2.6	-3.3	7.1								
Nera 18mg		41	27.2	2.4	40 (95.2%)	-0.1	2.2	-4.3	4.2	-1.9	3.4	-8.6	4.8	0.5678			
Week 36																	
Placebo		26	29.4	3.6	26 (92.9%)	1.1	2.7	-4.3	6.4								
Nera 18mg		38	24.7	2.3	38 (90.5%)	-2.9	2.3	-7.4	1.6	-4.0	3.5	-10.9	3.0	0.2666			
Week 44																	
Placebo		23	30.3	4.3	23 (82.1%)	0.0	2.9	-5.7	5.7								
Nera 18mg		37	26.0	2.7	36 (85.7%)	-1.5	2.4	-6.2	3.1	-1.5	3.7	-8.8	5.8	0.6814			
Week 52																	
Placebo		25	32.6	4.2	25 (89.3%)	3.5	3.1	-2.6	9.6								
Nera 18mg		37	26.5	2.9	37 (88.1%)	-0.0	2.5	-5.0	5.0	-3.5	4.0	-11.4	4.4	0.3835			
Week 64																	
Placebo		21	28.4	4.0	21 (75.0%)	2.0	3.1	-4.0	8.1								
Nera 18mg		33	24.0	2.5	33 (78.6%)	-0.7	2.5	-5.6	4.3	-2.7	4.0	-10.5	5.1	0.4996			
Week 76																	
Placebo		16	29.5	5.2	16 (57.1%)												
Nera 18mg		19	24.2	3.7	19 (45.2%)												
Week 88																	
Placebo		6	22.0	5.4	6 (21.4%)												
Nera 18mg		5	36.7	7.6	5 (11.9%)												
Week 100																	
Placebo		4	25.8	8.3	4 (14.3%)												
Nera 18mg		2	32.4	10.1	2 (4.8%)												
Week 112																	
Placebo		2	23.3	10.8	2 (7.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other ILD																	
Baseline																	
Placebo	24	24	32.5	3.6	23 (100.0%)												
Nera 18mg	25	25	25.6	2.7	24 (100.0%)												
Week 12																	
Placebo		23	30.9	3.3	23 (100.0%)	-0.2	2.4	-4.9	4.5								
Nera 18mg		23	31.0	3.7	23 (95.8%)	4.5	2.4	-0.2	9.2	4.7	3.4	-1.9	11.4	0.1625			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 26																	
Placebo		22	34.9	3.6	22 (95.7%)	4.5	2.9	-1.2	10.3								
Nera 18mg		23	34.3	3.3	23 (95.8%)	7.5	2.8	1.9	13.1	3.0	4.1	-5.1	11.0	0.4669			
Week 36																	
Placebo		21	34.6	4.3	21 (91.3%)	4.7	3.1	-1.3	10.8								
Nera 18mg		23	33.3	4.4	23 (95.8%)	7.4	2.9	1.6	13.2	2.6	4.3	-5.7	11.0	0.5349			
Week 44																	
Placebo		21	35.2	4.0	21 (91.3%)	5.4	3.1	-0.8	11.6								
Nera 18mg		21	34.0	3.7	21 (87.5%)	9.0	3.1	2.9	15.0	3.6	4.4	-5.1	12.3	0.4149			
Week 52																	
Placebo		21	37.1	4.2	21 (91.3%)	7.2	3.4	0.5	13.9								
Nera 18mg		22	37.8	4.1	22 (91.7%)	11.7	3.3	5.1	18.2	4.5	4.8	-4.9	13.9	0.3490			
Week 64																	
Placebo		19	35.3	4.1	19 (82.6%)	8.4	3.4	1.7	15.0								
Nera 18mg		19	35.7	4.6	19 (79.2%)	10.9	3.3	4.4	17.3	2.5	4.7	-6.8	11.8	0.5970			
Week 76																	
Placebo		13	26.0	3.7	13 (56.5%)												
Nera 18mg		17	39.1	5.2	17 (70.8%)												
Week 88																	
Placebo		5	39.0	12.2	5 (21.7%)												
Nera 18mg		8	39.6	8.6	8 (33.3%)												
Week 100																	
Placebo		2	34.2	12.2	2 (8.7%)												
Nera 18mg		2	39.0	0.4	2 (8.3%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Region																	
Test for homogeneity (H0)^																	
Week 12														0.4200			
Week 26														0.9981			
Week 36														0.9663			
Week 44														0.7826			
Week 52														0.5475			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 64														0.9167			
Europe																	
Baseline																	
Placebo	78	78	29.1	2.1	77 (100.0%)												
Nera 18mg	67	66	29.0	1.9	64 (100.0%)												
Week 12																	
Placebo		75	30.9	2.2	75 (97.4%)	2.4	1.3	-0.2	5.0								
Nera 18mg		65	31.1	1.9	64 (100.0%)	2.5	1.4	-0.3	5.4	0.1	1.9	-3.7	3.9	0.9584			
Week 26																	
Placebo		73	34.6	2.3	73 (94.8%)	5.9	1.6	2.8	9.1								
Nera 18mg		59	33.6	2.2	58 (90.6%)	5.1	1.8	1.6	8.6	-0.8	2.4	-5.5	3.9	0.7266			
Week 36																	
Placebo		69	32.6	2.3	69 (89.6%)	5.1	1.7	1.8	8.5								
Nera 18mg		55	32.7	2.4	55 (85.9%)	4.4	1.9	0.6	8.1	-0.8	2.5	-5.8	4.2	0.7638			
Week 44																	
Placebo		68	31.5	2.3	68 (88.3%)	4.1	1.8	0.7	7.6								
Nera 18mg		53	32.6	2.4	52 (81.3%)	5.2	2.0	1.3	9.0	1.0	2.6	-4.2	6.2	0.6954			
Week 52																	
Placebo		69	33.2	2.4	69 (89.6%)	5.9	1.9	2.2	9.6								
Nera 18mg		53	34.4	2.5	53 (82.8%)	6.1	2.1	1.9	10.3	0.2	2.8	-5.4	5.8	0.9361			
Week 64																	
Placebo		63	33.7	2.3	63 (81.8%)	7.8	1.9	4.1	11.4								
Nera 18mg		52	35.9	2.6	52 (81.3%)	8.0	2.1	3.9	12.1	0.3	2.8	-5.2	5.8	0.9273			
Week 76																	
Placebo		38	29.5	2.9	38 (49.4%)												
Nera 18mg		29	41.6	4.0	29 (45.3%)												
Week 88																	
Placebo		15	32.7	6.0	15 (19.5%)												
Nera 18mg		8	41.0	6.5	8 (12.5%)												
Week 100																	
Placebo		3	16.1	3.6	3 (3.9%)												
Nera 18mg		2	43.4	4.0	2 (3.1%)												
Week 112																	
Placebo		1	12.5	NC	1 (1.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Asia																	
Baseline																	
Placebo	45	45	25.6	2.4	43 (100.0%)												
Nera 18mg	41	41	30.7	2.8	39 (100.0%)												
Week 12																	
Placebo		43	24.3	2.6	43 (100.0%)	-1.7	1.7	-5.1	1.8								
Nera 18mg		39	32.3	3.0	39 (100.0%)	2.2	1.8	-1.4	5.8	3.9	2.5	-1.1	8.9	0.1306			
Week 26																	
Placebo		42	27.6	2.7	42 (97.7%)	2.0	2.1	-2.2	6.2								
Nera 18mg		36	28.8	2.9	36 (92.3%)	-1.0	2.3	-5.5	3.5	-3.0	3.1	-9.1	3.1	0.3313			
Week 36																	
Placebo		41	29.6	3.0	41 (95.3%)	4.4	2.2	0.0	8.8								
Nera 18mg		34	30.1	3.0	34 (87.2%)	0.3	2.4	-4.5	5.0	-4.1	3.3	-10.6	2.3	0.2098			
Week 44																	
Placebo		37	31.5	3.5	37 (86.0%)	5.8	2.3	1.2	10.4								
Nera 18mg		31	34.1	3.7	31 (79.5%)	2.7	2.5	-2.3	7.7	-3.1	3.4	-9.8	3.7	0.3730			
Week 52																	
Placebo		39	31.3	3.6	39 (90.7%)	6.1	2.5	1.2	11.1								
Nera 18mg		32	31.3	3.5	32 (82.1%)	3.0	2.7	-2.4	8.3	-3.1	3.7	-10.4	4.1	0.3959			
Week 64																	
Placebo		33	28.8	3.6	33 (76.7%)	6.3	2.5	1.4	11.3								
Nera 18mg		26	29.4	3.8	26 (66.7%)	2.7	2.7	-2.7	8.1	-3.6	3.7	-10.9	3.7	0.3309			
Week 76																	
Placebo		25	27.3	4.0	25 (58.1%)												
Nera 18mg		19	29.6	4.5	19 (48.7%)												
Week 88																	
Placebo		13	32.4	6.1	13 (30.2%)												
Nera 18mg		9	40.6	9.8	9 (23.1%)												
Week 100																	
Placebo		5	31.0	8.8	5 (11.6%)												
Nera 18mg		4	31.7	10.1	4 (10.3%)												
Week 112																	
Placebo		1	34.2	NC	1 (2.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	
Baseline																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo	30	30	27.7	2.8	30 (100.0%)												
Nera 18mg	37	37	24.9	2.0	37 (100.0%)												
Week 12																	
Placebo		29	27.0	2.7	29 (96.7%)	-1.1	2.1	-5.2	3.1								
Nera 18mg		36	28.3	2.3	36 (97.3%)	2.7	1.9	-1.1	6.4	3.7	2.8	-1.9	9.3	0.1901			
Week 26																	
Placebo		27	28.0	2.8	27 (90.0%)	1.1	2.6	-4.1	6.3								
Nera 18mg		34	28.5	2.4	34 (91.9%)	3.2	2.3	-1.4	7.8	2.1	3.5	-4.8	8.9	0.5558			
Week 36																	
Placebo		27	27.7	3.0	27 (90.0%)	0.8	2.7	-4.6	6.2								
Nera 18mg		34	28.4	2.4	34 (91.9%)	3.0	2.4	-1.9	7.8	2.2	3.7	-5.0	9.4	0.5563			
Week 44																	
Placebo		27	29.2	3.2	27 (90.0%)	2.8	2.8	-2.7	8.4								
Nera 18mg		33	30.1	3.0	33 (89.2%)	5.7	2.5	0.7	10.7	2.9	3.8	-4.6	10.3	0.4499			
Week 52																	
Placebo		26	28.9	3.4	26 (86.7%)	2.0	3.1	-4.1	8.0								
Nera 18mg		33	31.8	3.1	33 (89.2%)	6.9	2.8	1.5	12.3	4.9	4.1	-3.2	13.0	0.2316			
Week 64																	
Placebo		21	30.6	3.5	21 (70.0%)	5.4	3.1	-0.7	11.6								
Nera 18mg		27	31.9	2.9	27 (73.0%)	9.4	2.8	3.9	14.9	4.0	4.2	-4.2	12.1	0.3394			
Week 76																	
Placebo		17	34.0	5.0	17 (56.7%)												
Nera 18mg		20	36.3	4.2	20 (54.1%)												
Week 88																	
Placebo		9	38.0	5.2	9 (30.0%)												
Nera 18mg		11	40.0	6.4	11 (29.7%)												
Week 100																	
Placebo		3	24.8	7.7	3 (10.0%)												
Nera 18mg		3	50.1	5.8	3 (8.1%)												
Week 112																	
Placebo		2	21.2	6.6	2 (6.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Rest of the World																	
Baseline																	
Placebo	16	16	32.9	4.2	14 (100.0%)												
Nera 18mg	25	25	31.2	3.8	24 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 3 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms total score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 12																	
Placebo		14	32.9	5.1	14 (100.0%)	3.1	3.1	-2.9	9.2								
Nera 18mg		23	33.9	3.4	23 (95.8%)	2.3	2.4	-2.4	7.0	-0.8	3.9	-8.5	6.8	0.8263			
Week 26																	
Placebo		14	34.9	5.4	14 (100.0%)	5.2	3.7	-2.0	12.4								
Nera 18mg		24	34.4	4.2	24 (100.0%)	3.7	2.8	-1.9	9.2	-1.5	4.6	-10.6	7.6	0.7409			
Week 36																	
Placebo		14	31.5	5.0	14 (100.0%)	2.0	3.8	-5.6	9.6								
Nera 18mg		23	31.6	4.0	23 (95.8%)	1.2	3.0	-4.6	7.1	-0.8	4.9	-10.3	8.8	0.8747			
Week 44																	
Placebo		14	32.8	5.2	14 (100.0%)	3.3	3.9	-4.5	11.0								
Nera 18mg		22	33.1	4.3	22 (91.7%)	3.6	3.1	-2.5	9.7	0.4	5.0	-9.5	10.2	0.9427			
Week 52																	
Placebo		14	41.1	6.1	14 (100.0%)	11.5	4.3	3.1	19.9								
Nera 18mg		20	31.9	4.4	20 (83.3%)	3.4	3.4	-3.3	10.1	-8.0	5.5	-18.8	2.7	0.1420			
Week 64																	
Placebo		11	28.9	4.3	11 (78.6%)	5.2	4.3	-3.3	13.8								
Nera 18mg		17	30.9	5.3	17 (70.8%)	4.5	3.4	-2.3	11.2	-0.8	5.5	-11.7	10.1	0.8866			
Week 76																	
Placebo		8	31.3	6.2	8 (57.1%)												
Nera 18mg		11	22.6	5.5	11 (45.8%)												
Week 88																	
Placebo		1	30.9	NC	1 (7.1%)												
Nera 18mg		3	40.6	6.4	3 (12.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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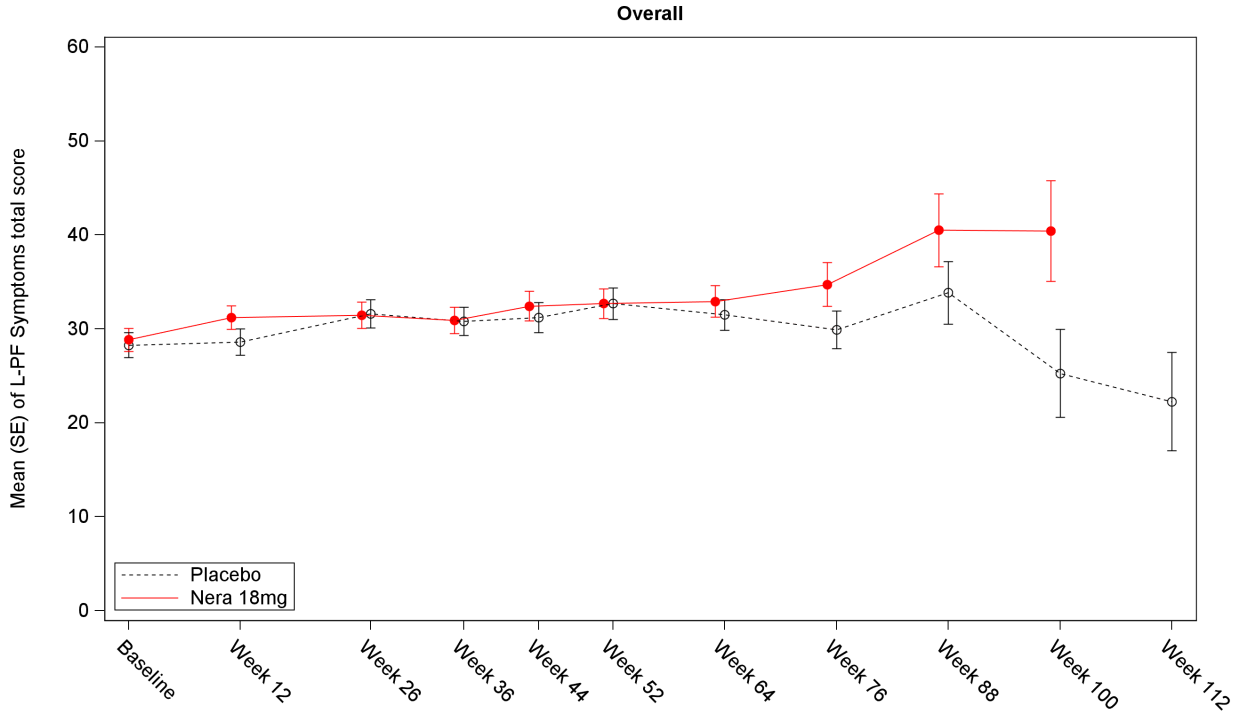

Number of patients

Placebo	169	161	156	151	146	148	128	88	38	11	4
Nera 18mg	169	163	153	146	139	138	122	79	31	9	0

Study: 1305-0023. Number of patients refers to the number of patients with observed data at visit.

Figure I.1.1.1.2.1: 3 Mean (SE) of L-PF Symptoms total score over the whole trial - 18mg - FAS (NIN background)

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Boehringer Ingelheim
BI Trial No.: x1305p3.hta

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Overall																	
Baseline																	
Placebo	169	169	31.9	1.8	164 (100.0%)												
Nera 18mg	170	169	34.0	2.0	164 (100.0%)												
Week 12																	
Placebo		162	32.4	1.9	162 (98.8%)	0.6	1.5	-2.3	3.6								
Nera 18mg		163	35.9	2.1	162 (98.8%)	2.2	1.5	-0.8	5.1	1.5	2.1	-2.6	5.7	0.4727			
Week 26																	
Placebo		156	36.0	2.1	156 (95.1%)	4.1	1.7	0.8	7.4								
Nera 18mg		153	36.2	2.1	152 (92.7%)	3.0	1.7	-0.4	6.3	-1.1	2.4	-5.8	3.6	0.6447			
Week 36																	
Placebo		151	34.0	2.0	151 (92.1%)	2.6	1.7	-0.8	6.0								
Nera 18mg		146	33.0	2.1	146 (89.0%)	-0.1	1.8	-3.5	3.4	-2.7	2.5	-7.5	2.2	0.2752			
Week 44																	
Placebo		146	34.8	2.2	146 (89.0%)	3.3	1.7	-0.1	6.7								
Nera 18mg		139	35.3	2.2	138 (84.1%)	2.8	1.8	-0.6	6.3	-0.5	2.5	-5.3	4.4	0.8546			
Week 52																	
Placebo		148	36.2	2.3	148 (90.2%)	4.9	1.9	1.2	8.6								
Nera 18mg		138	35.7	2.3	138 (84.1%)	3.6	1.9	-0.1	7.4	-1.3	2.7	-6.6	4.0	0.6352			
Week 64																	
Placebo		128	34.9	2.4	128 (78.0%)	5.4	1.9	1.6	9.2								
Nera 18mg		122	36.3	2.6	122 (74.4%)	5.0	2.0	1.1	8.9	-0.4	2.8	-5.8	5.0	0.8858			
Week 76																	
Placebo		88	31.3	2.7	88 (53.7%)												
Nera 18mg		79	38.2	3.3	79 (48.2%)												
Week 88																	
Placebo		38	40.2	4.3	38 (23.2%)												
Nera 18mg		31	45.8	5.3	31 (18.9%)												
Week 100																	
Placebo		11	24.2	5.5	11 (6.7%)												
Nera 18mg		9	51.4	7.4	9 (5.5%)												
Week 112																	
Placebo		4	24.0	3.9	4 (2.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Age																	
Test for homogeneity (H0)^																	
Week 12														0.4678			
Week 26														0.9287			
Week 36														0.3160			
Week 44														0.8975			
Week 52														0.2883			
Week 64														0.6391			
<65 years																	
Baseline																	
Placebo	65	65	32.4	2.7	64 (100.0%)												
Nera 18mg	64	64	35.0	3.3	62 (100.0%)												
Week 12																	
Placebo		64	33.7	3.0	64 (100.0%)	1.3	2.4	-3.3	6.0								
Nera 18mg		61	38.7	3.3	61 (98.4%)	4.8	2.4	0.0	9.6	3.5	3.4	-3.2	10.2	0.3046			
Week 26																	
Placebo		62	36.7	3.5	62 (96.9%)	4.5	2.7	-0.7	9.8								
Nera 18mg		58	37.1	3.6	58 (93.5%)	3.7	2.8	-1.7	9.2	-0.8	3.9	-8.4	6.8	0.8316			
Week 36																	
Placebo		62	38.2	3.5	62 (96.9%)	6.2	2.7	0.8	11.5								
Nera 18mg		56	33.6	3.7	56 (90.3%)	0.5	2.8	-5.1	6.1	-5.6	3.9	-13.4	2.1	0.1506			
Week 44																	
Placebo		61	35.5	3.3	61 (95.3%)	3.7	2.7	-1.6	9.1								
Nera 18mg		51	35.3	3.8	51 (82.3%)	3.7	2.9	-2.0	9.4	-0.0	4.0	-7.9	7.8	0.9915			
Week 52																	
Placebo		62	36.5	3.3	62 (96.9%)	4.4	2.9	-1.4	10.2								
Nera 18mg		52	39.2	4.2	52 (83.9%)	6.7	3.1	0.5	12.8	2.3	4.3	-6.1	10.7	0.5926			
Week 64																	
Placebo		57	38.2	3.7	57 (89.1%)	8.5	3.0	2.6	14.4								
Nera 18mg		45	37.3	4.6	45 (72.6%)	6.8	3.2	0.5	13.2	-1.7	4.4	-10.4	6.9	0.6979			
Week 76																	
Placebo		37	33.4	3.9	37 (57.8%)												
Nera 18mg		34	39.0	5.2	34 (54.8%)												
Week 88																	
Placebo		15	45.8	6.6	15 (23.4%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		7	54.2	9.3	7 (11.3%)												
Week 100																	
Placebo		4	25.0	8.8	4 (6.3%)												
Nera 18mg		1	33.3	NC	1 (1.6%)												
Week 112																	
Placebo		2	20.8	8.3	2 (3.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	104	104	31.6	2.4	100 (100.0%)												
Nera 18mg	106	105	33.5	2.5	102 (100.0%)												
Week 12																	
Placebo		98	31.5	2.6	98 (98.0%)	0.2	1.9	-3.6	4.0								
Nera 18mg		102	34.2	2.6	101 (99.0%)	0.5	1.9	-3.2	4.3	0.3	2.7	-5.0	5.6	0.8987			
Week 26																	
Placebo		94	35.5	2.6	94 (94.0%)	3.8	2.2	-0.5	8.1								
Nera 18mg		95	35.7	2.6	94 (92.2%)	2.5	2.2	-1.8	6.8	-1.3	3.1	-7.3	4.8	0.6820			
Week 36																	
Placebo		89	31.0	2.4	89 (89.0%)	0.1	2.2	-4.3	4.6								
Nera 18mg		90	32.6	2.6	90 (88.2%)	-0.4	2.2	-4.8	3.9	-0.6	3.2	-6.8	5.6	0.8516			
Week 44																	
Placebo		85	34.3	3.0	85 (85.0%)	3.0	2.3	-1.4	7.5								
Nera 18mg		88	35.4	2.8	87 (85.3%)	2.3	2.3	-2.1	6.8	-0.7	3.2	-7.0	5.6	0.8268			
Week 52																	
Placebo		86	36.0	3.1	86 (86.0%)	5.3	2.4	0.5	10.1								
Nera 18mg		86	33.6	2.8	86 (84.3%)	1.8	2.4	-3.0	6.6	-3.6	3.5	-10.4	3.2	0.3037			
Week 64																	
Placebo		71	32.2	3.2	71 (71.0%)	2.9	2.6	-2.1	8.0								
Nera 18mg		77	35.7	3.1	77 (75.5%)	3.9	2.5	-1.0	8.8	1.0	3.6	-6.1	8.0	0.7901			
Week 76																	
Placebo		51	29.8	3.7	51 (51.0%)												
Nera 18mg		45	37.6	4.3	45 (44.1%)												
Week 88																	
Placebo		23	36.6	5.7	23 (23.0%)												
Nera 18mg		24	43.4	6.3	24 (23.5%)												
Week 100																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		7	23.8	7.5	7 (7.0%)												
Nera 18mg		8	53.6	8.0	8 (7.8%)												
Week 112																	
Placebo		2	27.1	2.1	2 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Sex																	
Test for homogeneity (H0)^																	
Week 12														0.8985			
Week 26														0.1828			
Week 36														0.0367			
Week 44														0.0177			
Week 52														0.2973			
Week 64														0.1217			
Male																	
Baseline																	
Placebo	114	114	30.7	2.2	111 (100.0%)												
Nera 18mg	108	107	30.0	2.4	102 (100.0%)												
Week 12																	
Placebo		109	32.6	2.3	109 (98.2%)	2.0	1.8	-1.6	5.5								
Nera 18mg		102	34.2	2.5	101 (99.0%)	3.5	1.9	-0.3	7.2	1.5	2.6	-3.7	6.6	0.5677			
Week 26																	
Placebo		104	35.8	2.4	104 (93.7%)	4.8	2.1	0.8	8.8								
Nera 18mg		95	37.0	2.6	94 (92.2%)	6.3	2.2	2.1	10.6	1.5	3.0	-4.3	7.4	0.6058			
Week 36																	
Placebo		100	33.1	2.4	100 (90.1%)	2.6	2.1	-1.5	6.8								
Nera 18mg		88	35.0	2.7	88 (86.3%)	4.1	2.2	-0.3	8.5	1.5	3.1	-4.5	7.5	0.6318			
Week 44																	
Placebo		97	32.1	2.4	97 (87.4%)	1.7	2.1	-2.5	5.8								
Nera 18mg		82	35.1	2.7	81 (79.4%)	5.7	2.3	1.2	10.2	4.0	3.1	-2.1	10.1	0.1959			
Week 52																	
Placebo		97	36.1	2.7	97 (87.4%)	5.9	2.3	1.4	10.5								
Nera 18mg		82	36.5	3.0	82 (80.4%)	7.0	2.5	2.2	11.9	1.1	3.4	-5.5	7.7	0.7428			
Week 64																	

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		82	32.9	2.6	82 (73.9%)	5.6	2.4	0.9	10.3								
Nera 18mg		74	38.6	3.3	74 (72.5%)	8.7	2.5	3.7	13.6	3.1	3.5	-3.7	9.9	0.3723			
Week 76																	
Placebo		54	29.4	3.0	54 (48.6%)												
Nera 18mg		47	42.1	4.2	47 (46.1%)												
Week 88																	
Placebo		25	42.0	4.9	25 (22.5%)												
Nera 18mg		18	44.4	6.5	18 (17.6%)												
Week 100																	
Placebo		7	26.8	7.9	7 (6.3%)												
Nera 18mg		4	57.3	8.7	4 (3.9%)												
Week 112																	
Placebo		2	27.1	2.1	2 (1.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Female																	
Baseline																	
Placebo	55	55	34.4	3.2	53 (100.0%)												
Nera 18mg	62	62	41.1	3.3	62 (100.0%)												
Week 12																	
Placebo		53	31.8	3.6	53 (100.0%)	-2.1	2.6	-7.2	3.1								
Nera 18mg		61	38.7	3.6	61 (98.4%)	-0.0	2.5	-4.8	4.8	2.1	3.6	-5.0	9.1	0.5650			
Week 26																	
Placebo		52	36.3	4.1	52 (98.1%)	2.6	2.9	-3.1	8.4								
Nera 18mg		58	34.9	3.6	58 (93.5%)	-2.5	2.8	-8.0	2.9	-5.1	4.0	-13.1	2.8	0.2013			
Week 36																	
Placebo		51	35.7	3.8	51 (96.2%)	2.5	3.0	-3.3	8.3								
Nera 18mg		58	30.0	3.4	58 (93.5%)	-6.7	2.8	-12.3	-1.2	-9.2	4.1	-17.3	-1.2	0.0242	-0.43	-0.81	-0.05
Week 44																	
Placebo		49	40.1	4.5	49 (92.5%)	6.5	3.0	0.6	12.4								
Nera 18mg		57	35.7	3.7	57 (91.9%)	-1.8	2.8	-7.3	3.8	-8.3	4.1	-16.3	-0.2	0.0445	-0.39	-0.77	-0.01
Week 52																	
Placebo		51	36.4	4.3	51 (96.2%)	2.9	3.2	-3.4	9.3								
Nera 18mg		56	34.4	3.7	56 (90.3%)	-1.8	3.1	-7.9	4.2	-4.7	4.4	-13.5	4.0	0.2887			
Week 64																	
Placebo		46	38.3	4.9	46 (86.8%)	4.9	3.3	-1.6	11.4								
Nera 18mg		48	32.8	4.2	48 (77.4%)	-0.9	3.2	-7.1	5.3	-5.8	4.6	-14.8	3.2	0.2034			

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 76																	
Placebo		34	34.4	5.2	34 (64.2%)												
Nera 18mg		32	32.4	5.2	32 (51.6%)												
Week 88																	
Placebo		13	36.9	8.8	13 (24.5%)												
Nera 18mg		13	47.8	9.1	13 (21.0%)												
Week 100																	
Placebo		4	19.8	6.9	4 (7.5%)												
Nera 18mg		5	46.7	11.7	5 (8.1%)												
Week 112																	
Placebo		2	20.8	8.3	2 (3.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 12														0.1829			
Week 26														0.6639			
Week 36														0.8826			
Week 44														0.7008			
Week 52														0.4882			
Week 64														0.7963			
<=70%																	
Baseline																	
Placebo	95	95	35.8	2.4	91 (100.0%)												
Nera 18mg	97	97	35.9	2.6	96 (100.0%)												
Week 12																	
Placebo		89	35.1	2.7	89 (97.8%)	0.8	2.0	-3.2	4.7								
Nera 18mg		96	39.1	2.7	96 (100.0%)	4.6	1.9	0.8	8.4	3.8	2.8	-1.6	9.3	0.1681			
Week 26																	
Placebo		85	39.7	2.8	85 (93.4%)	5.2	2.3	0.7	9.7								
Nera 18mg		88	38.4	2.7	88 (91.7%)	4.9	2.2	0.5	9.3	-0.3	3.2	-6.6	6.0	0.9207			
Week 36																	
Placebo		83	38.2	2.8	83 (91.2%)	4.9	2.3	0.4	9.5								
Nera 18mg		85	35.4	2.9	85 (88.5%)	2.4	2.3	-2.1	6.9	-2.6	3.3	-9.0	3.8	0.4318			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 44																	
Placebo		80	37.8	2.9	80 (87.9%)	3.6	2.4	-1.1	8.2								
Nera 18mg		79	36.6	2.9	79 (82.3%)	3.9	2.3	-0.7	8.5	0.3	3.3	-6.2	6.8	0.9255			
Week 52																	
Placebo		80	41.4	3.1	80 (87.9%)	7.8	2.6	2.8	12.8								
Nera 18mg		79	37.1	3.0	79 (82.3%)	4.7	2.5	-0.3	9.7	-3.1	3.6	-10.1	3.9	0.3857			
Week 64																	
Placebo		70	37.9	3.4	70 (76.9%)	7.0	2.6	1.8	12.2								
Nera 18mg		70	38.7	3.3	70 (72.9%)	7.1	2.6	2.0	12.2	0.1	3.7	-7.2	7.3	0.9849			
Week 76																	
Placebo		45	32.9	4.0	45 (49.5%)												
Nera 18mg		44	42.4	4.4	44 (45.8%)												
Week 88																	
Placebo		20	39.4	6.1	20 (22.0%)												
Nera 18mg		19	49.1	6.1	19 (19.8%)												
Week 100																	
Placebo		5	32.5	5.0	5 (5.5%)												
Nera 18mg		5	46.7	3.6	5 (5.2%)												
Week 112																	
Placebo		3	23.6	5.6	3 (3.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	74	74	26.9	2.7	73 (100.0%)												
Nera 18mg	73	72	31.5	3.0	68 (100.0%)												
Week 12																	
Placebo		73	29.1	2.8	73 (100.0%)	0.5	2.2	-3.9	4.9								
Nera 18mg		67	31.2	3.1	66 (97.1%)	-1.4	2.3	-6.0	3.2	-1.8	3.2	-8.2	4.5	0.5694			
Week 26																	
Placebo		71	31.6	3.0	71 (97.3%)	2.7	2.5	-2.3	7.7								
Nera 18mg		65	33.3	3.2	64 (94.1%)	0.3	2.6	-4.9	5.5	-2.4	3.6	-9.6	4.8	0.5060			
Week 36																	
Placebo		68	28.9	2.8	68 (93.2%)	-0.2	2.6	-5.3	4.8								
Nera 18mg		61	29.6	3.1	61 (89.7%)	-3.5	2.7	-8.9	1.8	-3.3	3.7	-10.7	4.1	0.3781			
Week 44																	
Placebo		66	31.2	3.3	66 (90.4%)	3.0	2.6	-2.2	8.1								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		60	33.7	3.5	59 (86.8%)	1.3	2.7	-4.1	6.7	-1.6	3.8	-9.0	5.8	0.6675			
Week 52																	
Placebo		68	30.1	3.2	68 (93.2%)	1.4	2.8	-4.1	6.9								
Nera 18mg		59	33.8	3.6	59 (86.8%)	2.1	3.0	-3.7	7.9	0.6	4.1	-7.3	8.6	0.8741			
Week 64																	
Placebo		58	31.2	3.4	58 (79.5%)	3.4	2.9	-2.3	9.1								
Nera 18mg		52	33.1	4.0	52 (76.5%)	2.0	3.0	-4.0	8.0	-1.4	4.2	-9.6	6.9	0.7435			
Week 76																	
Placebo		43	29.7	3.7	43 (58.9%)												
Nera 18mg		35	32.9	4.9	35 (51.5%)												
Week 88																	
Placebo		18	41.2	6.4	18 (24.7%)												
Nera 18mg		12	40.6	9.7	12 (17.6%)												
Week 100																	
Placebo		6	17.4	8.6	6 (8.2%)												
Nera 18mg		4	57.3	16.9	4 (5.9%)												
Week 112																	
Placebo		1	25.0	NC	1 (1.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline HRCT pattern																	
Test for homogeneity (H0)^																	
Week 12														0.8148			
Week 26														0.4659			
Week 36														0.9987			
Week 44														0.9753			
Week 52														0.9432			
Week 64														0.7709			
UIP-like																	
Baseline																	
Placebo	116	116	30.0	2.2	113 (100.0%)												
Nera 18mg	121	120	34.0	2.4	117 (100.0%)												
Week 12																	
Placebo		111	31.2	2.4	111 (98.2%)	1.0	1.8	-2.5	4.6								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg		117	36.1	2.4	116 (99.1%)	2.2	1.8	-1.2	5.7	1.2	2.5	-3.8	6.2	0.6376			
Week 26																	
Placebo		107	35.3	2.5	107 (94.7%)	4.7	2.0	0.7	8.7								
Nera 18mg		110	36.1	2.4	109 (93.2%)	2.5	2.0	-1.5	6.4	-2.3	2.9	-7.9	3.4	0.4327			
Week 36																	
Placebo		103	33.5	2.3	103 (91.2%)	3.4	2.1	-0.7	7.6								
Nera 18mg		104	34.4	2.5	104 (88.9%)	0.7	2.1	-3.3	4.8	-2.7	3.0	-8.5	3.1	0.3653			
Week 44																	
Placebo		99	33.9	2.7	99 (87.6%)	4.3	2.1	0.1	8.5								
Nera 18mg		99	37.0	2.7	98 (83.8%)	3.9	2.1	-0.2	8.0	-0.4	3.0	-6.3	5.5	0.8953			
Week 52																	
Placebo		100	35.4	2.6	100 (88.5%)	5.6	2.3	1.1	10.1								
Nera 18mg		100	36.7	2.8	100 (85.5%)	4.4	2.3	-0.0	8.9	-1.1	3.2	-7.5	5.2	0.7222			
Week 64																	
Placebo		90	35.8	2.8	90 (79.6%)	6.8	2.3	2.2	11.4								
Nera 18mg		87	37.5	3.1	87 (74.4%)	5.9	2.3	1.3	10.5	-0.9	3.3	-7.4	5.6	0.7834			
Week 76																	
Placebo		60	31.1	3.0	60 (53.1%)												
Nera 18mg		58	38.8	3.9	58 (49.6%)												
Week 88																	
Placebo		26	41.8	5.2	26 (23.0%)												
Nera 18mg		23	51.3	5.9	23 (19.7%)												
Week 100																	
Placebo		9	25.5	6.7	9 (8.0%)												
Nera 18mg		8	51.6	8.4	8 (6.8%)												
Week 112																	
Placebo		3	27.8	1.4	3 (2.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other fibrotic patterns																	
Baseline																	
Placebo	53	53	36.0	3.3	51 (100.0%)												
Nera 18mg	49	49	34.2	3.3	47 (100.0%)												
Week 12																	
Placebo		51	35.0	3.3	51 (100.0%)	-0.3	2.7	-5.5	5.0								
Nera 18mg		46	35.3	3.9	46 (97.9%)	2.0	2.8	-3.5	7.5	2.3	3.9	-5.3	9.9	0.5561			
Week 26																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		49	37.5	3.9	49 (96.1%)	2.7	3.0	-3.2	8.6								
Nera 18mg		43	36.5	4.1	43 (91.5%)	4.3	3.2	-2.0	10.6	1.6	4.4	-7.1	10.3	0.7190			
Week 36																	
Placebo		48	35.1	4.0	48 (94.1%)	0.7	3.1	-5.4	6.8								
Nera 18mg		42	29.7	3.9	42 (89.4%)	-2.0	3.3	-8.4	4.5	-2.7	4.5	-11.5	6.2	0.5525			
Week 44																	
Placebo		47	36.6	3.8	47 (92.2%)	1.0	3.1	-5.0	7.1								
Nera 18mg		40	31.4	3.8	40 (85.1%)	0.5	3.3	-6.0	7.0	-0.6	4.5	-9.5	8.3	0.9013			
Week 52																	
Placebo		48	38.0	4.5	48 (94.1%)	3.4	3.3	-3.2	9.9								
Nera 18mg		38	33.1	4.3	38 (80.9%)	1.8	3.6	-5.4	8.9	-1.6	4.9	-11.3	8.1	0.7507			
Week 64																	
Placebo		38	32.7	4.6	38 (74.5%)	1.9	3.5	-5.0	8.8								
Nera 18mg		35	33.5	4.6	35 (74.5%)	2.7	3.7	-4.5	10.0	0.9	5.1	-9.2	10.9	0.8656			
Week 76																	
Placebo		28	31.8	5.6	28 (54.9%)												
Nera 18mg		21	36.5	5.9	21 (44.7%)												
Week 88																	
Placebo		12	36.8	8.0	12 (23.5%)												
Nera 18mg		8	30.2	10.0	8 (17.0%)												
Week 100																	
Placebo		2	18.8	2.1	2 (3.9%)												
Nera 18mg		1	50.0	NC	1 (2.1%)												
Week 112																	
Placebo		1	12.5	NC	1 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Underlying ILD diagnosis																	
Test for homogeneity (H0)^																	
Week 12														0.8854			
Week 26														0.2206			
Week 36														0.2666			
Week 44														0.8204			
Week 52														0.6748			
Week 64														0.1933			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
iNSIP																	
Baseline																	
Placebo	32	32	32.2	4.1	31 (100.0%)												
Nera 18mg	27	27	34.0	5.3	25 (100.0%)												
Week 12																	
Placebo		29	30.3	4.7	29 (93.5%)	-1.3	3.5	-8.2	5.6								
Nera 18mg		24	34.2	6.4	24 (96.0%)	1.3	3.9	-6.3	9.0	2.7	5.2	-7.6	12.9	0.6128			
Week 26																	
Placebo		29	34.2	5.1	29 (93.5%)	1.0	3.9	-6.6	8.6								
Nera 18mg		23	38.8	6.3	23 (92.0%)	7.6	4.3	-0.9	16.1	6.6	5.8	-4.9	18.0	0.2592			
Week 36																	
Placebo		28	36.2	5.0	28 (90.3%)	4.2	3.9	-3.5	11.9								
Nera 18mg		21	28.6	5.9	21 (84.0%)	-3.2	4.5	-12.0	5.6	-7.4	5.9	-19.1	4.3	0.2133			
Week 44																	
Placebo		28	36.5	5.5	28 (90.3%)	4.8	4.0	-3.1	12.6								
Nera 18mg		19	35.3	7.1	19 (76.0%)	6.5	4.7	-2.7	15.8	1.8	6.2	-10.4	14.0	0.7734			
Week 52																	
Placebo		27	34.7	4.9	27 (87.1%)	3.4	4.3	-5.2	11.9								
Nera 18mg		17	31.4	7.1	17 (68.0%)	5.4	5.2	-4.8	15.7	2.1	6.8	-11.3	15.4	0.7610			
Week 64																	
Placebo		23	32.4	5.3	23 (74.2%)	0.1	4.5	-8.7	8.9								
Nera 18mg		17	34.8	6.4	17 (68.0%)	9.2	5.2	-1.0	19.3	9.1	6.8	-4.4	22.5	0.1853			
Week 76																	
Placebo		16	39.6	7.8	16 (51.6%)												
Nera 18mg		10	43.3	11.1	10 (40.0%)												
Week 88																	
Placebo		9	41.7	9.7	9 (29.0%)												
Nera 18mg		3	44.4	22.7	3 (12.0%)												
Week 100																	
Placebo		2	12.5	12.5	2 (6.5%)												
Nera 18mg		1	50.0	NC	1 (4.0%)												
Week 112																	
Placebo		2	27.1	2.1	2 (6.5%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Unclassifiable IIP																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Baseline																	
Placebo	46	46	32.9	3.6	44 (100.0%)												
Nera 18mg	32	32	31.5	4.0	32 (100.0%)												
Week 12																	
Placebo		44	36.4	3.9	44 (100.0%)	4.0	2.9	-1.7	9.6								
Nera 18mg		32	35.0	4.0	32 (100.0%)	3.1	3.4	-3.5	9.8	-0.8	4.4	-9.6	7.9	0.8495			
Week 26																	
Placebo		40	37.0	4.0	40 (90.9%)	4.5	3.3	-1.9	11.0								
Nera 18mg		28	32.0	3.5	28 (87.5%)	-0.7	3.9	-8.4	7.0	-5.2	5.1	-15.3	4.9	0.3093			
Week 36																	
Placebo		38	34.8	4.1	38 (86.4%)	3.2	3.3	-3.4	9.7								
Nera 18mg		27	43.7	4.3	27 (84.4%)	10.6	3.9	2.8	18.3	7.4	5.2	-2.8	17.6	0.1523			
Week 44																	
Placebo		37	37.5	4.2	37 (84.1%)	5.6	3.4	-1.1	12.4								
Nera 18mg		27	36.7	4.4	27 (84.4%)	3.5	4.0	-4.4	11.5	-2.1	5.3	-12.5	8.4	0.6935			
Week 52																	
Placebo		38	38.3	4.9	38 (86.4%)	6.6	3.7	-0.6	13.8								
Nera 18mg		28	32.6	4.1	28 (87.5%)	-0.2	4.3	-8.7	8.2	-6.8	5.7	-18.0	4.3	0.2286			
Week 64																	
Placebo		32	36.6	4.6	32 (72.7%)	7.6	3.8	0.1	15.0								
Nera 18mg		23	42.4	5.7	23 (71.9%)	9.5	4.5	0.7	18.2	1.9	5.8	-9.6	13.4	0.7439			
Week 76																	
Placebo		25	28.8	4.5	25 (56.8%)												
Nera 18mg		16	35.9	6.2	16 (50.0%)												
Week 88																	
Placebo		10	45.8	7.6	10 (22.7%)												
Nera 18mg		10	46.2	11.3	10 (31.3%)												
Week 100																	
Placebo		2	33.3	8.3	2 (4.5%)												
Nera 18mg		3	48.6	20.5	3 (9.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
HP																	
Baseline																	
Placebo	38	38	26.4	3.9	38 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg	43	43	39.2	4.2	41 (100.0%)												
Week 12																	
Placebo		38	29.5	3.4	38 (100.0%)	1.5	3.1	-4.7	7.6								
Nera 18mg		41	44.2	3.8	41 (100.0%)	5.9	3.0	-0.0	11.8	4.4	4.3	-4.1	13.0	0.3078			
Week 26																	
Placebo		38	38.9	4.1	38 (100.0%)	10.4	3.4	3.7	17.2								
Nera 18mg		38	41.3	4.5	38 (92.7%)	5.2	3.4	-1.5	11.9	-5.2	4.8	-14.7	4.3	0.2839			
Week 36																	
Placebo		38	32.3	3.9	38 (100.0%)	3.6	3.4	-3.2	10.3								
Nera 18mg		37	36.8	3.9	37 (90.2%)	1.8	3.4	-4.9	8.6	-1.7	4.8	-11.3	7.8	0.7202			
Week 44																	
Placebo		37	31.3	4.1	37 (97.4%)	3.3	3.5	-3.6	10.2								
Nera 18mg		35	41.2	4.5	35 (85.4%)	4.8	3.5	-2.2	11.8	1.5	5.0	-8.3	11.4	0.7619			
Week 52																	
Placebo		37	33.0	4.3	37 (97.4%)	4.9	3.8	-2.6	12.3								
Nera 18mg		34	43.3	4.7	34 (82.9%)	8.0	3.8	0.4	15.5	3.1	5.4	-7.5	13.7	0.5659			
Week 64																	
Placebo		33	36.5	5.1	33 (86.8%)	10.1	3.9	2.5	17.6								
Nera 18mg		30	43.9	5.2	30 (73.2%)	8.0	3.9	0.2	15.7	-2.1	5.5	-12.9	8.7	0.7031			
Week 76																	
Placebo		18	34.3	5.9	18 (47.4%)												
Nera 18mg		17	42.9	7.2	17 (41.5%)												
Week 88																	
Placebo		8	44.3	9.7	8 (21.1%)												
Nera 18mg		5	50.8	12.2	5 (12.2%)												
Week 100																	
Placebo		1	0.0	NC	1 (2.6%)												
Nera 18mg		1	83.3	NC	1 (2.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Autoimmune ILD																	
Baseline																	
Placebo	29	29	34.3	4.1	28 (100.0%)												
Nera 18mg	43	42	30.2	3.7	42 (100.0%)												
Week 12																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		28	31.1	5.0	28 (100.0%)	-2.9	3.6	-10.0	4.2								
Nera 18mg		43	29.0	3.6	42 (100.0%)	-2.2	2.9	-8.0	3.6	0.6	4.7	-8.5	9.8	0.8898			
Week 26																	
Placebo		27	33.2	5.6	27 (96.4%)	-0.3	4.0	-8.2	7.6								
Nera 18mg		41	27.6	3.6	40 (95.2%)	-4.1	3.3	-10.6	2.4	-3.7	5.2	-13.9	6.5	0.4730			
Week 36																	
Placebo		26	32.4	4.4	26 (92.9%)	-0.9	4.1	-8.9	7.1								
Nera 18mg		38	19.8	3.3	38 (90.5%)	-12.3	3.3	-18.8	-5.7	-11.4	5.3	-21.7	-1.0	0.0312	-0.54	-1.05	-0.04
Week 44																	
Placebo		23	31.9	5.6	23 (82.1%)	-2.8	4.3	-11.2	5.6								
Nera 18mg		37	26.4	4.1	36 (85.7%)	-4.4	3.5	-11.2	2.5	-1.6	5.5	-12.4	9.2	0.7734			
Week 52																	
Placebo		25	35.7	5.9	25 (89.3%)	1.3	4.5	-7.5	10.2								
Nera 18mg		37	25.9	4.1	37 (88.1%)	-4.9	3.7	-12.2	2.5	-6.2	5.8	-17.7	5.3	0.2881			
Week 64																	
Placebo		21	29.2	6.4	21 (75.0%)	-3.0	4.6	-12.1	6.2								
Nera 18mg		33	22.2	3.8	33 (78.6%)	-6.4	3.8	-13.9	1.0	-3.5	6.0	-15.3	8.3	0.5595			
Week 76																	
Placebo		16	34.6	6.8	16 (57.1%)												
Nera 18mg		19	26.8	5.8	19 (45.2%)												
Week 88																	
Placebo		6	18.8	7.0	6 (21.4%)												
Nera 18mg		5	50.8	9.3	5 (11.9%)												
Week 100																	
Placebo		4	28.1	11.1	4 (14.3%)												
Nera 18mg		2	43.8	10.4	2 (4.8%)												
Week 112																	
Placebo		2	20.8	8.3	2 (7.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other ILD																	
Baseline																	
Placebo	24	24	35.4	4.9	23 (100.0%)												
Nera 18mg	25	25	35.0	5.4	24 (100.0%)												
Week 12																	
Placebo		23	33.7	5.5	23 (100.0%)	-0.3	4.0	-8.2	7.5								
Nera 18mg		23	36.8	6.5	23 (95.8%)	2.7	4.0	-5.1	10.5	3.0	5.6	-8.0	14.1	0.5881			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 26																	
Placebo		22	34.8	5.4	22 (95.7%)	1.9	4.5	-6.8	10.7								
Nera 18mg		23	45.5	5.6	23 (95.8%)	10.8	4.3	2.3	19.4	8.9	6.2	-3.3	21.2	0.1534			
Week 36																	
Placebo		21	34.5	6.1	21 (91.3%)	2.2	4.5	-6.7	11.1								
Nera 18mg		23	40.2	6.5	23 (95.8%)	7.3	4.3	-1.2	15.9	5.2	6.3	-7.2	17.5	0.4105			
Week 44																	
Placebo		21	37.1	6.2	21 (91.3%)	4.5	4.6	-4.6	13.6								
Nera 18mg		21	39.7	5.5	21 (87.5%)	7.6	4.5	-1.3	16.5	3.1	6.5	-9.6	15.9	0.6315			
Week 52																	
Placebo		21	40.9	6.4	21 (91.3%)	8.5	5.0	-1.3	18.2								
Nera 18mg		22	47.7	6.6	22 (91.7%)	14.2	4.8	4.7	23.7	5.7	6.9	-7.9	19.4	0.4104			
Week 64																	
Placebo		19	38.4	6.4	19 (82.6%)	9.5	5.0	-0.4	19.4								
Nera 18mg		19	42.8	7.8	19 (79.2%)	10.4	4.9	0.6	20.1	0.8	7.1	-13.0	14.7	0.9044			
Week 76																	
Placebo		13	17.9	4.6	13 (56.5%)												
Nera 18mg		17	45.3	7.8	17 (70.8%)												
Week 88																	
Placebo		5	45.8	14.9	5 (21.7%)												
Nera 18mg		8	39.6	10.4	8 (33.3%)												
Week 100																	
Placebo		2	31.3	10.4	2 (8.7%)												
Nera 18mg		2	47.9	2.1	2 (8.3%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Region																	
Test for homogeneity (H0)^																	
Week 12														0.8441			
Week 26														0.9764			
Week 36														0.3769			
Week 44														0.3473			
Week 52														0.2075			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 64														0.9202			
Europe																	
Baseline																	
Placebo	78	78	33.2	2.9	77 (100.0%)												
Nera 18mg	67	66	34.5	3.4	64 (100.0%)												
Week 12																	
Placebo		76	34.7	3.1	76 (98.7%)	2.2	2.2	-2.1	6.5								
Nera 18mg		65	36.1	3.4	64 (100.0%)	2.7	2.4	-2.0	7.4	0.6	3.2	-5.8	6.9	0.8637			
Week 26																	
Placebo		73	38.9	3.2	73 (94.8%)	5.9	2.5	1.1	10.8								
Nera 18mg		59	37.6	3.5	58 (90.6%)	4.3	2.8	-1.1	9.7	-1.6	3.7	-8.8	5.7	0.6678			
Week 36																	
Placebo		69	34.5	3.3	69 (89.6%)	2.6	2.6	-2.5	7.6								
Nera 18mg		55	36.5	3.6	55 (85.9%)	3.0	2.9	-2.7	8.6	0.4	3.8	-7.1	7.9	0.9182			
Week 44																	
Placebo		68	33.6	3.2	68 (88.3%)	1.9	2.6	-3.2	6.9								
Nera 18mg		53	36.6	3.7	52 (81.3%)	4.4	2.9	-1.3	10.1	2.5	3.9	-5.1	10.1	0.5209			
Week 52																	
Placebo		69	36.5	3.4	69 (89.6%)	4.6	2.7	-0.8	10.0								
Nera 18mg		53	39.6	3.8	53 (82.8%)	6.2	3.1	0.1	12.3	1.6	4.1	-6.5	9.7	0.6972			
Week 64																	
Placebo		63	37.0	3.6	63 (81.8%)	7.0	2.8	1.5	12.5								
Nera 18mg		52	40.9	4.0	52 (81.3%)	7.3	3.1	1.2	13.5	0.3	4.2	-7.9	8.6	0.9371			
Week 76																	
Placebo		38	27.9	4.0	38 (49.4%)												
Nera 18mg		29	46.1	5.7	29 (45.3%)												
Week 88																	
Placebo		15	40.0	7.9	15 (19.5%)												
Nera 18mg		8	52.6	8.9	8 (12.5%)												
Week 100																	
Placebo		3	12.5	6.4	3 (3.9%)												
Nera 18mg		2	60.4	14.6	2 (3.1%)												
Week 112																	
Placebo		1	12.5	NC	1 (1.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Asia																	
Baseline																	
Placebo	45	45	28.3	2.9	43 (100.0%)												
Nera 18mg	41	41	37.7	4.4	39 (100.0%)												
Week 12																	
Placebo		43	26.9	3.7	43 (100.0%)	-2.3	2.9	-8.0	3.4								
Nera 18mg		39	34.9	4.3	39 (100.0%)	-1.7	3.1	-7.8	4.3	0.6	4.2	-7.8	8.9	0.8918			
Week 26																	
Placebo		42	31.6	4.0	42 (97.7%)	2.3	3.3	-4.1	8.7								
Nera 18mg		36	32.9	4.2	36 (92.3%)	-3.3	3.5	-10.2	3.6	-5.6	4.8	-15.0	3.8	0.2445			
Week 36																	
Placebo		41	33.9	4.0	41 (95.3%)	4.3	3.3	-2.2	10.9								
Nera 18mg		34	30.8	4.5	34 (87.2%)	-5.1	3.6	-12.3	2.1	-9.5	5.0	-19.2	0.3	0.0573			
Week 44																	
Placebo		37	34.9	4.6	37 (86.0%)	4.6	3.4	-2.1	11.4								
Nera 18mg		31	37.9	5.1	31 (79.5%)	0.9	3.7	-6.5	8.2	-3.8	5.1	-13.7	6.2	0.4583			
Week 52																	
Placebo		39	33.3	4.4	39 (90.7%)	3.7	3.6	-3.4	10.9								
Nera 18mg		32	32.8	5.0	32 (82.1%)	-0.9	4.0	-8.7	6.9	-4.7	5.4	-15.2	5.9	0.3855			
Week 64																	
Placebo		33	30.4	4.9	33 (76.7%)	3.6	3.8	-3.8	11.1								
Nera 18mg		26	30.3	5.5	26 (66.7%)	-2.4	4.2	-10.6	5.8	-6.1	5.6	-17.2	5.0	0.2830			
Week 76																	
Placebo		25	29.8	4.6	25 (58.1%)												
Nera 18mg		19	32.5	6.9	19 (48.7%)												
Week 88																	
Placebo		13	36.5	7.8	13 (30.2%)												
Nera 18mg		9	51.4	12.1	9 (23.1%)												
Week 100																	
Placebo		5	25.0	9.4	5 (11.6%)												
Nera 18mg		4	39.6	12.1	4 (10.3%)												
Week 112																	
Placebo		1	29.2	NC	1 (2.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	
Baseline																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo	30	30	31.5	4.2	30 (100.0%)												
Nera 18mg	37	37	29.2	3.2	37 (100.0%)												
Week 12																	
Placebo		29	30.2	3.6	29 (96.7%)	-1.9	3.5	-8.8	5.1								
Nera 18mg		36	33.7	3.6	36 (97.3%)	3.6	3.2	-2.6	9.8	5.5	4.7	-3.8	14.8	0.2493			
Week 26																	
Placebo		27	30.4	3.5	27 (90.0%)	-1.2	4.1	-9.2	6.8								
Nera 18mg		34	36.2	3.4	34 (91.9%)	7.0	3.6	-0.1	14.1	8.2	5.4	-2.5	18.8	0.1315			
Week 36																	
Placebo		27	31.0	4.1	27 (90.0%)	-0.1	4.1	-8.3	8.0								
Nera 18mg		34	30.3	3.5	34 (91.9%)	1.0	3.7	-6.3	8.2	1.1	5.5	-9.8	12.0	0.8409			
Week 44																	
Placebo		27	35.8	4.7	27 (90.0%)	4.7	4.1	-3.5	12.8								
Nera 18mg		33	31.7	4.0	33 (89.2%)	3.4	3.7	-3.9	10.7	-1.3	5.5	-12.2	9.6	0.8188			
Week 52																	
Placebo		26	32.5	4.9	26 (86.7%)	1.8	4.5	-7.0	10.6								
Nera 18mg		33	36.1	4.4	33 (89.2%)	7.6	4.0	-0.2	15.5	5.8	6.0	-5.9	17.5	0.3308			
Week 64																	
Placebo		21	35.3	5.8	21 (70.0%)	4.6	4.7	-4.7	13.9								
Nera 18mg		27	36.1	4.9	27 (73.0%)	10.1	4.2	1.8	18.3	5.5	6.3	-6.9	17.8	0.3861			
Week 76																	
Placebo		17	39.0	7.6	17 (56.7%)												
Nera 18mg		20	42.7	5.6	20 (54.1%)												
Week 88																	
Placebo		9	44.4	6.8	9 (30.0%)												
Nera 18mg		11	43.9	7.6	11 (29.7%)												
Week 100																	
Placebo		3	34.7	9.7	3 (10.0%)												
Nera 18mg		3	61.1	11.1	3 (8.1%)												
Week 112																	
Placebo		2	27.1	2.1	2 (6.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Rest of the World																	
Baseline																	
Placebo	16	16	36.5	5.8	14 (100.0%)												
Nera 18mg	25	25	34.2	4.8	24 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 4 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Cough domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 12																	
Placebo		14	41.1	6.8	14 (100.0%)	6.7	5.1	-3.3	16.7								
Nera 18mg		23	40.2	6.0	23 (95.8%)	4.9	3.9	-2.9	12.6	-1.8	6.4	-14.4	10.9	0.7832			
Week 26																	
Placebo		14	44.6	7.8	14 (100.0%)	10.5	5.6	-0.7	21.6								
Nera 18mg		24	37.8	6.5	24 (100.0%)	3.6	4.3	-4.9	12.1	-6.9	7.1	-20.9	7.1	0.3324			
Week 36																	
Placebo		14	36.9	5.2	14 (100.0%)	3.0	5.8	-8.3	14.4								
Nera 18mg		23	32.1	6.3	23 (95.8%)	-1.2	4.5	-10.0	7.7	-4.2	7.3	-18.6	10.2	0.5671			
Week 44																	
Placebo		14	38.1	7.5	14 (100.0%)	4.0	5.8	-7.3	15.3								
Nera 18mg		22	34.3	6.0	22 (91.7%)	1.8	4.5	-7.1	10.7	-2.2	7.3	-16.6	12.2	0.7623			
Week 52																	
Placebo		14	49.7	8.0	14 (100.0%)	15.6	6.2	3.5	27.8								
Nera 18mg		20	29.2	6.4	20 (83.3%)	-1.8	4.9	-11.6	7.9	-17.4	7.9	-33.0	-1.9	0.0282	-0.76	-1.45	-0.07
Week 64																	
Placebo		11	34.8	6.0	11 (78.6%)	2.9	6.6	-10.0	15.8								
Nera 18mg		17	31.6	7.8	17 (70.8%)	2.7	5.2	-7.5	12.9	-0.1	8.4	-16.6	16.3	0.9879			
Week 76																	
Placebo		8	36.5	7.2	8 (57.1%)												
Nera 18mg		11	18.9	6.6	11 (45.8%)												
Week 88																	
Placebo		1	54.2	NC	1 (7.1%)												
Nera 18mg		3	18.1	16.0	3 (12.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Cough domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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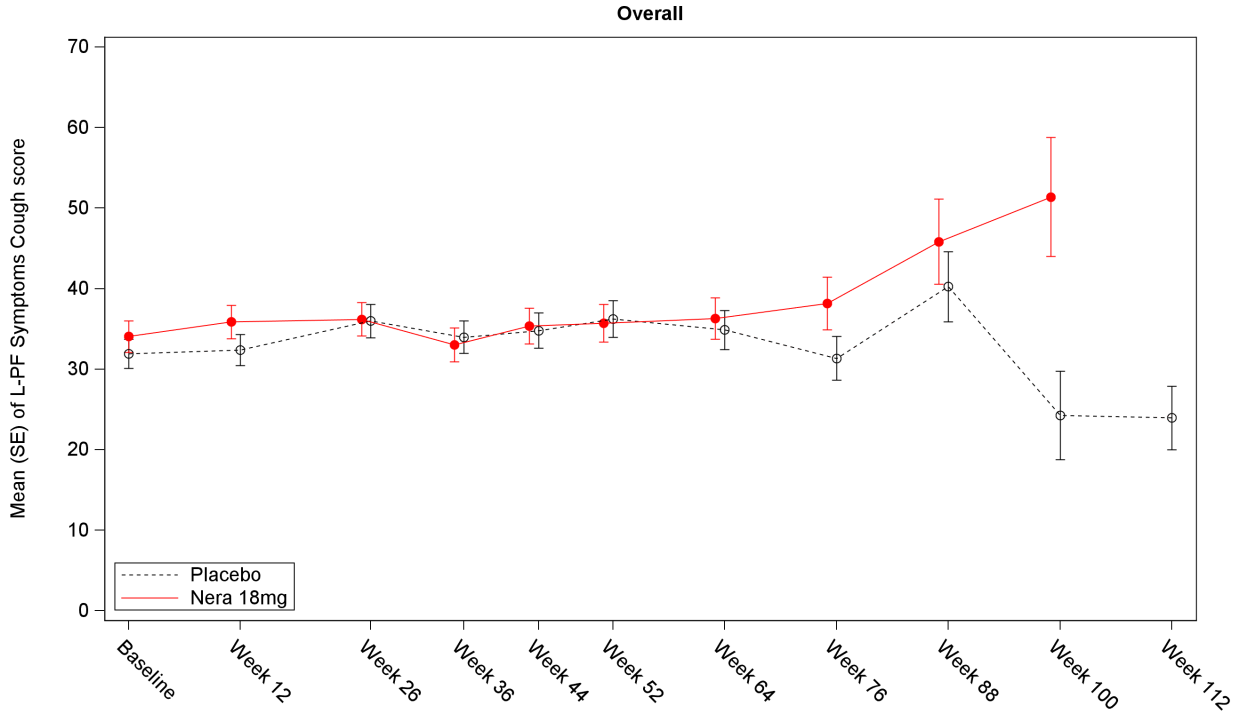

Number of patients

Placebo	169	162	156	151	146	148	128	88	38	11	4
Nera 18mg	169	163	153	146	139	138	122	79	31	9	0

Study: 1305-0023. Number of patients refers to the number of patients with observed data at visit.

Figure I.1.1.1.2.1: 4 Mean (SE) of L-PF Symptoms Cough domain score over the whole trial - 18mg - FAS (NIN background)

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Boehringer Ingelheim
BI Trial No.: x1305p3.hta

Figure I.1.1.1.2.1: 4

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Overall																	
Baseline																	
Placebo	169	169	20.1	1.4	164 (100.0%)												
Nera 18mg	170	169	18.4	1.2	164 (100.0%)												
Week 12																	
Placebo		162	19.5	1.4	162 (98.8%)	0.0	0.9	-1.7	1.7								
Nera 18mg		163	19.8	1.2	162 (98.8%)	1.4	0.9	-0.3	3.1	1.4	1.2	-1.1	3.8	0.2679			
Week 26																	
Placebo		156	22.1	1.6	156 (95.1%)	3.3	1.1	1.1	5.5								
Nera 18mg		153	20.5	1.3	152 (92.7%)	2.0	1.1	-0.2	4.2	-1.3	1.6	-4.4	1.9	0.4271			
Week 36																	
Placebo		151	22.0	1.6	151 (92.1%)	4.1	1.2	1.8	6.4								
Nera 18mg		146	21.1	1.3	146 (89.0%)	3.0	1.2	0.7	5.3	-1.1	1.7	-4.4	2.1	0.4930			
Week 44																	
Placebo		147	22.3	1.7	147 (89.6%)	4.6	1.3	2.1	7.1								
Nera 18mg		140	23.1	1.5	139 (84.8%)	5.1	1.3	2.6	7.7	0.5	1.8	-3.1	4.1	0.7812			
Week 52																	
Placebo		148	24.3	1.7	148 (90.2%)	6.6	1.3	3.9	9.2								
Nera 18mg		138	22.5	1.6	138 (84.1%)	5.0	1.4	2.3	7.7	-1.6	1.9	-5.4	2.2	0.4073			
Week 64																	
Placebo		128	22.1	1.7	128 (78.0%)	7.4	1.4	4.7	10.1								
Nera 18mg		122	22.8	1.6	122 (74.4%)	7.0	1.4	4.3	9.8	-0.3	2.0	-4.2	3.5	0.8613			
Week 76																	
Placebo		88	22.2	2.1	88 (53.7%)												
Nera 18mg		80	24.3	2.3	80 (48.8%)												
Week 88																	
Placebo		38	24.7	3.5	38 (23.2%)												
Nera 18mg		31	30.8	4.5	31 (18.9%)												
Week 100																	
Placebo		11	18.8	5.1	11 (6.7%)												
Nera 18mg		9	23.7	4.9	9 (5.5%)												
Week 112																	
Placebo		4	14.4	8.3	4 (2.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Dyspnea domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Age																	
Test for homogeneity (H0)^																	
Week 12														0.2834			
Week 26														0.6665			
Week 36														0.9447			
Week 44														0.5454			
Week 52														0.8066			
Week 64														0.3308			
<65 years																	
Baseline																	
Placebo	65	65	20.5	2.4	64 (100.0%)												
Nera 18mg	64	64	16.0	1.5	62 (100.0%)												
Week 12																	
Placebo		64	17.4	2.1	64 (100.0%)	-2.1	1.4	-4.8	0.6								
Nera 18mg		61	17.6	1.7	61 (98.4%)	0.9	1.4	-1.9	3.6	3.0	2.0	-0.9	6.9	0.1310			
Week 26																	
Placebo		62	20.7	2.5	62 (96.9%)	1.9	1.8	-1.6	5.4								
Nera 18mg		58	18.2	2.0	58 (93.5%)	1.5	1.9	-2.2	5.1	-0.4	2.6	-5.5	4.7	0.8701			
Week 36																	
Placebo		62	22.0	2.7	62 (96.9%)	3.1	1.8	-0.5	6.7								
Nera 18mg		56	18.6	2.1	56 (90.3%)	2.1	1.9	-1.7	5.8	-1.0	2.6	-6.2	4.2	0.7029			
Week 44																	
Placebo		61	20.5	2.4	61 (95.3%)	1.5	2.0	-2.4	5.4								
Nera 18mg		52	19.3	2.4	52 (83.9%)	3.2	2.1	-0.9	7.4	1.7	2.9	-3.9	7.4	0.5472			
Week 52																	
Placebo		62	23.1	2.7	62 (96.9%)	4.2	2.1	0.1	8.4								
Nera 18mg		52	19.3	2.3	52 (83.9%)	3.1	2.2	-1.3	7.5	-1.1	3.1	-7.1	5.0	0.7223			
Week 64																	
Placebo		57	20.2	2.2	57 (89.1%)	4.1	2.1	-0.1	8.3								
Nera 18mg		45	20.2	2.4	45 (72.6%)	6.0	2.3	1.5	10.5	1.9	3.1	-4.3	8.0	0.5485			
Week 76																	
Placebo		37	23.8	3.3	37 (57.8%)												
Nera 18mg		34	21.3	3.0	34 (54.8%)												
Week 88																	
Placebo		15	28.4	5.1	15 (23.4%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Dyspnea domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		7	33.7	10.2	7 (11.3%)												
Week 100																	
Placebo		4	24.6	10.3	4 (6.3%)												
Nera 18mg		1	8.6	NC	1 (1.6%)												
Week 112																	
Placebo		2	14.2	14.2	2 (3.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	104	104	19.9	1.7	100 (100.0%)												
Nera 18mg	106	105	19.9	1.6	102 (100.0%)												
Week 12																	
Placebo		98	20.9	1.9	98 (98.0%)	1.4	1.1	-0.8	3.6								
Nera 18mg		102	21.2	1.5	101 (99.0%)	1.7	1.1	-0.5	3.8	0.3	1.6	-2.8	3.4	0.8547			
Week 26																	
Placebo		94	23.0	2.1	94 (94.0%)	4.2	1.5	1.3	7.0								
Nera 18mg		95	22.0	1.8	94 (92.2%)	2.3	1.4	-0.5	5.2	-1.8	2.1	-5.9	2.2	0.3690			
Week 36																	
Placebo		89	22.0	2.0	89 (89.0%)	4.8	1.5	1.8	7.8								
Nera 18mg		90	22.7	1.7	90 (88.2%)	3.6	1.5	0.6	6.5	-1.2	2.1	-5.4	2.9	0.5587			
Week 44																	
Placebo		86	23.5	2.3	86 (86.0%)	6.8	1.6	3.6	10.0								
Nera 18mg		88	25.4	2.0	87 (85.3%)	6.3	1.6	3.1	9.5	-0.5	2.3	-5.1	4.1	0.8283			
Week 52																	
Placebo		86	25.2	2.3	86 (86.0%)	8.1	1.8	4.7	11.6								
Nera 18mg		86	24.5	2.1	86 (84.3%)	6.1	1.7	2.6	9.5	-2.1	2.5	-6.9	2.8	0.4052			
Week 64																	
Placebo		71	23.6	2.4	71 (71.0%)	9.7	1.8	6.2	13.2								
Nera 18mg		77	24.3	2.0	77 (75.5%)	7.7	1.8	4.2	11.1	-2.0	2.5	-7.0	2.9	0.4197			
Week 76																	
Placebo		51	21.0	2.8	51 (51.0%)												
Nera 18mg		46	26.6	3.2	46 (45.1%)												
Week 88																	
Placebo		23	22.3	4.7	23 (23.0%)												
Nera 18mg		24	30.0	5.1	24 (23.5%)												
Week 100																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Dyspnea domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		7	15.5	5.6	7 (7.0%)												
Nera 18mg		8	25.6	5.2	8 (7.8%)												
Week 112																	
Placebo		2	14.7	14.7	2 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Sex																	
Test for homogeneity (H0)^																	
Week 12														0.3866			
Week 26														0.4900			
Week 36														0.3427			
Week 44														0.7476			
Week 52														0.5803			
Week 64														0.4074			
Male																	
Baseline																	
Placebo	114	114	18.1	1.6	111 (100.0%)												
Nera 18mg	108	107	16.6	1.2	102 (100.0%)												
Week 12																	
Placebo		109	18.8	1.8	109 (98.2%)	0.8	1.1	-1.3	2.9								
Nera 18mg		102	18.4	1.4	101 (99.0%)	1.5	1.1	-0.7	3.6	0.7	1.5	-2.3	3.7	0.6640			
Week 26																	
Placebo		104	21.4	2.0	104 (93.7%)	4.3	1.4	1.5	7.0								
Nera 18mg		95	19.0	1.6	94 (92.2%)	2.3	1.5	-0.6	5.1	-2.0	2.0	-5.9	2.0	0.3239			
Week 36																	
Placebo		100	20.4	2.0	100 (90.1%)	4.5	1.4	1.7	7.3								
Nera 18mg		88	21.2	1.8	88 (86.3%)	4.7	1.5	1.7	7.7	0.2	2.1	-3.8	4.3	0.9109			
Week 44																	
Placebo		97	21.6	2.0	97 (87.4%)	6.2	1.6	3.1	9.2								
Nera 18mg		83	22.6	1.9	82 (80.4%)	6.5	1.7	3.2	9.8	0.3	2.3	-4.1	4.8	0.8867			
Week 52																	
Placebo		97	23.1	2.2	97 (87.4%)	7.6	1.7	4.3	10.8								
Nera 18mg		82	23.2	2.1	82 (80.4%)	7.1	1.8	3.6	10.5	-0.5	2.4	-5.2	4.2	0.8363			
Week 64																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo		82	20.7	2.0	82 (73.9%)	8.8	1.7	5.6	12.1								
Nera 18mg		74	25.5	2.2	74 (72.5%)	10.1	1.8	6.6	13.6	1.3	2.4	-3.5	6.0	0.6011			
Week 76																	
Placebo		54	21.0	2.6	54 (48.6%)												
Nera 18mg		47	28.0	3.4	47 (46.1%)												
Week 88																	
Placebo		25	23.5	4.0	25 (22.5%)												
Nera 18mg		18	35.7	6.7	18 (17.6%)												
Week 100																	
Placebo		7	20.5	7.4	7 (6.3%)												
Nera 18mg		4	28.6	5.8	4 (3.9%)												
Week 112																	
Placebo		2	14.7	14.7	2 (1.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Female																	
Baseline																	
Placebo	55	55	24.4	2.6	53 (100.0%)												
Nera 18mg	62	62	21.6	2.3	62 (100.0%)												
Week 12																	
Placebo		53	20.9	2.4	53 (100.0%)	-1.7	1.5	-4.7	1.4								
Nera 18mg		61	22.3	2.1	61 (98.4%)	1.2	1.4	-1.5	4.0	2.9	2.1	-1.2	7.0	0.1645			
Week 26																	
Placebo		52	23.4	2.6	52 (98.1%)	1.2	2.0	-2.6	5.1								
Nera 18mg		58	23.0	2.4	58 (93.5%)	1.6	1.9	-2.0	5.2	0.3	2.7	-5.0	5.7	0.8979			
Week 36																	
Placebo		51	25.1	2.8	51 (96.2%)	3.4	2.0	-0.6	7.4								
Nera 18mg		58	21.0	2.0	58 (93.5%)	0.4	1.9	-3.4	4.1	-3.0	2.8	-8.5	2.4	0.2701			
Week 44																	
Placebo		50	23.7	3.0	50 (94.3%)	1.5	2.2	-2.8	5.9								
Nera 18mg		57	23.9	2.6	57 (91.9%)	3.1	2.1	-1.0	7.1	1.5	3.0	-4.4	7.5	0.6091			
Week 52																	
Placebo		51	26.7	3.0	51 (96.2%)	4.5	2.3	-0.1	9.1								
Nera 18mg		56	21.4	2.5	56 (90.3%)	1.8	2.2	-2.5	6.1	-2.7	3.2	-9.0	3.6	0.3954			
Week 64																	
Placebo		46	24.6	2.8	46 (86.8%)	4.3	2.3	-0.2	8.9								
Nera 18mg		48	18.7	2.0	48 (77.4%)	2.3	2.2	-2.0	6.6	-2.1	3.2	-8.3	4.2	0.5190			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 76																	
Placebo		34	24.1	3.6	34 (64.2%)												
Nera 18mg		33	19.1	2.4	33 (53.2%)												
Week 88																	
Placebo		13	26.9	6.9	13 (24.5%)												
Nera 18mg		13	24.0	4.9	13 (21.0%)												
Week 100																	
Placebo		4	15.8	5.9	4 (7.5%)												
Nera 18mg		5	19.8	7.7	5 (8.1%)												
Week 112																	
Placebo		2	14.2	14.2	2 (3.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 12														0.9421			
Week 26														0.4191			
Week 36														0.4313			
Week 44														0.5426			
Week 52														0.5892			
Week 64														0.7773			
<=70%																	
Baseline																	
Placebo	95	95	22.8	2.0	91 (100.0%)												
Nera 18mg	97	97	22.7	1.6	96 (100.0%)												
Week 12																	
Placebo		89	22.2	2.1	89 (97.8%)	1.1	1.2	-1.2	3.4								
Nera 18mg		96	23.9	1.5	96 (100.0%)	2.4	1.1	0.2	4.6	1.3	1.6	-1.9	4.5	0.4159			
Week 26																	
Placebo		85	25.7	2.2	85 (93.4%)	5.4	1.5	2.4	8.4								
Nera 18mg		88	24.2	1.7	88 (91.7%)	2.8	1.5	-0.1	5.8	-2.6	2.1	-6.7	1.6	0.2294			
Week 36																	
Placebo		83	26.5	2.3	83 (91.2%)	6.9	1.6	3.8	10.0								
Nera 18mg		85	25.5	1.8	85 (88.5%)	4.4	1.5	1.4	7.5	-2.5	2.2	-6.7	1.8	0.2586			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Dyspnea domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 44																	
Placebo		81	25.3	2.3	81 (89.0%)	5.9	1.7	2.6	9.3								
Nera 18mg		80	27.8	2.0	80 (83.3%)	7.2	1.7	3.9	10.6	1.3	2.4	-3.4	6.0	0.5868			
Week 52																	
Placebo		80	29.0	2.6	80 (87.9%)	9.3	1.8	5.7	12.9								
Nera 18mg		79	27.2	2.1	79 (82.3%)	6.6	1.8	3.0	10.2	-2.7	2.5	-7.7	2.3	0.2901			
Week 64																	
Placebo		70	26.0	2.3	70 (76.9%)	10.2	1.8	6.6	13.8								
Nera 18mg		70	27.5	2.0	70 (72.9%)	9.2	1.8	5.6	12.8	-1.0	2.6	-6.1	4.0	0.6898			
Week 76																	
Placebo		45	25.6	3.0	45 (49.5%)												
Nera 18mg		44	31.9	3.3	44 (45.8%)												
Week 88																	
Placebo		20	26.3	5.2	20 (22.0%)												
Nera 18mg		19	37.6	6.0	19 (19.8%)												
Week 100																	
Placebo		5	30.2	8.6	5 (5.5%)												
Nera 18mg		5	22.5	5.6	5 (5.2%)												
Week 112																	
Placebo		3	19.2	9.6	3 (3.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	74	74	16.7	1.9	73 (100.0%)												
Nera 18mg	73	72	12.6	1.5	68 (100.0%)												
Week 12																	
Placebo		73	16.2	1.9	73 (100.0%)	-1.3	1.3	-3.8	1.3								
Nera 18mg		67	13.9	1.7	66 (97.1%)	-0.1	1.4	-2.8	2.6	1.1	1.9	-2.6	4.8	0.5448			
Week 26																	
Placebo		71	17.8	2.2	71 (97.3%)	0.8	1.7	-2.5	4.0								
Nera 18mg		65	15.5	1.9	64 (94.1%)	0.8	1.8	-2.7	4.3	0.1	2.4	-4.7	4.8	0.9824			
Week 36																	
Placebo		68	16.5	2.1	68 (93.2%)	0.8	1.7	-2.6	4.1								
Nera 18mg		61	15.0	1.7	61 (89.7%)	0.9	1.8	-2.7	4.5	0.1	2.5	-4.8	5.0	0.9530			
Week 44																	
Placebo		66	18.6	2.3	66 (90.4%)	3.1	1.9	-0.6	6.8								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Dyspnea domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		60	16.9	2.2	59 (86.8%)	2.2	2.0	-1.8	6.2	-0.9	2.7	-6.3	4.5	0.7385			
Week 52																	
Placebo		68	18.8	2.1	68 (93.2%)	3.3	2.0	-0.6	7.2								
Nera 18mg		59	16.2	2.3	59 (86.8%)	2.6	2.1	-1.6	6.8	-0.6	2.9	-6.3	5.1	0.8316			
Week 64																	
Placebo		58	17.4	2.3	58 (79.5%)	3.9	2.0	-0.1	7.9								
Nera 18mg		52	16.5	2.2	52 (76.5%)	4.0	2.2	-0.3	8.3	0.1	2.9	-5.7	5.9	0.9790			
Week 76																	
Placebo		43	18.6	3.0	43 (58.9%)												
Nera 18mg		36	15.1	2.2	36 (52.9%)												
Week 88																	
Placebo		18	22.8	4.7	18 (24.7%)												
Nera 18mg		12	20.1	5.6	12 (17.6%)												
Week 100																	
Placebo		6	9.4	2.2	6 (8.2%)												
Nera 18mg		4	25.3	9.6	4 (5.9%)												
Week 112																	
Placebo		1	0.0	NC	1 (1.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline HRCT pattern																	
Test for homogeneity (H0)^																	
Week 12														0.7498			
Week 26														0.4025			
Week 36														0.3621			
Week 44														0.6866			
Week 52														0.2970			
Week 64														0.3913			
UIP-like																	
Baseline																	
Placebo	116	116	18.3	1.6	113 (100.0%)												
Nera 18mg	121	120	18.2	1.4	117 (100.0%)												
Week 12																	
Placebo		111	18.5	1.7	111 (98.2%)	0.4	1.0	-1.6	2.5								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Dyspnea domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		117	20.5	1.5	116 (99.1%)	2.0	1.0	0.0	4.1	1.6	1.5	-1.3	4.5	0.2711			
Week 26																	
Placebo		107	19.9	1.8	107 (94.7%)	2.4	1.4	-0.2	5.1								
Nera 18mg		110	20.7	1.6	109 (93.2%)	2.1	1.3	-0.6	4.7	-0.4	1.9	-4.2	3.4	0.8350			
Week 36																	
Placebo		103	19.7	1.8	103 (91.2%)	3.5	1.4	0.7	6.3								
Nera 18mg		104	21.5	1.6	104 (88.9%)	3.4	1.4	0.6	6.1	-0.1	2.0	-4.0	3.7	0.9412			
Week 44																	
Placebo		99	20.5	1.9	99 (87.6%)	4.7	1.5	1.6	7.7								
Nera 18mg		100	24.0	1.9	99 (84.6%)	5.6	1.5	2.6	8.6	1.0	2.2	-3.3	5.2	0.6546			
Week 52																	
Placebo		100	21.3	1.9	100 (88.5%)	5.4	1.6	2.2	8.6								
Nera 18mg		100	22.7	1.9	100 (85.5%)	5.2	1.6	2.0	8.3	-0.3	2.3	-4.8	4.2	0.9035			
Week 64																	
Placebo		90	21.4	2.1	90 (79.6%)	6.9	1.7	3.7	10.2								
Nera 18mg		87	23.3	2.0	87 (74.4%)	7.7	1.6	4.4	10.9	0.8	2.3	-3.8	5.3	0.7452			
Week 76																	
Placebo		60	20.1	2.6	60 (53.1%)												
Nera 18mg		59	23.4	2.4	59 (50.4%)												
Week 88																	
Placebo		26	23.6	4.3	26 (23.0%)												
Nera 18mg		23	29.9	5.0	23 (19.7%)												
Week 100																	
Placebo		9	20.4	6.1	9 (8.0%)												
Nera 18mg		8	21.4	4.9	8 (6.8%)												
Week 112																	
Placebo		3	19.2	9.6	3 (2.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other fibrotic patterns																	
Baseline																	
Placebo	53	53	24.1	2.8	51 (100.0%)												
Nera 18mg	49	49	19.0	2.2	47 (100.0%)												
Week 12																	
Placebo		51	21.5	2.6	51 (100.0%)	-1.0	1.6	-4.0	2.1								
Nera 18mg		46	18.1	1.8	46 (97.9%)	-0.2	1.6	-3.4	3.0	0.8	2.3	-3.7	5.2	0.7373			
Week 26																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Dyspnea domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		49	26.9	3.1	49 (96.1%)	5.1	2.0	1.2	9.1								
Nera 18mg		43	20.2	2.4	43 (91.5%)	1.8	2.1	-2.4	6.0	-3.3	2.9	-9.1	2.4	0.2569			
Week 36																	
Placebo		48	26.9	3.3	48 (94.1%)	5.5	2.1	1.4	9.6								
Nera 18mg		42	20.3	2.5	42 (89.4%)	2.0	2.2	-2.3	6.4	-3.4	3.0	-9.4	2.5	0.2552			
Week 44																	
Placebo		48	26.0	3.2	48 (94.1%)	4.6	2.3	0.1	9.0								
Nera 18mg		40	21.0	2.6	40 (85.1%)	4.0	2.4	-0.8	8.7	-0.6	3.3	-7.1	5.9	0.8496			
Week 52																	
Placebo		48	30.5	3.5	48 (94.1%)	9.1	2.4	4.4	13.8								
Nera 18mg		38	22.0	2.8	38 (80.9%)	4.4	2.6	-0.7	9.5	-4.7	3.5	-11.6	2.3	0.1855			
Week 64																	
Placebo		38	23.8	2.7	38 (74.5%)	8.3	2.5	3.5	13.2								
Nera 18mg		35	21.6	2.6	35 (74.5%)	5.4	2.6	0.3	10.5	-2.9	3.6	-10.0	4.2	0.4170			
Week 76																	
Placebo		28	26.5	3.5	28 (54.9%)												
Nera 18mg		21	26.9	5.3	21 (44.7%)												
Week 88																	
Placebo		12	27.0	6.2	12 (23.5%)												
Nera 18mg		8	33.4	10.1	8 (17.0%)												
Week 100																	
Placebo		2	11.9	3.2	2 (3.9%)												
Nera 18mg		1	42.4	NC	1 (2.1%)												
Week 112																	
Placebo		1	0.0	NC	1 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Underlying ILD diagnosis																	
Test for homogeneity (H0)^																	
Week 12														0.7118			
Week 26														0.2279			
Week 36														0.2551			
Week 44														0.3207			
Week 52														0.3753			
Week 64														0.1100			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
iNSIP																	
Baseline																	
Placebo	32	32	23.2	3.5	31 (100.0%)												
Nera 18mg	27	27	20.1	3.2	25 (100.0%)												
Week 12																	
Placebo		29	18.4	3.7	29 (93.5%)	-2.3	2.0	-6.3	1.7								
Nera 18mg		24	19.2	3.5	24 (96.0%)	0.5	2.2	-3.9	4.9	2.8	3.0	-3.1	8.8	0.3513			
Week 26																	
Placebo		29	19.4	3.8	29 (93.5%)	-1.3	2.6	-6.4	3.9								
Nera 18mg		23	19.8	3.6	23 (92.0%)	2.0	2.9	-3.7	7.8	3.3	3.9	-4.4	11.0	0.4015			
Week 36																	
Placebo		28	19.4	3.4	28 (90.3%)	-0.0	2.7	-5.4	5.3								
Nera 18mg		21	20.6	3.8	21 (84.0%)	3.6	3.1	-2.5	9.6	3.6	4.1	-4.5	11.7	0.3804			
Week 44																	
Placebo		28	22.0	3.8	28 (90.3%)	2.5	2.9	-3.3	8.2								
Nera 18mg		19	24.9	5.4	19 (76.0%)	7.9	3.4	1.2	14.6	5.4	4.5	-3.5	14.2	0.2325			
Week 52																	
Placebo		27	23.1	4.1	27 (87.1%)	3.5	3.1	-2.7	9.7								
Nera 18mg		17	20.5	4.3	17 (68.0%)	6.6	3.7	-0.7	13.9	3.1	4.9	-6.5	12.7	0.5256			
Week 64																	
Placebo		23	21.7	4.6	23 (74.2%)	3.0	3.2	-3.2	9.2								
Nera 18mg		17	24.9	4.5	17 (68.0%)	10.8	3.7	3.6	18.0	7.8	4.9	-1.8	17.3	0.1108			
Week 76																	
Placebo		16	24.9	6.8	16 (51.6%)												
Nera 18mg		10	34.3	9.1	10 (40.0%)												
Week 88																	
Placebo		9	30.8	8.5	9 (29.0%)												
Nera 18mg		3	44.6	19.7	3 (12.0%)												
Week 100																	
Placebo		2	3.6	0.2	2 (6.5%)												
Nera 18mg		1	42.4	NC	1 (4.0%)												
Week 112																	
Placebo		2	14.7	14.7	2 (6.5%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Unclassifiable IIP																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Dyspnea domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Baseline																	
Placebo	46	46	19.7	2.5	44 (100.0%)												
Nera 18mg	32	32	17.2	2.9	32 (100.0%)												
Week 12																	
Placebo		44	20.7	2.7	44 (100.0%)	1.4	1.7	-1.9	4.6								
Nera 18mg		32	18.1	2.3	32 (100.0%)	0.3	2.0	-3.6	4.2	-1.1	2.6	-6.1	4.0	0.6810			
Week 26																	
Placebo		40	21.7	2.9	40 (90.9%)	4.5	2.2	0.2	8.9								
Nera 18mg		28	19.4	2.8	28 (87.5%)	1.6	2.6	-3.6	6.8	-2.9	3.4	-9.7	3.9	0.3979			
Week 36																	
Placebo		38	21.1	2.9	38 (86.4%)	5.5	2.3	1.0	10.1								
Nera 18mg		27	22.5	3.1	27 (84.4%)	4.7	2.7	-0.7	10.0	-0.9	3.6	-7.9	6.2	0.8115			
Week 44																	
Placebo		37	23.6	3.3	37 (84.1%)	8.6	2.5	3.7	13.6								
Nera 18mg		27	24.3	3.1	27 (84.4%)	6.4	2.9	0.6	12.2	-2.2	3.9	-9.8	5.4	0.5621			
Week 52																	
Placebo		38	25.2	3.2	38 (86.4%)	9.8	2.7	4.6	15.1								
Nera 18mg		28	18.8	3.2	28 (87.5%)	1.1	3.1	-5.1	7.2	-8.8	4.1	-16.8	-0.7	0.0334	-0.53	-1.02	-0.04
Week 64																	
Placebo		32	23.5	3.4	32 (72.7%)	9.9	2.7	4.6	15.2								
Nera 18mg		23	23.2	4.0	23 (71.9%)	7.7	3.2	1.5	14.0	-2.2	4.1	-10.3	6.0	0.6004			
Week 76																	
Placebo		25	19.2	3.3	25 (56.8%)												
Nera 18mg		17	22.6	4.1	17 (53.1%)												
Week 88																	
Placebo		10	26.6	5.8	10 (22.7%)												
Nera 18mg		10	25.5	5.9	10 (31.3%)												
Week 100																	
Placebo		2	31.1	18.9	2 (4.5%)												
Nera 18mg		3	22.4	13.0	3 (9.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
HP																	
Baseline																	
Placebo	38	38	15.4	2.6	38 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Dyspnea domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg	43	43	21.2	2.5	41 (100.0%)												
Week 12																	
Placebo		38	18.1	2.9	38 (100.0%)	2.2	1.8	-1.4	5.7								
Nera 18mg		41	22.3	2.2	41 (100.0%)	1.5	1.7	-1.9	4.9	-0.7	2.5	-5.6	4.2	0.7744			
Week 26																	
Placebo		38	22.3	3.4	38 (100.0%)	6.0	2.3	1.4	10.6								
Nera 18mg		38	24.9	3.1	38 (92.7%)	4.0	2.3	-0.5	8.5	-2.0	3.3	-8.4	4.4	0.5404			
Week 36																	
Placebo		38	22.1	3.4	38 (100.0%)	5.9	2.4	1.2	10.5								
Nera 18mg		37	22.5	2.6	37 (90.2%)	1.6	2.4	-3.0	6.3	-4.2	3.3	-10.8	2.3	0.2062			
Week 44																	
Placebo		37	19.5	3.2	37 (97.4%)	4.1	2.6	-0.9	9.2								
Nera 18mg		35	26.0	3.0	35 (85.4%)	6.7	2.6	1.7	11.8	2.6	3.6	-4.6	9.7	0.4767			
Week 52																	
Placebo		37	24.0	3.9	37 (97.4%)	8.5	2.7	3.1	13.9								
Nera 18mg		34	29.2	3.6	34 (82.9%)	8.4	2.8	2.9	13.8	-0.1	3.9	-7.8	7.5	0.9698			
Week 64																	
Placebo		33	21.2	3.3	33 (86.8%)	10.6	2.7	5.2	16.0								
Nera 18mg		30	28.4	3.5	30 (73.2%)	9.8	2.8	4.4	15.3	-0.8	3.9	-8.5	6.9	0.8381			
Week 76																	
Placebo		18	26.3	4.6	18 (47.4%)												
Nera 18mg		17	28.8	4.7	17 (41.5%)												
Week 88																	
Placebo		8	20.5	7.7	8 (21.1%)												
Nera 18mg		5	35.2	10.0	5 (12.2%)												
Week 100																	
Placebo		1	13.2	NC	1 (2.6%)												
Nera 18mg		1	34.0	NC	1 (2.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Autoimmune ILD																	
Baseline																	
Placebo	29	29	21.9	3.8	28 (100.0%)												
Nera 18mg	43	42	19.7	2.3	42 (100.0%)												
Week 12																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Dyspnea domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo		28	20.3	4.0	28 (100.0%)	-1.3	2.1	-5.4	2.8								
Nera 18mg		43	20.3	2.5	42 (100.0%)	0.9	1.7	-2.5	4.2	2.2	2.7	-3.1	7.5	0.4200			
Week 26																	
Placebo		27	21.9	4.0	27 (96.4%)	1.6	2.7	-3.7	7.0								
Nera 18mg		41	19.1	2.6	40 (95.2%)	-0.8	2.2	-5.2	3.6	-2.4	3.5	-9.3	4.5	0.4936			
Week 36																	
Placebo		26	21.8	4.4	26 (92.9%)	2.2	2.8	-3.3	7.7								
Nera 18mg		38	19.8	2.5	38 (90.5%)	0.5	2.3	-4.1	5.0	-1.8	3.6	-8.9	5.4	0.6252			
Week 44																	
Placebo		24	21.0	4.4	24 (85.7%)	0.5	3.1	-5.6	6.5								
Nera 18mg		37	19.1	2.8	36 (85.7%)	-1.1	2.5	-6.1	3.9	-1.6	4.0	-9.4	6.2	0.6927			
Week 52																	
Placebo		25	23.9	4.3	25 (89.3%)	3.9	3.2	-2.5	10.3								
Nera 18mg		37	20.2	3.1	37 (88.1%)	1.3	2.7	-4.0	6.6	-2.6	4.2	-10.9	5.6	0.5327			
Week 64																	
Placebo		21	19.6	3.8	21 (75.0%)	3.1	3.3	-3.4	9.5								
Nera 18mg		33	16.7	2.2	33 (78.6%)	0.3	2.7	-4.9	5.6	-2.7	4.2	-11.0	5.6	0.5214			
Week 76																	
Placebo		16	18.7	5.2	16 (57.1%)												
Nera 18mg		19	15.3	2.8	19 (45.2%)												
Week 88																	
Placebo		6	14.4	4.7	6 (21.4%)												
Nera 18mg		5	21.2	7.9	5 (11.9%)												
Week 100																	
Placebo		4	15.5	5.9	4 (14.3%)												
Nera 18mg		2	15.9	7.3	2 (4.8%)												
Week 112																	
Placebo		2	14.2	14.2	2 (7.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other ILD																	
Baseline																	
Placebo	24	24	22.4	3.6	23 (100.0%)												
Nera 18mg	25	25	11.1	1.7	24 (100.0%)												
Week 12																	
Placebo		23	19.8	2.8	23 (100.0%)	-1.6	2.3	-6.1	3.0								
Nera 18mg		23	17.6	2.8	23 (95.8%)	4.4	2.3	-0.1	9.0	6.0	3.3	-0.5	12.5	0.0689			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Dyspnea domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 26																	
Placebo		22	26.2	4.4	22 (95.7%)	4.4	3.0	-1.5	10.3								
Nera 18mg		23	18.0	2.6	23 (95.8%)	4.0	2.9	-1.8	9.8	-0.4	4.2	-8.8	7.9	0.9220			
Week 36																	
Placebo		21	27.1	4.6	21 (91.3%)	6.4	3.1	0.3	12.6								
Nera 18mg		23	19.9	3.8	23 (95.8%)	7.1	3.0	1.1	13.0	0.7	4.4	-7.9	9.3	0.8778			
Week 44																	
Placebo		21	26.8	4.5	21 (91.3%)	6.2	3.4	-0.4	12.9								
Nera 18mg		22	22.5	3.9	22 (91.7%)	9.3	3.3	2.9	15.8	3.1	4.7	-6.2	12.4	0.5128			
Week 52																	
Placebo		21	25.4	4.4	21 (91.3%)	4.6	3.6	-2.5	11.7								
Nera 18mg		22	22.4	3.7	22 (91.7%)	9.5	3.5	2.6	16.4	5.0	5.0	-5.0	14.9	0.3264			
Week 64																	
Placebo		19	24.4	3.6	19 (82.6%)	7.4	3.6	0.3	14.5								
Nera 18mg		19	22.3	3.8	19 (79.2%)	10.0	3.5	3.1	17.0	2.6	5.0	-7.3	12.6	0.6030			
Week 76																	
Placebo		13	23.1	4.5	13 (56.5%)												
Nera 18mg		17	26.0	5.6	17 (70.8%)												
Week 88																	
Placebo		5	28.9	13.3	5 (21.7%)												
Nera 18mg		8	35.5	12.2	8 (33.3%)												
Week 100																	
Placebo		2	31.2	16.1	2 (8.7%)												
Nera 18mg		2	19.1	1.8	2 (8.3%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Region																	
Test for homogeneity (H0)^																	
Week 12														0.4153			
Week 26														0.7502			
Week 36														0.5275			
Week 44														0.6208			
Week 52														0.8720			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Dyspnea domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 64														0.6060			
Europe																	
Baseline																	
Placebo	78	78	20.3	2.1	77 (100.0%)												
Nera 18mg	67	66	18.6	1.6	64 (100.0%)												
Week 12																	
Placebo		76	21.6	2.1	76 (98.7%)	1.9	1.3	-0.6	4.3								
Nera 18mg		65	20.5	1.6	64 (100.0%)	1.9	1.4	-0.8	4.6	0.0	1.9	-3.7	3.7	0.9922			
Week 26																	
Placebo		73	24.9	2.5	73 (94.8%)	5.3	1.7	2.1	8.6								
Nera 18mg		59	22.8	2.2	58 (90.6%)	3.6	1.8	-0.0	7.2	-1.7	2.5	-6.6	3.1	0.4825			
Week 36																	
Placebo		69	24.0	2.3	69 (89.6%)	6.1	1.7	2.7	9.5								
Nera 18mg		55	22.4	2.1	55 (85.9%)	4.0	1.9	0.3	7.8	-2.1	2.6	-7.2	3.0	0.4162			
Week 44																	
Placebo		68	22.2	2.4	68 (88.3%)	4.2	1.9	0.5	7.9								
Nera 18mg		54	23.8	2.4	53 (82.8%)	5.9	2.1	1.7	10.0	1.6	2.8	-3.9	7.2	0.5649			
Week 52																	
Placebo		69	24.3	2.4	69 (89.6%)	6.5	2.0	2.6	10.4								
Nera 18mg		53	23.3	2.6	53 (82.8%)	4.9	2.2	0.5	9.3	-1.6	3.0	-7.5	4.2	0.5854			
Week 64																	
Placebo		63	24.7	2.3	63 (81.8%)	8.3	2.0	4.3	12.2								
Nera 18mg		52	24.1	2.6	52 (81.3%)	6.8	2.2	2.4	11.2	-1.4	3.0	-7.4	4.5	0.6304			
Week 76																	
Placebo		38	24.8	3.1	38 (49.4%)												
Nera 18mg		30	30.8	4.1	30 (46.9%)												
Week 88																	
Placebo		15	24.2	5.9	15 (19.5%)												
Nera 18mg		8	27.2	7.8	8 (12.5%)												
Week 100																	
Placebo		3	9.2	3.3	3 (3.9%)												
Nera 18mg		2	14.7	2.6	2 (3.1%)												
Week 112																	
Placebo		1	0.0	NC	1 (1.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Dyspnea domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Asia																	
Baseline																	
Placebo	45	45	17.8	2.5	43 (100.0%)												
Nera 18mg	41	41	18.8	2.7	39 (100.0%)												
Week 12																	
Placebo		43	15.2	2.5	43 (100.0%)	-3.0	1.7	-6.3	0.3								
Nera 18mg		39	21.1	3.2	39 (100.0%)	2.7	1.8	-0.8	6.1	5.6	2.4	0.8	10.4	0.0216	0.50	0.07	0.94
Week 26																	
Placebo		42	18.2	2.6	42 (97.7%)	0.8	2.2	-3.5	5.1								
Nera 18mg		36	18.7	3.1	36 (92.3%)	0.4	2.3	-4.2	5.0	-0.3	3.2	-6.6	5.9	0.9135			
Week 36																	
Placebo		41	20.4	3.1	41 (95.3%)	3.6	2.2	-0.9	8.0								
Nera 18mg		34	20.6	3.1	34 (87.2%)	2.5	2.4	-2.3	7.3	-1.1	3.3	-7.6	5.4	0.7414			
Week 44																	
Placebo		38	22.1	3.4	38 (88.4%)	6.3	2.5	1.4	11.1								
Nera 18mg		31	23.7	4.0	31 (79.5%)	4.2	2.7	-1.1	9.5	-2.1	3.7	-9.3	5.1	0.5688			
Week 52																	
Placebo		39	24.4	3.5	39 (90.7%)	8.4	2.6	3.3	13.5								
Nera 18mg		32	21.8	3.6	32 (82.1%)	5.3	2.8	-0.3	10.8	-3.2	3.8	-10.7	4.4	0.4101			
Week 64																	
Placebo		33	20.7	3.9	33 (76.7%)	7.3	2.7	2.1	12.6								
Nera 18mg		26	20.8	3.2	26 (66.7%)	7.5	2.9	1.7	13.3	0.2	4.0	-7.7	8.0	0.9683			
Week 76																	
Placebo		25	18.0	4.1	25 (58.1%)												
Nera 18mg		19	17.8	4.0	19 (48.7%)												
Week 88																	
Placebo		13	22.6	6.6	13 (30.2%)												
Nera 18mg		9	30.0	9.8	9 (23.1%)												
Week 100																	
Placebo		5	30.0	8.7	5 (11.6%)												
Nera 18mg		4	21.8	9.6	4 (10.3%)												
Week 112																	
Placebo		1	28.3	NC	1 (2.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	
Baseline																	

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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo	30	30	20.6	3.6	30 (100.0%)												
Nera 18mg	37	37	15.1	1.7	37 (100.0%)												
Week 12																	
Placebo		29	19.8	3.5	29 (96.7%)	-0.2	2.1	-4.2	3.8								
Nera 18mg		36	15.6	1.9	36 (97.3%)	-0.2	1.8	-3.8	3.4	-0.0	2.7	-5.4	5.4	0.9891			
Week 26																	
Placebo		27	19.8	3.4	27 (90.0%)	1.7	2.7	-3.6	7.0								
Nera 18mg		34	16.4	2.0	34 (91.9%)	1.0	2.4	-3.8	5.7	-0.7	3.6	-7.8	6.4	0.8397			
Week 36																	
Placebo		27	18.5	3.5	27 (90.0%)	0.4	2.8	-5.0	5.9								
Nera 18mg		34	18.4	2.6	34 (91.9%)	3.0	2.5	-1.9	7.9	2.5	3.7	-4.8	9.8	0.4960			
Week 44																	
Placebo		27	20.9	3.2	27 (90.0%)	3.2	3.0	-2.8	9.1								
Nera 18mg		33	21.4	3.1	33 (89.2%)	6.3	2.7	0.9	11.7	3.1	4.1	-4.8	11.1	0.4387			
Week 52																	
Placebo		26	19.1	3.7	26 (86.7%)	0.7	3.2	-5.6	7.0								
Nera 18mg		33	20.8	3.0	33 (89.2%)	5.5	2.9	-0.2	11.1	4.8	4.3	-3.6	13.2	0.2641			
Week 64																	
Placebo		21	18.6	2.8	21 (70.0%)	5.0	3.3	-1.6	11.6								
Nera 18mg		27	20.2	2.8	27 (73.0%)	7.5	3.0	1.6	13.3	2.4	4.4	-6.3	11.2	0.5836			
Week 76																	
Placebo		17	22.4	4.7	17 (56.7%)												
Nera 18mg		20	22.1	4.0	20 (54.1%)												
Week 88																	
Placebo		9	30.3	5.9	9 (30.0%)												
Nera 18mg		11	28.3	6.6	11 (29.7%)												
Week 100																	
Placebo		3	9.8	3.2	3 (10.0%)												
Nera 18mg		3	32.4	6.3	3 (8.1%)												
Week 112																	
Placebo		2	14.7	14.7	2 (6.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Rest of the World																	
Baseline																	
Placebo	16	16	25.2	4.6	14 (100.0%)												
Nera 18mg	25	25	22.3	4.3	24 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Dyspnea domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 5 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Dyspnea domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 12																	
Placebo		14	20.5	5.6	14 (100.0%)	-0.4	2.9	-6.2	5.4								
Nera 18mg		23	22.2	3.0	23 (95.8%)	0.3	2.3	-4.2	4.8	0.7	3.7	-6.6	8.0	0.8480			
Week 26																	
Placebo		14	23.9	6.4	14 (100.0%)	2.9	3.8	-4.5	10.4								
Nera 18mg		24	23.5	3.6	24 (100.0%)	2.0	2.9	-3.7	7.7	-0.9	4.8	-10.3	8.5	0.8457			
Week 36																	
Placebo		14	23.3	7.2	14 (100.0%)	2.4	3.9	-5.3	10.0								
Nera 18mg		23	22.9	3.3	23 (95.8%)	1.2	3.0	-4.7	7.1	-1.2	4.9	-10.8	8.5	0.8141			
Week 44																	
Placebo		14	25.9	7.5	14 (100.0%)	4.9	4.2	-3.4	13.3								
Nera 18mg		22	23.3	3.4	22 (91.7%)	3.1	3.3	-3.4	9.6	-1.8	5.4	-12.4	8.7	0.7332			
Week 52																	
Placebo		14	33.7	8.0	14 (100.0%)	12.6	4.4	3.8	21.3								
Nera 18mg		20	24.4	4.4	20 (83.3%)	4.1	3.6	-2.8	11.1	-8.4	5.7	-19.6	2.7	0.1385			
Week 64																	
Placebo		11	18.1	5.5	11 (78.6%)	7.3	4.6	-1.8	16.5								
Nera 18mg		17	26.1	4.7	17 (70.8%)	6.8	3.7	-0.5	14.0	-0.6	5.9	-12.2	11.0	0.9211			
Week 76																	
Placebo		8	22.1	8.5	8 (57.1%)												
Nera 18mg		11	22.0	6.1	11 (45.8%)												
Week 88																	
Placebo		1	8.6	NC	1 (7.1%)												
Nera 18mg		3	52.2	18.5	3 (12.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Dyspnea domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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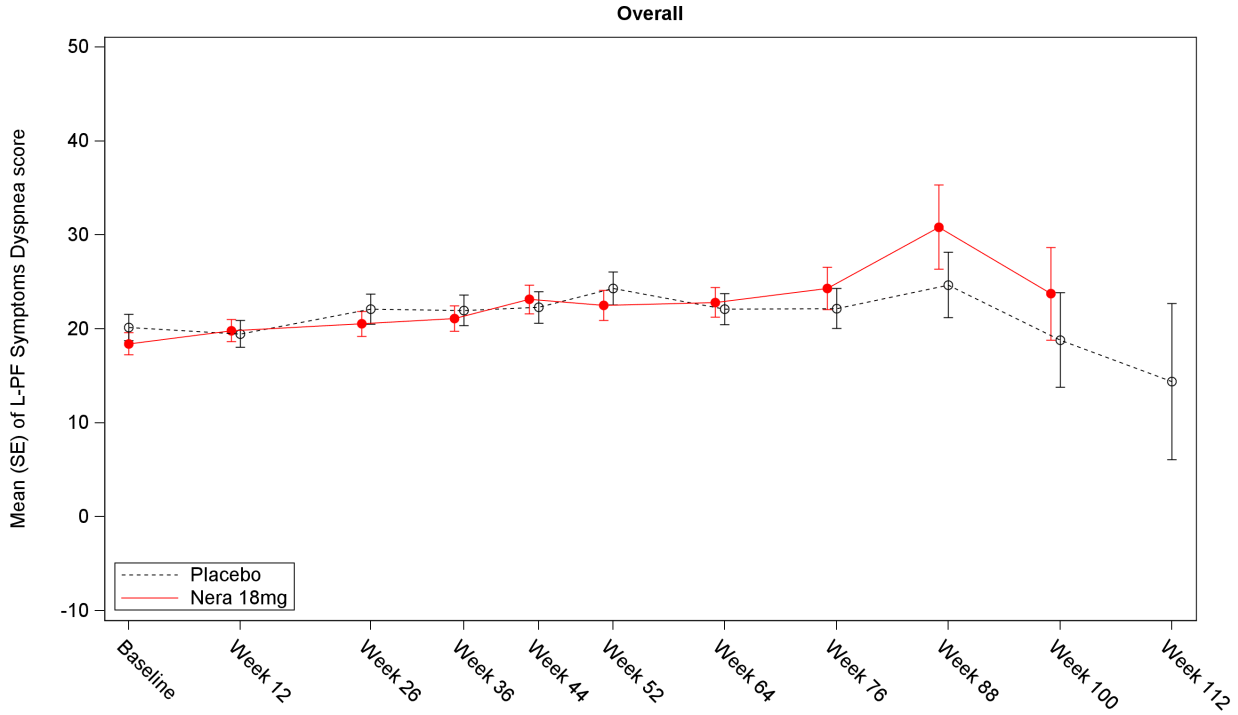

Number of patients

Placebo	169	162	156	151	147	148	128	88	38	11	4
Nera 18mg	169	163	153	146	140	138	122	80	31	9	0

Study: 1305-0023. Number of patients refers to the number of patients with observed data at visit.

Figure I.1.1.1.2.1: 5 Mean (SE) of L-PF Symptoms Dyspnea domain score over the whole trial - 18mg - FAS (NIN background)

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Overall																	
Baseline																	
Placebo	169	169	32.8	1.4	164 (100.0%)												
Nera 18mg	170	169	34.1	1.3	164 (100.0%)												
Week 12																	
Placebo		161	34.0	1.5	161 (98.2%)	1.7	1.1	-0.5	3.8								
Nera 18mg		163	37.9	1.4	162 (98.8%)	4.1	1.1	2.0	6.2	2.4	1.5	-0.6	5.4	0.1116			
Week 26																	
Placebo		156	36.7	1.5	156 (95.1%)	4.4	1.2	2.1	6.8								
Nera 18mg		153	37.7	1.6	152 (92.7%)	4.2	1.2	1.9	6.6	-0.2	1.7	-3.6	3.2	0.9087			
Week 36																	
Placebo		151	36.4	1.6	151 (92.1%)	4.6	1.3	2.1	7.1								
Nera 18mg		146	38.6	1.5	146 (89.0%)	5.1	1.3	2.6	7.7	0.5	1.8	-3.0	4.1	0.7646			
Week 44																	
Placebo		147	36.1	1.6	147 (89.6%)	4.5	1.3	2.0	6.9								
Nera 18mg		140	39.1	1.7	139 (84.8%)	5.5	1.3	3.0	8.1	1.1	1.8	-2.5	4.6	0.5500			
Week 52																	
Placebo		148	37.5	1.7	148 (90.2%)	5.5	1.3	2.8	8.1								
Nera 18mg		138	39.9	1.7	138 (84.1%)	7.1	1.4	4.4	9.8	1.6	1.9	-2.2	5.4	0.4005			
Week 64																	
Placebo		128	37.5	1.7	128 (78.0%)	7.0	1.3	4.4	9.7								
Nera 18mg		122	39.7	1.7	122 (74.4%)	7.9	1.4	5.2	10.6	0.8	1.9	-2.9	4.6	0.6571			
Week 76																	
Placebo		88	36.2	2.0	88 (53.7%)												
Nera 18mg		80	41.5	2.3	80 (48.8%)												
Week 88																	
Placebo		38	36.6	3.4	38 (23.2%)												
Nera 18mg		31	44.8	3.9	31 (18.9%)												
Week 100																	
Placebo		11	32.7	4.9	11 (6.7%)												
Nera 18mg		9	46.1	6.0	9 (5.5%)												
Week 112																	
Placebo		4	28.4	5.7	4 (2.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Fatigue domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Age																	
Test for homogeneity (H0)^																	
Week 12														0.6648			
Week 26														0.9210			
Week 36														0.2883			
Week 44														0.6031			
Week 52														0.9366			
Week 64														0.5930			
<65 years																	
Baseline																	
Placebo	65	65	32.3	2.4	64 (100.0%)												
Nera 18mg	64	64	30.5	1.9	62 (100.0%)												
Week 12																	
Placebo		63	32.7	2.4	63 (98.4%)	0.5	1.7	-2.9	3.9								
Nera 18mg		61	35.2	2.2	61 (98.4%)	3.8	1.8	0.3	7.2	3.3	2.5	-1.6	8.1	0.1858			
Week 26																	
Placebo		62	34.3	2.2	62 (96.9%)	2.4	1.9	-1.4	6.1								
Nera 18mg		58	33.9	2.3	58 (93.5%)	1.9	2.0	-2.0	5.8	-0.4	2.7	-5.8	4.9	0.8718			
Week 36																	
Placebo		62	37.0	2.4	62 (96.9%)	5.0	2.0	1.0	9.0								
Nera 18mg		56	34.9	2.5	56 (90.3%)	3.1	2.1	-1.0	7.3	-1.9	2.9	-7.6	3.9	0.5243			
Week 44																	
Placebo		61	35.7	2.4	61 (95.3%)	3.6	2.0	-0.3	7.5								
Nera 18mg		52	34.0	2.7	52 (83.9%)	3.5	2.1	-0.6	7.6	-0.1	2.9	-5.8	5.5	0.9654			
Week 52																	
Placebo		62	36.5	2.6	62 (96.9%)	4.0	2.1	-0.1	8.1								
Nera 18mg		52	36.9	2.7	52 (83.9%)	5.8	2.2	1.4	10.2	1.8	3.1	-4.3	7.8	0.5638			
Week 64																	
Placebo		57	37.3	2.4	57 (89.1%)	6.1	2.0	2.1	10.1								
Nera 18mg		45	34.7	3.0	45 (72.6%)	5.6	2.2	1.2	10.0	-0.5	3.0	-6.5	5.5	0.8687			
Week 76																	
Placebo		37	36.8	3.5	37 (57.8%)												
Nera 18mg		34	36.3	3.3	34 (54.8%)												
Week 88																	
Placebo		15	41.0	6.3	15 (23.4%)												

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		7	43.6	8.6	7 (11.3%)												
Week 100																	
Placebo		4	35.0	10.6	4 (6.3%)												
Nera 18mg		1	25.0	NC	1 (1.6%)												
Week 112																	
Placebo		2	35.0	10.0	2 (3.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	104	104	33.1	1.8	100 (100.0%)												
Nera 18mg	106	105	36.2	1.7	102 (100.0%)												
Week 12																	
Placebo		98	34.9	1.9	98 (98.0%)	2.4	1.4	-0.3	5.1								
Nera 18mg		102	39.5	1.8	101 (99.0%)	4.3	1.4	1.6	7.0	1.9	2.0	-1.9	5.7	0.3311			
Week 26																	
Placebo		94	38.3	1.9	94 (94.0%)	5.8	1.5	2.8	8.8								
Nera 18mg		95	40.0	2.1	94 (92.2%)	5.7	1.5	2.6	8.7	-0.1	2.2	-4.4	4.2	0.9659			
Week 36																	
Placebo		89	36.0	2.1	89 (89.0%)	4.2	1.7	1.0	7.5								
Nera 18mg		90	40.9	1.9	90 (88.2%)	6.4	1.7	3.1	9.6	2.1	2.4	-2.5	6.8	0.3656			
Week 44																	
Placebo		86	36.5	2.2	86 (86.0%)	5.0	1.6	1.8	8.2								
Nera 18mg		88	42.1	2.1	87 (85.3%)	6.8	1.6	3.6	10.0	1.8	2.3	-2.8	6.3	0.4375			
Week 52																	
Placebo		86	38.3	2.2	86 (86.0%)	6.4	1.7	3.0	9.9								
Nera 18mg		86	41.7	2.1	86 (84.3%)	7.9	1.7	4.4	11.3	1.5	2.5	-3.4	6.3	0.5569			
Week 64																	
Placebo		71	37.7	2.3	71 (71.0%)	7.7	1.8	4.2	11.1								
Nera 18mg		77	42.7	2.0	77 (75.5%)	9.3	1.7	5.9	12.7	1.6	2.5	-3.3	6.5	0.5189			
Week 76																	
Placebo		51	35.7	2.5	51 (51.0%)												
Nera 18mg		46	45.3	3.1	46 (45.1%)												
Week 88																	
Placebo		23	33.7	3.8	23 (23.0%)												
Nera 18mg		24	45.2	4.4	24 (23.5%)												
Week 100																	

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		7	31.4	5.4	7 (7.0%)												
Nera 18mg		8	48.8	6.1	8 (7.8%)												
Week 112																	
Placebo		2	21.9	3.1	2 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Sex																	
Test for homogeneity (H0)^																	
Week 12														0.5015			
Week 26														0.5623			
Week 36														0.3929			
Week 44														0.5207			
Week 52														0.4007			
Week 64														0.0406			
Male																	
Baseline																	
Placebo	114	114	30.4	1.7	111 (100.0%)												
Nera 18mg	108	107	33.0	1.7	102 (100.0%)												
Week 12																	
Placebo		109	33.3	1.7	109 (98.2%)	2.7	1.3	0.1	5.3								
Nera 18mg		102	37.5	1.7	101 (99.0%)	4.4	1.4	1.8	7.1	1.8	1.9	-2.0	5.5	0.3500			
Week 26																	
Placebo		104	35.3	1.8	104 (93.7%)	4.7	1.5	1.8	7.6								
Nera 18mg		95	38.2	2.0	94 (92.2%)	5.4	1.5	2.3	8.4	0.7	2.1	-3.6	4.9	0.7597			
Week 36																	
Placebo		100	35.1	1.9	100 (90.1%)	5.0	1.6	1.9	8.1								
Nera 18mg		88	39.9	2.0	88 (86.3%)	6.9	1.7	3.6	10.1	1.9	2.3	-2.6	6.4	0.4088			
Week 44																	
Placebo		97	34.7	2.0	97 (87.4%)	4.8	1.5	1.8	7.8								
Nera 18mg		83	39.7	2.1	82 (80.4%)	6.9	1.6	3.6	10.1	2.1	2.3	-2.4	6.5	0.3569			
Week 52																	
Placebo		97	36.1	2.0	97 (87.4%)	6.0	1.7	2.8	9.3								
Nera 18mg		82	41.4	2.2	82 (80.4%)	9.1	1.8	5.6	12.5	3.0	2.4	-1.7	7.8	0.2069			
Week 64																	

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		82	34.4	2.0	82 (73.9%)	6.1	1.6	2.9	9.4								
Nera 18mg		74	42.1	2.1	74 (72.5%)	10.1	1.7	6.7	13.5	4.0	2.4	-0.7	8.7	0.0960			
Week 76																	
Placebo		54	34.8	2.6	54 (48.6%)												
Nera 18mg		47	45.5	3.2	47 (46.1%)												
Week 88																	
Placebo		25	37.9	4.2	25 (22.5%)												
Nera 18mg		18	48.3	5.5	18 (17.6%)												
Week 100																	
Placebo		7	35.0	6.4	7 (6.3%)												
Nera 18mg		4	56.3	5.2	4 (3.9%)												
Week 112																	
Placebo		2	21.9	3.1	2 (1.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Female																	
Baseline																	
Placebo	55	55	37.7	2.6	53 (100.0%)												
Nera 18mg	62	62	35.8	2.1	62 (100.0%)												
Week 12																	
Placebo		52	35.6	2.8	52 (98.1%)	-0.4	1.9	-4.2	3.3								
Nera 18mg		61	38.5	2.3	61 (98.4%)	3.5	1.8	0.0	6.9	3.9	2.6	-1.2	9.0	0.1293			
Week 26																	
Placebo		52	39.5	2.5	52 (98.1%)	3.9	2.1	-0.3	8.0								
Nera 18mg		58	36.9	2.6	58 (93.5%)	2.4	2.0	-1.4	6.3	-1.4	2.9	-7.1	4.2	0.6198			
Week 36																	
Placebo		51	39.1	2.8	51 (96.2%)	3.8	2.2	-0.6	8.2								
Nera 18mg		58	36.7	2.5	58 (93.5%)	2.4	2.1	-1.7	6.5	-1.4	3.0	-7.3	4.6	0.6528			
Week 44																	
Placebo		50	38.9	2.7	50 (94.3%)	3.7	2.2	-0.5	8.0								
Nera 18mg		57	38.3	2.8	57 (91.9%)	3.4	2.0	-0.6	7.4	-0.3	3.0	-6.2	5.5	0.9137			
Week 52																	
Placebo		51	40.1	3.0	51 (96.2%)	4.4	2.3	-0.2	8.9								
Nera 18mg		56	37.7	2.5	56 (90.3%)	4.0	2.2	-0.2	8.3	-0.3	3.2	-6.6	5.9	0.9218			
Week 64																	
Placebo		46	43.1	2.9	46 (86.8%)	8.5	2.2	4.1	12.9								
Nera 18mg		48	36.0	2.7	48 (77.4%)	4.4	2.1	0.2	8.6	-4.1	3.1	-10.2	2.0	0.1875			

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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 76																	
Placebo		34	38.3	3.3	34 (64.2%)												
Nera 18mg		33	35.8	3.1	33 (53.2%)												
Week 88																	
Placebo		13	34.1	5.8	13 (24.5%)												
Nera 18mg		13	40.0	5.0	13 (21.0%)												
Week 100																	
Placebo		4	28.8	8.3	4 (7.5%)												
Nera 18mg		5	38.0	8.7	5 (8.1%)												
Week 112																	
Placebo		2	35.0	10.0	2 (3.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 12														0.2833			
Week 26														0.4070			
Week 36														0.6160			
Week 44														0.7484			
Week 52														0.4069			
Week 64														0.9718			
<=70%																	
Baseline																	
Placebo	95	95	34.7	2.0	91 (100.0%)												
Nera 18mg	97	97	37.0	1.6	96 (100.0%)												
Week 12																	
Placebo		88	37.4	2.0	88 (96.7%)	4.0	1.4	1.1	6.8								
Nera 18mg		96	40.4	1.8	96 (100.0%)	4.9	1.4	2.1	7.7	0.9	2.0	-3.0	4.9	0.6525			
Week 26																	
Placebo		85	39.0	2.1	85 (93.4%)	5.5	1.6	2.3	8.6								
Nera 18mg		88	41.5	1.9	88 (91.7%)	6.4	1.6	3.3	9.6	1.0	2.3	-3.5	5.4	0.6708			
Week 36																	
Placebo		83	38.9	2.2	83 (91.2%)	5.8	1.7	2.4	9.2								
Nera 18mg		85	41.9	1.9	85 (88.5%)	7.1	1.7	3.7	10.4	1.3	2.4	-3.5	6.0	0.6019			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Fatigue domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 44																	
Placebo		81	39.8	2.1	81 (89.0%)	6.7	1.7	3.4	10.0								
Nera 18mg		80	42.7	2.2	80 (83.3%)	8.2	1.7	4.9	11.5	1.4	2.4	-3.2	6.1	0.5455			
Week 52																	
Placebo		80	43.0	2.3	80 (87.9%)	9.4	1.8	5.9	12.9								
Nera 18mg		79	43.7	2.1	79 (82.3%)	9.4	1.8	5.9	12.9	0.0	2.5	-4.9	4.9	0.9960			
Week 64																	
Placebo		70	41.3	2.4	70 (76.9%)	9.7	1.8	6.2	13.2								
Nera 18mg		70	43.1	2.1	70 (72.9%)	10.4	1.8	6.8	13.9	0.6	2.5	-4.3	5.6	0.8019			
Week 76																	
Placebo		45	38.4	3.0	45 (49.5%)												
Nera 18mg		44	46.4	3.3	44 (45.8%)												
Week 88																	
Placebo		20	38.0	4.7	20 (22.0%)												
Nera 18mg		19	49.5	4.6	19 (19.8%)												
Week 100																	
Placebo		5	42.0	6.0	5 (5.5%)												
Nera 18mg		5	49.0	7.3	5 (5.2%)												
Week 112																	
Placebo		3	31.7	6.7	3 (3.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	74	74	30.3	2.0	73 (100.0%)												
Nera 18mg	73	72	30.1	2.1	68 (100.0%)												
Week 12																	
Placebo		73	29.9	2.0	73 (100.0%)	-1.2	1.6	-4.4	1.9								
Nera 18mg		67	34.2	2.1	66 (97.1%)	3.0	1.7	-0.3	6.3	4.2	2.3	-0.3	8.7	0.0703			
Week 26																	
Placebo		71	34.0	2.0	71 (97.3%)	3.2	1.8	-0.4	6.7								
Nera 18mg		65	32.4	2.5	64 (94.1%)	1.3	1.9	-2.4	5.0	-1.9	2.6	-7.0	3.2	0.4652			
Week 36																	
Placebo		68	33.4	2.2	68 (93.2%)	3.1	1.9	-0.7	6.8								
Nera 18mg		61	34.1	2.5	61 (89.7%)	2.5	2.0	-1.5	6.4	-0.6	2.8	-6.0	4.9	0.8340			
Week 44																	
Placebo		66	31.7	2.4	66 (90.4%)	1.7	1.9	-2.0	5.3								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Fatigue domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		60	34.3	2.5	59 (86.8%)	1.9	2.0	-1.9	5.8	0.3	2.7	-5.0	5.6	0.9166			
Week 52																	
Placebo		68	31.0	2.2	68 (93.2%)	0.7	2.0	-3.1	4.6								
Nera 18mg		59	34.8	2.6	59 (86.8%)	3.9	2.1	-0.2	8.0	3.2	2.8	-2.4	8.7	0.2667			
Week 64																	
Placebo		58	33.0	2.2	58 (79.5%)	3.7	2.0	-0.1	7.6								
Nera 18mg		52	35.2	2.6	52 (76.5%)	4.5	2.1	0.4	8.6	0.8	2.8	-4.8	6.4	0.7882			
Week 76																	
Placebo		43	33.9	2.7	43 (58.9%)												
Nera 18mg		36	35.5	2.9	36 (52.9%)												
Week 88																	
Placebo		18	35.0	4.9	18 (24.7%)												
Nera 18mg		12	37.5	6.5	12 (17.6%)												
Week 100																	
Placebo		6	25.0	6.1	6 (8.2%)												
Nera 18mg		4	42.5	10.9	4 (5.9%)												
Week 112																	
Placebo		1	18.8	NC	1 (1.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline HRCT pattern																	
Test for homogeneity (H0)^																	
Week 12														0.3725			
Week 26														0.6135			
Week 36														0.1861			
Week 44														0.9050			
Week 52														0.7202			
Week 64														0.3065			
UIP-like																	
Baseline																	
Placebo	116	116	32.2	1.8	113 (100.0%)												
Nera 18mg	121	120	34.2	1.5	117 (100.0%)												
Week 12																	
Placebo		111	33.1	1.8	111 (98.2%)	1.1	1.3	-1.5	3.6								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Fatigue domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg		117	38.4	1.6	116 (99.1%)	4.4	1.3	1.9	6.9	3.3	1.8	-0.3	6.9	0.0692			
Week 26																	
Placebo		107	36.5	1.7	107 (94.7%)	4.7	1.5	1.8	7.5								
Nera 18mg		110	37.6	1.8	109 (93.2%)	3.9	1.4	1.1	6.8	-0.8	2.0	-4.8	3.3	0.7089			
Week 36																	
Placebo		103	34.5	1.9	103 (91.2%)	3.4	1.5	0.4	6.4								
Nera 18mg		104	39.4	1.9	104 (88.9%)	5.6	1.5	2.5	8.6	2.1	2.2	-2.1	6.4	0.3252			
Week 44																	
Placebo		99	36.3	2.0	99 (87.6%)	5.7	1.5	2.7	8.7								
Nera 18mg		100	40.9	2.0	99 (84.6%)	6.9	1.5	3.9	9.9	1.2	2.2	-3.0	5.4	0.5745			
Week 52																	
Placebo		100	36.1	2.1	100 (88.5%)	5.1	1.6	1.9	8.3								
Nera 18mg		100	40.1	2.1	100 (85.5%)	7.2	1.6	4.0	10.4	2.1	2.3	-2.4	6.6	0.3674			
Week 64																	
Placebo		90	37.4	2.1	90 (79.6%)	7.4	1.6	4.2	10.6								
Nera 18mg		87	41.3	2.0	87 (74.4%)	9.5	1.6	6.4	12.7	2.1	2.3	-2.4	6.6	0.3504			
Week 76																	
Placebo		60	34.9	2.4	60 (53.1%)												
Nera 18mg		59	42.3	2.5	59 (50.4%)												
Week 88																	
Placebo		26	35.1	4.1	26 (23.0%)												
Nera 18mg		23	45.0	4.4	23 (19.7%)												
Week 100																	
Placebo		9	33.9	5.9	9 (8.0%)												
Nera 18mg		8	43.1	5.9	8 (6.8%)												
Week 112																	
Placebo		3	29.6	7.9	3 (2.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other fibrotic patterns																	
Baseline																	
Placebo	53	53	34.0	2.6	51 (100.0%)												
Nera 18mg	49	49	33.6	2.6	47 (100.0%)												
Week 12																	
Placebo		50	36.2	2.6	50 (98.0%)	3.0	1.9	-0.8	6.8								
Nera 18mg		46	36.6	2.7	46 (97.9%)	3.3	2.0	-0.6	7.3	0.3	2.8	-5.1	5.8	0.9026			
Week 26																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Fatigue domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		49	37.3	2.7	49 (96.1%)	3.9	2.1	-0.3	8.1								
Nera 18mg		43	37.9	3.0	43 (91.5%)	5.1	2.3	0.6	9.5	1.1	3.1	-5.0	7.3	0.7189			
Week 36																	
Placebo		48	40.5	2.7	48 (94.1%)	7.2	2.3	2.7	11.7								
Nera 18mg		42	36.6	2.8	42 (89.4%)	4.1	2.4	-0.7	8.8	-3.1	3.3	-9.6	3.4	0.3483			
Week 44																	
Placebo		48	35.9	2.7	48 (94.1%)	1.8	2.2	-2.6	6.1								
Nera 18mg		40	34.6	3.0	40 (85.1%)	2.5	2.4	-2.2	7.2	0.7	3.3	-5.7	7.1	0.8195			
Week 52																	
Placebo		48	40.4	2.9	48 (94.1%)	6.3	2.4	1.6	10.9								
Nera 18mg		38	39.4	2.6	38 (80.9%)	6.8	2.6	1.7	11.9	0.6	3.5	-6.3	7.5	0.8716			
Week 64																	
Placebo		38	37.8	2.8	38 (74.5%)	6.1	2.4	1.3	10.8								
Nera 18mg		35	35.8	3.1	35 (74.5%)	3.9	2.5	-1.1	8.9	-2.2	3.5	-9.1	4.7	0.5385			
Week 76																	
Placebo		28	38.9	3.8	28 (54.9%)												
Nera 18mg		21	39.1	5.4	21 (44.7%)												
Week 88																	
Placebo		12	39.7	6.2	12 (23.5%)												
Nera 18mg		8	44.4	8.6	8 (17.0%)												
Week 100																	
Placebo		2	27.5	2.5	2 (3.9%)												
Nera 18mg		1	70.0	NC	1 (2.1%)												
Week 112																	
Placebo		1	25.0	NC	1 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Underlying ILD diagnosis																	
Test for homogeneity (H0)^																	
Week 12														0.4127			
Week 26														0.5002			
Week 36														0.9400			
Week 44														0.0731			
Week 52														0.0228			
Week 64														0.3525			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Fatigue domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
iNSIP																	
Baseline																	
Placebo	32	32	31.3	3.6	31 (100.0%)												
Nera 18mg	27	27	32.7	3.5	25 (100.0%)												
Week 12																	
Placebo		29	31.5	3.8	29 (93.5%)	0.4	2.5	-4.6	5.4								
Nera 18mg		24	38.5	4.7	24 (96.0%)	6.1	2.8	0.6	11.6	5.7	3.8	-1.8	13.1	0.1354			
Week 26																	
Placebo		29	34.8	3.7	29 (93.5%)	3.2	2.8	-2.3	8.7								
Nera 18mg		23	37.0	4.0	23 (92.0%)	5.4	3.1	-0.8	11.5	2.2	4.2	-6.1	10.5	0.5987			
Week 36																	
Placebo		28	34.5	4.1	28 (90.3%)	4.0	3.0	-1.9	9.9								
Nera 18mg		21	36.5	4.0	21 (84.0%)	5.3	3.4	-1.5	12.0	1.3	4.5	-7.7	10.2	0.7758			
Week 44																	
Placebo		28	33.2	4.2	28 (90.3%)	2.3	2.9	-3.3	8.0								
Nera 18mg		19	42.1	5.3	19 (76.0%)	11.3	3.4	4.7	18.0	9.0	4.4	0.3	17.8	0.0438	0.59	0.00	1.17
Week 52																	
Placebo		27	33.3	4.2	27 (87.1%)	2.3	3.1	-3.8	8.4								
Nera 18mg		17	43.8	4.8	17 (68.0%)	14.4	3.7	7.1	21.7	12.0	4.8	2.5	21.6	0.0132	0.75	0.13	1.37
Week 64																	
Placebo		23	36.5	4.3	23 (74.2%)	5.5	3.1	-0.7	11.7								
Nera 18mg		17	40.7	5.5	17 (68.0%)	11.1	3.7	3.8	18.3	5.5	4.8	-4.0	15.1	0.2537			
Week 76																	
Placebo		16	37.1	5.7	16 (51.6%)												
Nera 18mg		10	52.5	8.8	10 (40.0%)												
Week 88																	
Placebo		9	34.0	7.4	9 (29.0%)												
Nera 18mg		3	61.7	18.3	3 (12.0%)												
Week 100																	
Placebo		2	17.5	7.5	2 (6.5%)												
Nera 18mg		1	70.0	NC	1 (4.0%)												
Week 112																	
Placebo		2	21.9	3.1	2 (6.5%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Unclassifiable IIP																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Fatigue domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Baseline																	
Placebo	46	46	31.4	2.5	44 (100.0%)												
Nera 18mg	32	32	34.1	2.9	32 (100.0%)												
Week 12																	
Placebo		44	35.2	2.8	44 (100.0%)	4.1	2.1	0.1	8.2								
Nera 18mg		32	36.4	2.9	32 (100.0%)	2.8	2.4	-2.1	7.6	-1.4	3.2	-7.7	4.9	0.6654			
Week 26																	
Placebo		40	36.0	3.0	40 (90.9%)	4.6	2.4	-0.0	9.3								
Nera 18mg		28	33.7	3.0	28 (87.5%)	-0.6	2.8	-6.2	4.9	-5.3	3.7	-12.5	2.0	0.1563			
Week 36																	
Placebo		38	36.5	3.1	38 (86.4%)	5.9	2.6	0.9	10.9								
Nera 18mg		27	40.3	3.7	27 (84.4%)	6.6	3.0	0.6	12.5	0.7	4.0	-7.1	8.5	0.8579			
Week 44																	
Placebo		37	38.5	3.4	37 (84.1%)	8.3	2.5	3.4	13.2								
Nera 18mg		27	37.6	3.5	27 (84.4%)	3.2	2.9	-2.5	8.9	-5.1	3.8	-12.6	2.4	0.1816			
Week 52																	
Placebo		38	38.2	3.3	38 (86.4%)	7.7	2.6	2.6	12.8								
Nera 18mg		28	35.1	3.8	28 (87.5%)	0.7	3.1	-5.3	6.7	-7.0	4.0	-14.9	0.9	0.0813			
Week 64																	
Placebo		32	37.6	3.2	32 (72.7%)	8.7	2.7	3.4	13.9								
Nera 18mg		23	39.8	3.1	23 (71.9%)	8.0	3.1	1.8	14.2	-0.7	4.1	-8.8	7.5	0.8700			
Week 76																	
Placebo		25	35.0	3.7	25 (56.8%)												
Nera 18mg		17	39.2	3.8	17 (53.1%)												
Week 88																	
Placebo		10	42.9	6.1	10 (22.7%)												
Nera 18mg		10	41.0	6.9	10 (31.3%)												
Week 100																	
Placebo		2	42.5	12.5	2 (4.5%)												
Nera 18mg		3	38.3	14.2	3 (9.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
HP																	
Baseline																	
Placebo	38	38	29.8	2.8	38 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Fatigue domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg	43	43	40.6	2.8	41 (100.0%)												
Week 12																	
Placebo		38	31.7	2.6	38 (100.0%)	0.9	2.2	-3.5	5.3								
Nera 18mg		41	41.6	2.8	41 (100.0%)	2.9	2.2	-1.5	7.2	1.9	3.1	-4.2	8.1	0.5372			
Week 26																	
Placebo		38	34.1	3.1	38 (100.0%)	3.1	2.5	-1.8	8.0								
Nera 18mg		38	43.0	3.5	38 (92.7%)	5.0	2.5	0.1	9.9	1.9	3.5	-5.0	8.8	0.5935			
Week 36																	
Placebo		38	36.2	2.7	38 (100.0%)	5.0	2.6	-0.1	10.2								
Nera 18mg		37	42.2	2.9	37 (90.2%)	4.7	2.6	-0.5	9.8	-0.4	3.7	-7.7	6.9	0.9229			
Week 44																	
Placebo		37	33.2	2.6	37 (97.4%)	2.6	2.5	-2.3	7.6								
Nera 18mg		35	44.1	3.7	35 (85.4%)	6.7	2.6	1.7	11.8	4.1	3.6	-3.0	11.2	0.2575			
Week 52																	
Placebo		37	35.1	3.2	37 (97.4%)	3.9	2.7	-1.4	9.2								
Nera 18mg		34	46.7	3.2	34 (82.9%)	9.5	2.8	4.1	15.0	5.6	3.9	-1.9	13.2	0.1446			
Week 64																	
Placebo		33	35.7	3.4	33 (86.8%)	6.4	2.7	1.1	11.7								
Nera 18mg		30	44.8	3.3	30 (73.2%)	8.3	2.8	2.8	13.8	1.9	3.9	-5.7	9.6	0.6158			
Week 76																	
Placebo		18	37.6	4.5	18 (47.4%)												
Nera 18mg		17	44.9	4.9	17 (41.5%)												
Week 88																	
Placebo		8	30.9	7.9	8 (21.1%)												
Nera 18mg		5	51.0	4.8	5 (12.2%)												
Week 100																	
Placebo		1	25.0	NC	1 (2.6%)												
Nera 18mg		1	55.0	NC	1 (2.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Autoimmune ILD																	
Baseline																	
Placebo	29	29	34.7	3.8	28 (100.0%)												
Nera 18mg	43	42	30.1	2.3	42 (100.0%)												
Week 12																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Fatigue domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo		27	33.6	4.4	27 (96.4%)	-0.1	2.6	-5.3	5.1								
Nera 18mg		43	34.7	2.2	42 (100.0%)	3.7	2.1	-0.5	7.9	3.8	3.4	-2.9	10.5	0.2624			
Week 26																	
Placebo		27	37.9	3.3	27 (96.4%)	4.5	2.9	-1.2	10.3								
Nera 18mg		41	34.8	3.2	40 (95.2%)	4.2	2.4	-0.5	8.9	-0.3	3.8	-7.7	7.1	0.9311			
Week 36																	
Placebo		26	34.0	3.9	26 (92.9%)	1.3	3.1	-4.8	7.4								
Nera 18mg		38	34.4	3.1	38 (90.5%)	2.7	2.6	-2.3	7.8	1.4	4.0	-6.5	9.3	0.7291			
Week 44																	
Placebo		24	35.6	4.2	24 (85.7%)	2.8	3.0	-3.2	8.8								
Nera 18mg		37	32.5	2.9	36 (85.7%)	0.7	2.5	-4.3	5.6	-2.1	3.9	-9.9	5.6	0.5860			
Week 52																	
Placebo		25	38.4	4.4	25 (89.3%)	5.1	3.2	-1.3	11.4								
Nera 18mg		37	33.5	3.1	37 (88.1%)	3.2	2.7	-2.0	8.4	-1.9	4.2	-10.1	6.3	0.6496			
Week 64																	
Placebo		21	36.4	3.8	21 (75.0%)	6.0	3.3	-0.4	12.5								
Nera 18mg		33	33.0	3.3	33 (78.6%)	3.4	2.7	-1.9	8.6	-2.7	4.2	-11.0	5.6	0.5260			
Week 76																	
Placebo		16	35.0	5.2	16 (57.1%)												
Nera 18mg		19	30.6	3.9	19 (45.2%)												
Week 88																	
Placebo		6	32.8	7.7	6 (21.4%)												
Nera 18mg		5	38.0	7.2	5 (11.9%)												
Week 100																	
Placebo		4	33.8	9.9	4 (14.3%)												
Nera 18mg		2	37.5	12.5	2 (4.8%)												
Week 112																	
Placebo		2	35.0	10.0	2 (7.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other ILD																	
Baseline																	
Placebo	24	24	39.6	3.9	23 (100.0%)												
Nera 18mg	25	25	30.9	3.0	24 (100.0%)												
Week 12																	
Placebo		23	39.3	3.3	23 (100.0%)	1.9	2.9	-3.7	7.6								
Nera 18mg		23	38.5	3.8	23 (95.8%)	6.5	2.9	0.9	12.2	4.6	4.1	-3.4	12.6	0.2589			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Fatigue domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 26																	
Placebo		22	43.8	2.9	22 (95.7%)	7.8	3.2	1.5	14.2								
Nera 18mg		23	39.4	3.5	23 (95.8%)	7.9	3.1	1.7	14.0	0.0	4.5	-8.9	8.9	0.9932			
Week 36																	
Placebo		21	42.2	4.2	21 (91.3%)	6.2	3.5	-0.6	13.0								
Nera 18mg		23	39.7	4.1	23 (95.8%)	8.1	3.3	1.6	14.6	1.9	4.8	-7.5	11.4	0.6876			
Week 44																	
Placebo		21	41.7	4.0	21 (91.3%)	5.6	3.3	-0.9	12.2								
Nera 18mg		22	41.5	3.7	22 (91.7%)	9.6	3.2	3.3	16.0	4.0	4.6	-5.1	13.1	0.3893			
Week 52																	
Placebo		21	45.0	3.7	21 (91.3%)	8.7	3.5	1.7	15.7								
Nera 18mg		22	43.2	4.0	22 (91.7%)	11.7	3.4	4.9	18.5	3.0	5.0	-6.7	12.8	0.5433			
Week 64																	
Placebo		19	43.1	4.5	19 (82.6%)	8.5	3.5	1.6	15.5								
Nera 18mg		19	42.6	4.0	19 (79.2%)	12.3	3.5	5.5	19.2	3.8	5.0	-6.0	13.6	0.4461			
Week 76																	
Placebo		13	36.9	4.2	13 (56.5%)												
Nera 18mg		17	46.0	5.0	17 (70.8%)												
Week 88																	
Placebo		5	42.3	11.2	5 (21.7%)												
Nera 18mg		8	43.8	9.1	8 (33.3%)												
Week 100																	
Placebo		2	40.0	10.0	2 (8.7%)												
Nera 18mg		2	50.0	5.0	2 (8.3%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Region																	
Test for homogeneity (H0)^																	
Week 12														0.2104			
Week 26														0.8875			
Week 36														0.5008			
Week 44														0.2358			
Week 52														0.8102			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 64														0.4956			
Europe																	
Baseline																	
Placebo	78	78	33.9	2.1	77 (100.0%)												
Nera 18mg	67	66	34.0	2.1	64 (100.0%)												
Week 12																	
Placebo		75	36.5	2.2	75 (97.4%)	3.5	1.6	0.4	6.6								
Nera 18mg		65	36.7	1.9	64 (100.0%)	3.2	1.7	-0.2	6.6	-0.3	2.3	-4.9	4.3	0.9025			
Week 26																	
Placebo		73	40.0	2.2	73 (94.8%)	6.8	1.7	3.4	10.2								
Nera 18mg		59	40.3	2.3	58 (90.6%)	7.5	2.0	3.7	11.4	0.7	2.6	-4.4	5.9	0.7814			
Week 36																	
Placebo		69	39.1	2.4	69 (89.6%)	6.7	1.9	3.0	10.4								
Nera 18mg		55	39.1	2.4	55 (85.9%)	6.3	2.1	2.1	10.5	-0.4	2.8	-6.0	5.2	0.8887			
Week 44																	
Placebo		68	38.7	2.3	68 (88.3%)	6.2	1.8	2.6	9.8								
Nera 18mg		54	38.1	2.6	53 (82.8%)	5.2	2.1	1.1	9.3	-1.0	2.8	-6.5	4.5	0.7177			
Week 52																	
Placebo		69	38.8	2.4	69 (89.6%)	6.3	2.0	2.5	10.2								
Nera 18mg		53	40.4	2.6	53 (82.8%)	7.5	2.2	3.1	11.8	1.1	3.0	-4.8	7.0	0.7108			
Week 64																	
Placebo		63	39.3	2.4	63 (81.8%)	7.7	1.9	4.0	11.5								
Nera 18mg		52	42.8	2.6	52 (81.3%)	10.1	2.1	5.9	14.3	2.4	2.9	-3.2	8.0	0.4042			
Week 76																	
Placebo		38	35.7	3.0	38 (49.4%)												
Nera 18mg		30	46.9	3.7	30 (46.9%)												
Week 88																	
Placebo		15	34.0	5.6	15 (19.5%)												
Nera 18mg		8	43.1	6.7	8 (12.5%)												
Week 100																	
Placebo		3	26.7	1.7	3 (3.9%)												
Nera 18mg		2	55.0	0.0	2 (3.1%)												
Week 112																	
Placebo		1	25.0	NC	1 (1.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Fatigue domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Asia																	
Baseline																	
Placebo	45	45	30.6	3.0	43 (100.0%)												
Nera 18mg	41	41	35.7	2.6	39 (100.0%)												
Week 12																	
Placebo		43	30.9	3.0	43 (100.0%)	-0.2	2.1	-4.3	4.0								
Nera 18mg		39	40.9	3.0	39 (100.0%)	6.3	2.2	2.0	10.6	6.5	3.0	0.5	12.4	0.0348	0.46	0.03	0.90
Week 26																	
Placebo		42	33.0	2.7	42 (97.7%)	2.3	2.3	-2.2	6.9								
Nera 18mg		36	35.0	2.9	36 (92.3%)	0.6	2.5	-4.3	5.5	-1.7	3.4	-8.4	5.0	0.6169			
Week 36																	
Placebo		41	34.5	3.1	41 (95.3%)	4.2	2.5	-0.7	9.1								
Nera 18mg		34	38.9	3.1	34 (87.2%)	4.6	2.7	-0.7	9.9	0.4	3.7	-6.8	7.6	0.9174			
Week 44																	
Placebo		38	35.8	3.6	38 (88.4%)	5.5	2.5	0.7	10.4								
Nera 18mg		31	40.8	3.4	31 (79.5%)	4.5	2.7	-0.8	9.7	-1.1	3.6	-8.2	6.1	0.7669			
Week 52																	
Placebo		39	36.1	3.7	39 (90.7%)	5.5	2.6	0.3	10.6								
Nera 18mg		32	39.2	3.2	32 (82.1%)	5.8	2.9	0.2	11.4	0.3	3.9	-7.3	8.0	0.9298			
Week 64																	
Placebo		33	35.2	3.5	33 (76.7%)	7.3	2.6	2.2	12.4								
Nera 18mg		26	36.9	3.8	26 (66.7%)	3.9	2.9	-1.8	9.5	-3.4	3.9	-11.0	4.2	0.3783			
Week 76																	
Placebo		25	34.2	4.4	25 (58.1%)												
Nera 18mg		19	38.6	4.5	19 (48.7%)												
Week 88																	
Placebo		13	38.1	6.4	13 (30.2%)												
Nera 18mg		9	40.6	8.8	9 (23.1%)												
Week 100																	
Placebo		5	38.0	8.7	5 (11.6%)												
Nera 18mg		4	33.8	9.9	4 (10.3%)												
Week 112																	
Placebo		1	45.0	NC	1 (2.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	
Baseline																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Fatigue domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo	30	30	30.9	3.0	30 (100.0%)												
Nera 18mg	37	37	30.3	2.6	37 (100.0%)												
Week 12																	
Placebo		29	31.0	2.9	29 (96.7%)	-1.2	2.6	-6.3	3.8								
Nera 18mg		36	35.7	3.4	36 (97.3%)	4.3	2.3	-0.2	8.8	5.5	3.4	-1.2	12.3	0.1046			
Week 26																	
Placebo		27	33.9	3.1	27 (90.0%)	2.4	2.9	-3.3	8.0								
Nera 18mg		34	32.9	3.2	34 (91.9%)	1.2	2.6	-3.9	6.2	-1.2	3.8	-8.7	6.3	0.7531			
Week 36																	
Placebo		27	33.5	3.2	27 (90.0%)	1.6	3.1	-4.4	7.6								
Nera 18mg		34	36.5	3.0	34 (91.9%)	4.7	2.7	-0.7	10.0	3.0	4.1	-5.0	11.1	0.4572			
Week 44																	
Placebo		27	31.0	3.1	27 (90.0%)	0.2	3.0	-5.6	6.1								
Nera 18mg		33	37.3	3.4	33 (89.2%)	6.8	2.7	1.5	12.0	6.5	4.0	-1.3	14.3	0.1003			
Week 52																	
Placebo		26	34.9	3.3	26 (86.7%)	2.8	3.2	-3.5	9.2								
Nera 18mg		33	38.4	3.6	33 (89.2%)	7.2	2.9	1.5	12.8	4.4	4.3	-4.1	12.8	0.3090			
Week 64																	
Placebo		21	37.7	3.6	21 (70.0%)	5.8	3.2	-0.6	12.1								
Nera 18mg		27	39.4	3.1	27 (73.0%)	10.5	2.9	4.9	16.2	4.8	4.3	-3.7	13.2	0.2700			
Week 76																	
Placebo		17	40.6	4.2	17 (56.7%)												
Nera 18mg		20	44.1	4.3	20 (54.1%)												
Week 88																	
Placebo		9	39.4	6.0	9 (30.0%)												
Nera 18mg		11	47.7	6.6	11 (29.7%)												
Week 100																	
Placebo		3	30.0	11.5	3 (10.0%)												
Nera 18mg		3	56.7	7.3	3 (8.1%)												
Week 112																	
Placebo		2	21.9	3.1	2 (6.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Rest of the World																	
Baseline																	
Placebo	16	16	37.0	5.4	14 (100.0%)												
Nera 18mg	25	25	37.1	3.7	24 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Fatigue domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 6 Adjusted mean (SE) of absolute change from baseline in L-PF Symptoms Fatigue domain score (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 12																	
Placebo		14	37.0	5.5	14 (100.0%)	3.4	3.7	-3.8	10.6								
Nera 18mg		23	39.4	3.8	23 (95.8%)	2.5	2.9	-3.1	8.1	-0.9	4.6	-10.0	8.3	0.8522			
Week 26																	
Placebo		14	36.1	5.5	14 (100.0%)	2.6	4.0	-5.3	10.5								
Nera 18mg		24	42.0	5.1	24 (100.0%)	6.2	3.1	0.1	12.2	3.6	5.1	-6.4	13.5	0.4796			
Week 36																	
Placebo		14	34.4	4.7	14 (100.0%)	0.8	4.3	-7.5	9.2								
Nera 18mg		23	39.9	5.0	23 (95.8%)	4.0	3.3	-2.6	10.5	3.1	5.4	-7.5	13.7	0.5628			
Week 44																	
Placebo		14	34.6	4.9	14 (100.0%)	1.2	4.1	-6.9	9.4								
Nera 18mg		22	41.6	5.0	22 (91.7%)	6.1	3.3	-0.3	12.5	4.9	5.3	-5.5	15.2	0.3567			
Week 52																	
Placebo		14	40.0	6.2	14 (100.0%)	6.5	4.5	-2.3	15.3								
Nera 18mg		20	42.3	5.2	20 (83.3%)	8.0	3.6	0.9	15.1	1.5	5.7	-9.8	12.8	0.7933			
Week 64																	
Placebo		11	33.6	4.9	11 (78.6%)	5.5	4.5	-3.2	14.3								
Nera 18mg		17	35.1	5.0	17 (70.8%)	3.3	3.6	-3.7	10.3	-2.2	5.7	-13.5	9.0	0.6950			
Week 76																	
Placebo		8	35.3	6.1	8 (57.1%)												
Nera 18mg		11	26.9	6.2	11 (45.8%)												
Week 88																	
Placebo		1	30.0	NC	1 (7.1%)												
Nera 18mg		3	51.7	9.3	3 (12.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline L-PF Symptoms Fatigue domain score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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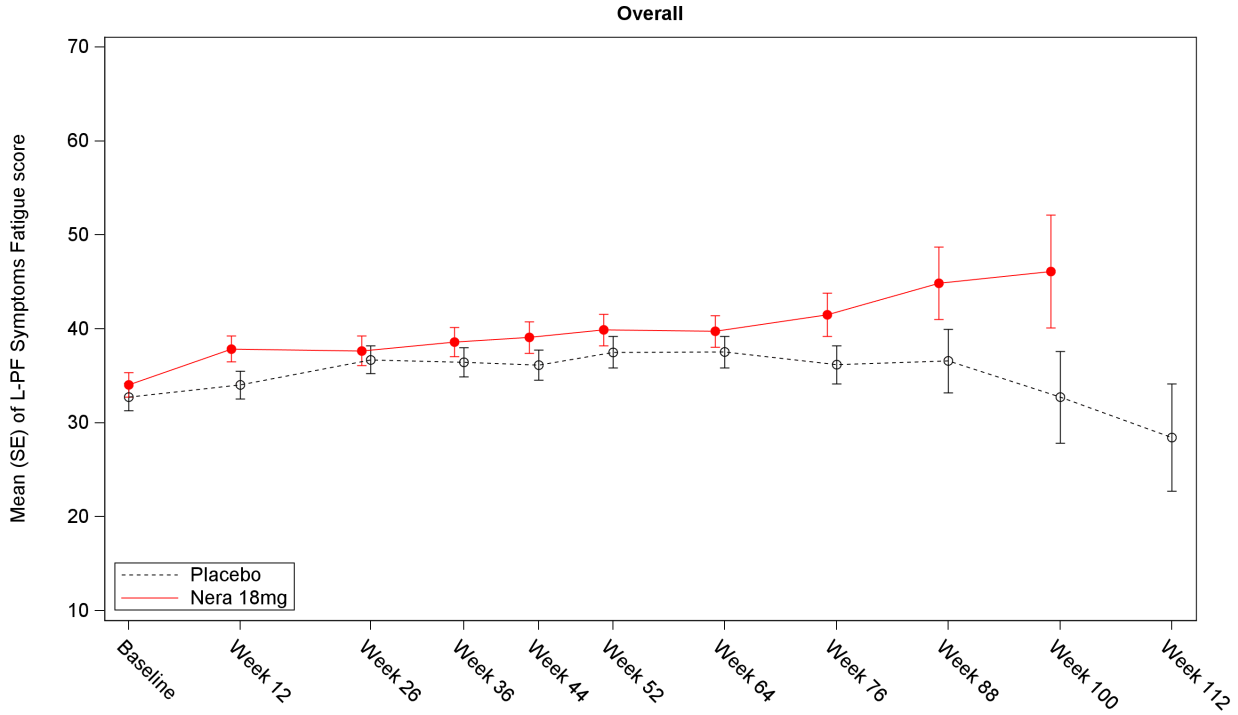

Number of patients

Placebo	169	161	156	151	147	148	128	88	38	11	4
Nera 18mg	169	163	153	146	140	138	122	80	31	9	0

Study: 1305-0023. Number of patients refers to the number of patients with observed data at visit.

Figure I.1.1.1.2.1: 6 Mean (SE) of L-PF Symptoms Fatigue domain score over the whole trial - 18mg - FAS (NIN background)

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	95% CI upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	95% CI upper	p-value	Hedges'g value	95% CI lower	95% CI upper
Overall																	
Baseline																	
Placebo	169	167	70.7	1.3	163 (100.0%)												
Nera 18mg	170	165	70.9	1.3	163 (100.0%)												
Week 6																	
Placebo		163	75.2	1.3	161 (98.8%)	4.2	1.0	2.2	6.2								
Nera 18mg		166	72.2	1.3	161 (98.8%)	0.9	1.0	-1.1	3.0	-3.3	1.4	-6.1	-0.4	0.0239	-0.25	-0.47	-0.03
Week 12																	
Placebo		158	69.6	1.4	156 (95.7%)	-1.5	1.1	-3.6	0.6								
Nera 18mg		158	69.6	1.2	155 (95.1%)	-1.7	1.1	-3.8	0.4	-0.2	1.5	-3.2	2.8	0.9045			
Week 18																	
Placebo		159	71.3	1.3	157 (96.3%)	-0.2	1.1	-2.4	1.9								
Nera 18mg		157	70.8	1.4	153 (93.9%)	-0.5	1.1	-2.7	1.6	-0.3	1.6	-3.4	2.8	0.8418			
Week 26																	
Placebo		155	68.3	1.5	153 (93.9%)	-2.7	1.1	-4.9	-0.5								
Nera 18mg		149	69.8	1.3	145 (89.0%)	-1.9	1.1	-4.2	0.4	0.8	1.6	-2.4	4.0	0.6196			
Week 36																	
Placebo		149	70.4	1.4	147 (90.2%)	-1.3	1.2	-3.7	1.0								
Nera 18mg		143	70.0	1.4	141 (86.5%)	-1.3	1.2	-3.6	1.1	0.1	1.7	-3.3	3.4	0.9653			
Week 44																	
Placebo		147	69.6	1.6	145 (89.0%)	-2.3	1.2	-4.7	0.1								
Nera 18mg		139	69.9	1.4	136 (83.4%)	-1.4	1.2	-3.9	1.0	0.8	1.7	-2.6	4.3	0.6249			
Week 52																	
Placebo		148	67.9	1.7	146 (89.6%)	-4.1	1.4	-6.8	-1.4								
Nera 18mg		136	68.4	1.6	134 (82.2%)	-3.1	1.4	-5.9	-0.3	1.0	2.0	-2.9	4.9	0.6062			
Week 64																	
Placebo		128	69.4	1.6	127 (77.9%)	-3.9	1.3	-6.4	-1.3								
Nera 18mg		121	68.3	1.6	119 (73.0%)	-4.1	1.3	-6.8	-1.5	-0.3	1.9	-4.0	3.4	0.8803			
Week 76																	
Placebo		88	71.2	1.9	87 (53.4%)												
Nera 18mg		80	69.6	2.1	78 (47.9%)												
Week 88																	
Placebo		38	68.5	3.0	37 (22.7%)												
Nera 18mg		31	64.4	4.4	31 (19.0%)												
Week 100																	
Placebo		11	75.5	4.4	11 (6.7%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg		9	74.0	7.2	9 (5.5%)												
Week 112																	
Placebo		4	86.3	3.1	4 (2.5%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Age																	
Test for homogeneity (H0)^																	
Week 6														0.1499			
Week 12														0.2866			
Week 18														0.4830			
Week 26														0.6497			
Week 36														0.4291			
Week 44														0.8864			
Week 52														0.5411			
Week 64														0.2602			
<65 years																	
Baseline																	
Placebo	65	65	73.1	1.9	64 (100.0%)												
Nera 18mg	64	62	71.0	2.3	61 (100.0%)												
Week 6																	
Placebo		63	75.1	2.2	63 (98.4%)	2.7	1.6	-0.6	5.9								
Nera 18mg		62	73.8	2.2	60 (98.4%)	2.0	1.7	-1.3	5.3	-0.6	2.3	-5.2	4.0	0.7855			
Week 12																	
Placebo		63	73.0	2.2	63 (98.4%)	0.1	1.7	-3.2	3.5								
Nera 18mg		61	69.2	2.2	59 (96.7%)	-2.0	1.7	-5.5	1.4	-2.2	2.4	-6.9	2.6	0.3725			
Week 18																	
Placebo		63	74.2	2.0	63 (98.4%)	1.5	1.8	-1.9	5.0								
Nera 18mg		60	71.6	2.3	58 (95.1%)	-0.1	1.8	-3.7	3.4	-1.7	2.5	-6.6	3.3	0.5123			
Week 26																	
Placebo		62	71.5	2.1	62 (96.9%)	-1.1	1.8	-4.6	2.4								
Nera 18mg		57	72.4	2.1	55 (90.2%)	0.7	1.9	-3.0	4.3	1.8	2.6	-3.3	6.9	0.4860			
Week 36																	
Placebo		61	70.9	2.3	61 (95.3%)	-1.4	1.9	-5.1	2.2								
Nera 18mg		54	71.2	2.5	53 (86.9%)	0.3	2.0	-3.5	4.2	1.8	2.7	-3.6	7.1	0.5149			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 44																	
Placebo		61	71.3	2.5	61 (95.3%)	-1.4	1.9	-5.1	2.3								
Nera 18mg		51	71.1	2.5	50 (82.0%)	-0.8	2.0	-4.9	3.2	0.6	2.8	-4.9	6.0	0.8387			
Week 52																	
Placebo		62	72.6	2.4	62 (96.9%)	-0.1	2.1	-4.3	4.1								
Nera 18mg		52	70.8	2.7	51 (83.6%)	-0.4	2.3	-4.8	4.1	-0.3	3.1	-6.4	5.9	0.9333			
Week 64																	
Placebo		57	72.9	2.4	57 (89.1%)	-1.0	2.0	-5.0	3.0								
Nera 18mg		45	69.1	3.0	44 (72.1%)	-3.8	2.2	-8.1	0.5	-2.8	3.0	-8.6	3.1	0.3523			
Week 76																	
Placebo		37	72.1	2.8	37 (57.8%)												
Nera 18mg		34	72.5	3.2	33 (54.1%)												
Week 88																	
Placebo		15	68.9	4.9	15 (23.4%)												
Nera 18mg		7	61.4	11.4	7 (11.5%)												
Week 100																	
Placebo		4	73.8	9.4	4 (6.3%)												
Nera 18mg		1	92.0	NC	1 (1.6%)												
Week 112																	
Placebo		2	82.5	2.5	2 (3.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	104	102	69.3	1.8	99 (100.0%)												
Nera 18mg	106	103	70.9	1.5	102 (100.0%)												
Week 6																	
Placebo		100	75.2	1.6	98 (99.0%)	5.2	1.3	2.7	7.8								
Nera 18mg		104	71.3	1.6	101 (99.0%)	0.3	1.3	-2.3	2.8	-4.9	1.8	-8.6	-1.3	0.0077	-0.38	-0.66	-0.10
Week 12																	
Placebo		95	67.4	1.7	93 (93.9%)	-2.6	1.4	-5.4	0.1								
Nera 18mg		97	69.8	1.5	96 (94.1%)	-1.5	1.4	-4.2	1.2	1.2	1.9	-2.7	5.0	0.5534			
Week 18																	
Placebo		96	69.4	1.8	94 (94.9%)	-1.4	1.4	-4.2	1.4								
Nera 18mg		97	70.3	1.7	95 (93.1%)	-0.8	1.4	-3.6	2.0	0.6	2.0	-3.4	4.6	0.7607			
Week 26																	
Placebo		93	66.3	2.0	91 (91.9%)	-3.8	1.5	-6.6	-0.9								

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n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		92	68.2	1.6	90 (88.2%)	-3.5	1.5	-6.3	-0.6	0.3	2.1	-3.8	4.4	0.8861			
Week 36																	
Placebo		88	70.1	1.8	86 (86.9%)	-1.2	1.5	-4.3	1.8								
Nera 18mg		89	69.3	1.7	88 (86.3%)	-2.2	1.5	-5.2	0.8	-1.0	2.2	-5.3	3.3	0.6503			
Week 44																	
Placebo		86	68.4	2.0	84 (84.8%)	-2.9	1.6	-6.0	0.3								
Nera 18mg		88	69.2	1.8	86 (84.3%)	-1.8	1.6	-4.9	1.3	1.1	2.2	-3.3	5.5	0.6300			
Week 52																	
Placebo		86	64.5	2.3	84 (84.8%)	-7.0	1.8	-10.5	-3.5								
Nera 18mg		84	67.0	2.0	83 (81.4%)	-4.8	1.8	-8.3	-1.3	2.2	2.5	-2.8	7.1	0.3853			
Week 64																	
Placebo		71	66.6	2.2	70 (70.7%)	-5.9	1.7	-9.3	-2.5								
Nera 18mg		76	67.9	1.8	75 (73.5%)	-4.4	1.7	-7.7	-1.0	1.6	2.4	-3.2	6.3	0.5204			
Week 76																	
Placebo		51	70.6	2.6	50 (50.5%)												
Nera 18mg		46	67.4	2.7	45 (44.1%)												
Week 88																	
Placebo		23	68.2	3.8	22 (22.2%)												
Nera 18mg		24	65.3	4.7	24 (23.5%)												
Week 100																	
Placebo		7	76.4	5.1	7 (7.1%)												
Nera 18mg		8	71.8	7.7	8 (7.8%)												
Week 112																	
Placebo		2	90.0	5.0	2 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Sex																	
Test for homogeneity (H0)^																	
Week 6														0.5301			
Week 12														0.5138			
Week 18														0.2506			
Week 26														0.3116			
Week 36														0.1348			
Week 44														0.1538			
Week 52														0.6266			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 64														0.3837			
Male																	
Baseline																	
Placebo	114	113	71.6	1.6	111 (100.0%)												
Nera 18mg	108	104	71.7	1.6	102 (100.0%)												
Week 6																	
Placebo		111	74.5	1.6	110 (99.1%)	2.7	1.2	0.3	5.1								
Nera 18mg		105	71.7	1.7	101 (99.0%)	-0.1	1.3	-2.7	2.4	-2.9	1.8	-6.3	0.6	0.1095			
Week 12																	
Placebo		105	70.1	1.7	104 (93.7%)	-1.9	1.3	-4.5	0.7								
Nera 18mg		99	68.9	1.7	96 (94.1%)	-2.9	1.4	-5.6	-0.3	-1.1	1.9	-4.7	2.6	0.5758			
Week 18																	
Placebo		107	71.5	1.7	106 (95.5%)	-0.8	1.3	-3.4	1.8								
Nera 18mg		100	69.4	1.8	96 (94.1%)	-2.6	1.4	-5.4	0.1	-1.8	1.9	-5.6	2.0	0.3414			
Week 26																	
Placebo		103	68.5	1.8	102 (91.9%)	-3.2	1.4	-5.9	-0.5								
Nera 18mg		94	68.7	1.6	90 (88.2%)	-3.8	1.5	-6.7	-1.0	-0.6	2.0	-4.5	3.3	0.7634			
Week 36																	
Placebo		98	70.3	1.8	97 (87.4%)	-2.2	1.4	-5.1	0.6								
Nera 18mg		87	67.6	1.8	85 (83.3%)	-4.4	1.5	-7.4	-1.4	-2.1	2.1	-6.2	2.0	0.3047			
Week 44																	
Placebo		97	69.8	1.9	96 (86.5%)	-2.9	1.5	-5.8	-0.0								
Nera 18mg		82	67.7	2.0	79 (77.5%)	-4.2	1.6	-7.3	-1.1	-1.3	2.2	-5.6	2.9	0.5427			
Week 52																	
Placebo		97	68.0	2.2	96 (86.5%)	-5.1	1.7	-8.4	-1.8								
Nera 18mg		81	66.9	2.2	79 (77.5%)	-5.0	1.8	-8.6	-1.5	0.1	2.5	-4.7	5.0	0.9623			
Week 64																	
Placebo		82	70.3	2.0	82 (73.9%)	-4.7	1.6	-7.9	-1.6								
Nera 18mg		73	66.0	2.0	71 (69.6%)	-6.5	1.7	-9.9	-3.1	-1.7	2.3	-6.4	2.9	0.4579			
Week 76																	
Placebo		54	72.9	2.2	54 (48.6%)												
Nera 18mg		47	65.2	2.8	45 (44.1%)												
Week 88																	
Placebo		25	67.6	3.4	25 (22.5%)												
Nera 18mg		18	53.7	6.0	18 (17.6%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 100																	
Placebo		7	75.0	6.0	7 (6.3%)												
Nera 18mg		4	63.8	13.6	4 (3.9%)												
Week 112																	
Placebo		2	90.0	5.0	2 (1.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Female																	
Baseline																	
Placebo	55	54	69.0	2.4	52 (100.0%)												
Nera 18mg	62	61	69.5	2.1	61 (100.0%)												
Week 6																	
Placebo		52	76.7	2.4	51 (98.1%)	7.5	1.8	3.9	11.0								
Nera 18mg		61	73.1	2.0	60 (98.4%)	2.7	1.7	-0.6	6.0	-4.8	2.5	-9.6	0.1	0.0541			
Week 12																	
Placebo		53	68.8	2.4	52 (100.0%)	-0.7	1.9	-4.3	3.0								
Nera 18mg		59	70.7	1.8	59 (96.7%)	0.4	1.7	-3.1	3.8	1.0	2.6	-4.0	6.1	0.6895			
Week 18																	
Placebo		52	70.8	2.3	51 (98.1%)	1.0	1.9	-2.8	4.8								
Nera 18mg		57	73.3	2.1	57 (93.4%)	2.9	1.8	-0.6	6.5	1.9	2.7	-3.3	7.2	0.4659			
Week 26																	
Placebo		52	68.0	2.6	51 (98.1%)	-1.6	2.0	-5.5	2.2								
Nera 18mg		55	71.8	2.2	55 (90.2%)	1.2	1.9	-2.5	4.8	2.8	2.7	-2.5	8.1	0.3002			
Week 36																	
Placebo		51	70.7	2.4	50 (96.2%)	0.6	2.0	-3.3	4.6								
Nera 18mg		56	73.7	2.1	56 (91.8%)	3.7	1.9	-0.0	7.5	3.1	2.8	-2.4	8.5	0.2704			
Week 44																	
Placebo		50	69.1	2.7	49 (94.2%)	-0.9	2.1	-5.0	3.2								
Nera 18mg		57	73.1	2.0	57 (93.4%)	2.9	1.9	-0.9	6.7	3.8	2.9	-1.8	9.4	0.1833			
Week 52																	
Placebo		51	67.7	2.6	50 (96.2%)	-2.1	2.4	-6.8	2.6								
Nera 18mg		55	70.7	2.5	55 (90.2%)	0.0	2.2	-4.4	4.4	2.1	3.3	-4.3	8.5	0.5192			
Week 64																	
Placebo		46	67.8	2.8	45 (86.5%)	-2.0	2.3	-6.5	2.4								
Nera 18mg		48	71.8	2.5	48 (78.7%)	-0.4	2.1	-4.6	3.8	1.7	3.1	-4.5	7.8	0.5943			
Week 76																	
Placebo		34	68.6	3.6	33 (63.5%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		33	75.7	2.8	33 (54.1%)												
Week 88																	
Placebo		13	70.1	5.8	12 (23.1%)												
Nera 18mg		13	79.2	3.1	13 (21.3%)												
Week 100																	
Placebo		4	76.3	7.5	4 (7.7%)												
Nera 18mg		5	82.2	6.1	5 (8.2%)												
Week 112																	
Placebo		2	82.5	2.5	2 (3.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 6														0.4250			
Week 12														0.2100			
Week 18														0.4994			
Week 26														0.6416			
Week 36														0.1633			
Week 44														0.2014			
Week 52														0.4962			
Week 64														0.8376			
<=70%																	
Baseline																	
Placebo	95	95	69.5	1.9	92 (100.0%)												
Nera 18mg	97	93	68.3	1.7	93 (100.0%)												
Week 6																	
Placebo		91	74.1	1.7	91 (98.9%)	3.7	1.4	1.0	6.4								
Nera 18mg		95	69.3	1.7	91 (97.8%)	-0.5	1.4	-3.2	2.1	-4.3	1.9	-8.1	-0.5	0.0269	-0.33	-0.62	-0.04
Week 12																	
Placebo		88	69.1	1.8	88 (95.7%)	-1.7	1.4	-4.5	1.1								
Nera 18mg		90	66.5	1.7	88 (94.6%)	-3.5	1.4	-6.3	-0.7	-1.8	2.0	-5.7	2.1	0.3674			
Week 18																	
Placebo		87	69.7	1.8	87 (94.6%)	-1.3	1.5	-4.2	1.6								
Nera 18mg		90	67.3	1.8	87 (93.5%)	-2.5	1.5	-5.4	0.4	-1.2	2.1	-5.3	2.9	0.5705			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 26																	
Placebo		85	66.9	1.9	85 (92.4%)	-3.4	1.5	-6.3	-0.4								
Nera 18mg		85	67.1	1.8	82 (88.2%)	-3.2	1.5	-6.2	-0.2	0.2	2.1	-4.0	4.4	0.9323			
Week 36																	
Placebo		82	68.4	2.1	82 (89.1%)	-2.3	1.6	-5.4	0.7								
Nera 18mg		83	65.5	1.9	81 (87.1%)	-4.2	1.6	-7.3	-1.1	-1.9	2.2	-6.2	2.5	0.3952			
Week 44																	
Placebo		81	67.8	2.2	81 (88.0%)	-3.1	1.6	-6.2	0.1								
Nera 18mg		79	65.9	1.9	77 (82.8%)	-4.1	1.6	-7.3	-0.9	-1.0	2.3	-5.5	3.5	0.6579			
Week 52																	
Placebo		80	65.4	2.5	80 (87.0%)	-5.5	1.8	-9.1	-1.9								
Nera 18mg		79	64.0	2.2	77 (82.8%)	-5.5	1.9	-9.2	-1.9	-0.1	2.6	-5.2	5.1	0.9782			
Week 64																	
Placebo		70	66.7	2.3	70 (76.1%)	-5.7	1.8	-9.2	-2.3								
Nera 18mg		70	64.7	2.2	68 (73.1%)	-6.2	1.8	-9.7	-2.8	-0.5	2.5	-5.4	4.4	0.8324			
Week 76																	
Placebo		45	70.1	2.8	45 (48.9%)												
Nera 18mg		44	65.1	3.1	42 (45.2%)												
Week 88																	
Placebo		20	69.0	4.3	20 (21.7%)												
Nera 18mg		19	58.8	6.4	19 (20.4%)												
Week 100																	
Placebo		5	69.0	6.4	5 (5.4%)												
Nera 18mg		5	72.6	12.9	5 (5.4%)												
Week 112																	
Placebo		3	83.3	1.7	3 (3.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	74	72	72.4	1.8	71 (100.0%)												
Nera 18mg	73	72	74.3	1.8	70 (100.0%)												
Week 6																	
Placebo		72	76.5	1.9	70 (98.6%)	4.9	1.6	1.8	7.9								
Nera 18mg		71	76.0	1.9	70 (100.0%)	2.9	1.6	-0.2	6.0	-1.9	2.2	-6.3	2.4	0.3770			
Week 12																	
Placebo		70	70.3	2.0	68 (95.8%)	-1.3	1.6	-4.5	1.9								

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n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		68	73.7	1.7	67 (95.7%)	0.7	1.6	-2.5	3.9	2.0	2.3	-2.5	6.5	0.3801			
Week 18																	
Placebo		72	73.2	2.0	70 (98.6%)	1.2	1.7	-2.1	4.4								
Nera 18mg		67	75.5	1.9	66 (94.3%)	2.1	1.7	-1.2	5.4	0.9	2.4	-3.7	5.6	0.6888			
Week 26																	
Placebo		70	70.1	2.3	68 (95.8%)	-1.9	1.7	-5.2	1.5								
Nera 18mg		64	73.5	1.8	63 (90.0%)	-0.2	1.8	-3.7	3.3	1.7	2.4	-3.1	6.5	0.4875			
Week 36																	
Placebo		67	72.9	1.9	65 (91.5%)	-0.0	1.8	-3.5	3.5								
Nera 18mg		60	76.3	1.8	60 (85.7%)	2.8	1.8	-0.8	6.4	2.8	2.5	-2.2	7.8	0.2673			
Week 44																	
Placebo		66	71.8	2.1	64 (90.1%)	-1.2	1.8	-4.8	2.3								
Nera 18mg		60	75.2	2.1	59 (84.3%)	2.2	1.9	-1.5	5.9	3.4	2.6	-1.7	8.5	0.1897			
Week 52																	
Placebo		68	70.8	2.2	66 (93.0%)	-2.4	2.0	-6.5	1.6								
Nera 18mg		57	74.6	2.2	57 (81.4%)	0.2	2.2	-4.1	4.4	2.6	3.0	-3.2	8.4	0.3782			
Week 64																	
Placebo		58	72.8	2.3	57 (80.3%)	-1.5	2.0	-5.4	2.3								
Nera 18mg		51	73.3	2.1	51 (72.9%)	-1.3	2.0	-5.3	2.7	0.2	2.8	-5.3	5.8	0.9308			
Week 76																	
Placebo		43	72.4	2.7	42 (59.2%)												
Nera 18mg		36	75.0	2.4	36 (51.4%)												
Week 88																	
Placebo		18	67.9	4.1	17 (23.9%)												
Nera 18mg		12	73.2	3.8	12 (17.1%)												
Week 100																	
Placebo		6	80.8	5.7	6 (8.5%)												
Nera 18mg		4	75.8	5.5	4 (5.7%)												
Week 112																	
Placebo		1	95.0	NC	1 (1.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline HRCT pattern																	
Test for homogeneity (H0)^																	
Week 6														0.9301			

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 12														0.5351			
Week 18														0.3939			
Week 26														0.9369			
Week 36														0.6684			
Week 44														0.9177			
Week 52														0.5238			
Week 64														0.9974			
UIP-like																	
Baseline																	
Placebo	116	114	71.6		1.6 111 (100.0%)												
Nera 18mg	121	119	71.0		1.6 117 (100.0%)												
Week 6																	
Placebo		111	76.5		1.6 109 (98.2%)	4.9	1.2	2.5	7.4								
Nera 18mg		118	72.8		1.6 116 (99.1%)	1.6	1.2	-0.8	3.9	-3.4	1.7	-6.8	0.0	0.0528			
Week 12																	
Placebo		108	70.4		1.6 106 (95.5%)	-1.2	1.3	-3.7	1.4								
Nera 18mg		116	70.4		1.5 114 (97.4%)	-0.8	1.3	-3.2	1.7	0.4	1.8	-3.1	4.0	0.8155			
Week 18																	
Placebo		109	71.5		1.6 107 (96.4%)	-0.6	1.3	-3.3	2.0								
Nera 18mg		113	71.2		1.7 111 (94.9%)	-0.1	1.3	-2.6	2.5	0.6	1.9	-3.1	4.2	0.7690			
Week 26																	
Placebo		106	69.6		1.8 104 (93.7%)	-2.1	1.4	-4.8	0.6								
Nera 18mg		107	70.4		1.6 105 (89.7%)	-1.2	1.3	-3.9	1.4	0.9	1.9	-2.9	4.7	0.6496			
Week 36																	
Placebo		102	72.1		1.6 100 (90.1%)	-0.7	1.4	-3.5	2.2								
Nera 18mg		102	70.1		1.8 102 (87.2%)	-1.1	1.4	-3.9	1.7	-0.4	2.0	-4.4	3.6	0.8384			
Week 44																	
Placebo		99	70.4		1.9 97 (87.4%)	-2.4	1.5	-5.3	0.6								
Nera 18mg		99	69.8		1.8 98 (83.8%)	-1.6	1.5	-4.5	1.2	0.7	2.1	-3.4	4.8	0.7281			
Week 52																	
Placebo		100	70.1		2.0 98 (88.3%)	-3.0	1.7	-6.3	0.3								
Nera 18mg		98	68.8		2.0 98 (83.8%)	-2.8	1.7	-6.1	0.4	0.2	2.4	-4.4	4.8	0.9373			
Week 64																	
Placebo		90	70.4		1.9 89 (80.2%)	-3.7	1.6	-6.8	-0.6								
Nera 18mg		86	69.1		2.0 86 (73.5%)	-4.0	1.6	-7.1	-0.9	-0.3	2.2	-4.7	4.1	0.8942			

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 76																	
Placebo		60	74.5	2.1	59 (53.2%)												
Nera 18mg		59	69.4	2.4	59 (50.4%)												
Week 88																	
Placebo		26	70.2	3.2	25 (22.5%)												
Nera 18mg		23	65.7	4.8	23 (19.7%)												
Week 100																	
Placebo		9	76.7	5.1	9 (8.1%)												
Nera 18mg		8	79.5	5.2	8 (6.8%)												
Week 112																	
Placebo		3	86.7	4.4	3 (2.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other fibrotic patterns																	
Baseline																	
Placebo	53	53	68.8	2.2	52 (100.0%)												
Nera 18mg	49	46	70.7	2.1	46 (100.0%)												
Week 6																	
Placebo		52	72.5	2.3	52 (100.0%)	2.6	1.8	-1.0	6.2								
Nera 18mg		48	70.8	2.2	45 (97.8%)	-0.5	1.9	-4.3	3.3	-3.1	2.6	-8.3	2.1	0.2435			
Week 12																	
Placebo		50	68.0	2.5	50 (96.2%)	-2.4	1.9	-6.2	1.3								
Nera 18mg		42	67.4	2.2	41 (89.1%)	-4.1	2.1	-8.1	-0.0	-1.6	2.8	-7.1	3.9	0.5565			
Week 18																	
Placebo		50	70.8	2.4	50 (96.2%)	0.6	2.0	-3.3	4.4								
Nera 18mg		44	69.7	2.2	42 (91.3%)	-1.8	2.1	-6.0	2.4	-2.4	2.9	-8.1	3.3	0.4085			
Week 26																	
Placebo		49	65.6	2.7	49 (94.2%)	-4.2	2.0	-8.1	-0.2								
Nera 18mg		42	68.3	2.2	40 (87.0%)	-3.6	2.2	-7.9	0.7	0.6	3.0	-5.2	6.4	0.8415			
Week 36																	
Placebo		47	66.8	2.8	47 (90.4%)	-2.8	2.1	-7.0	1.3								
Nera 18mg		41	69.7	2.3	39 (84.8%)	-1.6	2.3	-6.2	2.9	1.2	3.1	-4.9	7.3	0.7047			
Week 44																	
Placebo		48	67.8	2.8	48 (92.3%)	-2.0	2.1	-6.2	2.2								
Nera 18mg		40	70.2	2.3	38 (82.6%)	-0.9	2.4	-5.5	3.7	1.1	3.2	-5.1	7.4	0.7253			
Week 52																	
Placebo		48	63.3	3.0	48 (92.3%)	-6.6	2.4	-11.4	-1.9								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		38	67.5	2.6	36 (78.3%)	-3.7	2.7	-9.0	1.6	2.9	3.6	-4.2	10.1	0.4171			
Week 64																	
Placebo		38	67.1	3.2	38 (73.1%)	-4.3	2.4	-9.0	0.4								
Nera 18mg		35	66.3	2.5	33 (71.7%)	-4.6	2.6	-9.6	0.4	-0.3	3.5	-7.2	6.6	0.9351			
Week 76																	
Placebo		28	64.3	3.7	28 (53.8%)												
Nera 18mg		21	70.0	4.0	19 (41.3%)												
Week 88																	
Placebo		12	64.8	6.3	12 (23.1%)												
Nera 18mg		8	60.6	10.2	8 (17.4%)												
Week 100																	
Placebo		2	70.0	10.0	2 (3.8%)												
Nera 18mg		1	30.0	NC	1 (2.2%)												
Week 112																	
Placebo		1	85.0	NC	1 (1.9%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Underlying ILD diagnosis																	
Test for homogeneity (H0)^																	
Week 6														0.3155			
Week 12														0.4453			
Week 18														0.6009			
Week 26														0.4549			
Week 36														0.9295			
Week 44														0.4295			
Week 52														0.9535			
Week 64														0.1008			
iNSIP																	
Baseline																	
Placebo	32	32	68.5	3.2	31 (100.0%)												
Nera 18mg	27	26	69.8	2.9	26 (100.0%)												
Week 6																	
Placebo		31	75.3	3.3	31 (100.0%)	5.3	2.3	0.7	9.9								
Nera 18mg		26	69.5	3.2	25 (96.2%)	-0.7	2.6	-5.8	4.4	-6.0	3.5	-12.9	0.9	0.0860			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 12																	
Placebo		27	70.9	3.7	27 (87.1%)	0.4	2.5	-4.5	5.4								
Nera 18mg		23	69.2	2.8	23 (88.5%)	-2.4	2.7	-7.8	2.9	-2.9	3.7	-10.2	4.4	0.4408			
Week 18																	
Placebo		28	71.5	3.9	28 (90.3%)	-0.7	2.6	-5.8	4.4								
Nera 18mg		25	68.0	2.8	24 (92.3%)	-3.4	2.8	-8.9	2.2	-2.7	3.8	-10.2	4.8	0.4844			
Week 26																	
Placebo		29	69.0	3.9	29 (93.5%)	-2.2	2.6	-7.2	2.9								
Nera 18mg		23	72.3	2.6	22 (84.6%)	1.2	2.9	-4.5	6.9	3.4	3.9	-4.3	11.0	0.3864			
Week 36																	
Placebo		28	74.0	3.3	28 (90.3%)	1.6	2.7	-3.7	6.9								
Nera 18mg		20	74.0	2.9	19 (73.1%)	1.8	3.1	-4.4	7.9	0.1	4.1	-8.0	8.3	0.9747			
Week 44																	
Placebo		28	72.4	3.8	28 (90.3%)	0.3	2.7	-5.1	5.6								
Nera 18mg		19	74.7	3.4	18 (69.2%)	4.0	3.2	-2.3	10.4	3.7	4.2	-4.6	12.1	0.3782			
Week 52																	
Placebo		27	70.6	4.4	27 (87.1%)	-2.5	3.2	-8.8	3.7								
Nera 18mg		17	68.5	4.1	16 (61.5%)	-1.6	3.8	-9.2	5.9	0.9	5.0	-8.9	10.7	0.8584			
Week 64																	
Placebo		23	67.8	4.9	23 (74.2%)	-6.1	3.0	-12.1	-0.2								
Nera 18mg		17	69.7	3.5	16 (61.5%)	-0.2	3.5	-7.1	6.7	5.9	4.6	-3.2	15.0	0.2027			
Week 76																	
Placebo		16	65.2	5.4	16 (51.6%)												
Nera 18mg		10	64.5	6.8	9 (34.6%)												
Week 88																	
Placebo		9	66.7	6.8	9 (29.0%)												
Nera 18mg		3	56.7	17.4	3 (11.5%)												
Week 100																	
Placebo		2	87.5	7.5	2 (6.5%)												
Nera 18mg		1	30.0	NC	1 (3.8%)												
Week 112																	
Placebo		2	90.0	5.0	2 (6.5%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Unclassifiable IIP																	
Baseline																	
Placebo	46	46	70.4	2.8	45 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg	32	32	70.3	3.2	32 (100.0%)												
Week 6																	
Placebo		45	76.5	2.4	45 (100.0%)	5.3	1.9	1.5	9.1								
Nera 18mg		32	73.2	3.1	32 (100.0%)	2.4	2.3	-2.1	6.9	-2.9	3.0	-8.8	3.0	0.3351			
Week 12																	
Placebo		44	68.3	2.8	44 (97.8%)	-3.2	2.0	-7.1	0.8								
Nera 18mg		31	71.5	2.7	31 (96.9%)	0.2	2.4	-4.5	5.0	3.4	3.1	-2.8	9.6	0.2771			
Week 18																	
Placebo		43	69.5	2.8	43 (95.6%)	-1.9	2.1	-6.0	2.3								
Nera 18mg		30	71.5	3.4	30 (93.8%)	0.5	2.5	-4.4	5.5	2.4	3.3	-4.0	8.9	0.4624			
Week 26																	
Placebo		40	66.7	3.2	40 (88.9%)	-3.7	2.2	-7.9	0.5								
Nera 18mg		28	70.2	3.0	28 (87.5%)	-0.9	2.6	-6.0	4.2	2.8	3.4	-3.8	9.4	0.4042			
Week 36																	
Placebo		38	69.6	3.1	38 (84.4%)	-2.5	2.3	-6.9	2.0								
Nera 18mg		27	67.7	3.1	27 (84.4%)	-3.4	2.7	-8.7	2.0	-0.9	3.5	-7.8	6.1	0.8051			
Week 44																	
Placebo		37	68.5	3.5	37 (82.2%)	-3.2	2.3	-7.7	1.4								
Nera 18mg		27	69.3	3.8	27 (84.4%)	-1.2	2.7	-6.6	4.1	1.9	3.6	-5.1	9.0	0.5909			
Week 52																	
Placebo		38	66.4	3.7	38 (84.4%)	-5.6	2.7	-10.8	-0.4								
Nera 18mg		28	71.3	3.8	28 (87.5%)	-0.1	3.1	-6.2	6.1	5.5	4.1	-2.5	13.6	0.1782			
Week 64																	
Placebo		32	71.2	3.4	32 (71.1%)	-3.3	2.5	-8.2	1.7								
Nera 18mg		23	66.3	4.0	23 (71.9%)	-5.0	3.0	-10.9	0.9	-1.7	3.9	-9.4	6.0	0.6666			
Week 76																	
Placebo		25	75.7	3.5	25 (55.6%)												
Nera 18mg		17	70.5	4.6	17 (53.1%)												
Week 88																	
Placebo		10	66.0	6.7	10 (22.2%)												
Nera 18mg		10	71.5	6.0	10 (31.3%)												
Week 100																	
Placebo		2	67.5	17.5	2 (4.4%)												
Nera 18mg		3	75.0	7.6	3 (9.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg		0	NC	NC	0 (0.0%)												
HP																	
Baseline																	
Placebo	38	38	73.8	2.1	38 (100.0%)												
Nera 18mg	43	42	70.7	2.7	41 (100.0%)												
Week 6																	
Placebo		37	74.9	2.1	37 (97.4%)	2.2	2.1	-2.0	6.4								
Nera 18mg		42	68.2	2.5	41 (100.0%)	-2.3	2.0	-6.3	1.7	-4.5	2.9	-10.3	1.3	0.1257			
Week 12																	
Placebo		37	70.7	2.4	37 (97.4%)	-2.5	2.2	-6.8	1.9								
Nera 18mg		37	66.2	3.2	37 (90.2%)	-4.3	2.2	-8.6	-0.1	-1.9	3.1	-7.9	4.2	0.5466			
Week 18																	
Placebo		38	71.8	2.2	38 (100.0%)	-1.0	2.3	-5.5	3.4								
Nera 18mg		39	68.8	2.8	39 (95.1%)	-1.6	2.2	-6.0	2.7	-0.6	3.2	-6.8	5.6	0.8545			
Week 26																	
Placebo		38	68.4	2.6	38 (100.0%)	-4.1	2.3	-8.6	0.3								
Nera 18mg		36	68.2	2.8	36 (87.8%)	-2.9	2.3	-7.3	1.6	1.3	3.2	-5.0	7.6	0.6906			
Week 36																	
Placebo		37	67.4	2.7	37 (97.4%)	-4.8	2.4	-9.5	-0.1								
Nera 18mg		37	68.0	2.9	37 (90.2%)	-2.6	2.3	-7.2	1.9	2.2	3.3	-4.4	8.7	0.5167			
Week 44																	
Placebo		37	69.5	2.5	37 (97.4%)	-3.8	2.4	-8.5	0.9								
Nera 18mg		35	67.5	3.1	35 (85.4%)	-3.9	2.4	-8.6	0.8	-0.1	3.4	-6.7	6.6	0.9837			
Week 52																	
Placebo		37	66.2	3.3	37 (97.4%)	-6.8	2.8	-12.3	-1.4								
Nera 18mg		33	67.3	3.2	33 (80.5%)	-4.4	2.8	-10.0	1.1	2.4	3.9	-5.4	10.1	0.5460			
Week 64																	
Placebo		33	67.4	2.9	33 (86.8%)	-7.2	2.6	-12.3	-2.0								
Nera 18mg		29	66.6	3.3	29 (70.7%)	-6.0	2.7	-11.2	-0.7	1.2	3.7	-6.1	8.5	0.7462			
Week 76																	
Placebo		18	64.5	4.3	18 (47.4%)												
Nera 18mg		17	69.6	4.0	17 (41.5%)												
Week 88																	
Placebo		8	69.0	5.0	8 (21.1%)												
Nera 18mg		5	69.6	6.6	5 (12.2%)												
Week 100																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		1	70.0	NC	1 (2.6%)												
Nera 18mg		1	78.0	NC	1 (2.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Autoimmune ILD																	
Baseline																	
Placebo	29	28	70.1	3.6	27 (100.0%)												
Nera 18mg	43	42	71.2	2.4	42 (100.0%)												
Week 6																	
Placebo		28	77.4	3.4	27 (100.0%)	6.6	2.5	1.6	11.5								
Nera 18mg		43	73.8	2.6	42 (100.0%)	2.7	2.0	-1.3	6.6	-3.9	3.2	-10.2	2.4	0.2256			
Week 12																	
Placebo		28	74.5	2.8	27 (100.0%)	3.8	2.6	-1.2	8.9								
Nera 18mg		43	71.4	2.2	42 (100.0%)	0.5	2.1	-3.6	4.5	-3.3	3.3	-9.8	3.1	0.3110			
Week 18																	
Placebo		27	76.7	2.9	26 (96.3%)	5.7	2.7	0.3	11.0								
Nera 18mg		39	75.0	2.7	38 (90.5%)	3.1	2.2	-1.3	7.4	-2.6	3.5	-9.4	4.3	0.4612			
Week 26																	
Placebo		27	76.4	2.5	26 (96.3%)	4.8	2.7	-0.5	10.1								
Nera 18mg		39	70.6	2.7	38 (90.5%)	-1.2	2.2	-5.5	3.2	-6.0	3.5	-12.9	0.9	0.0868			
Week 36																	
Placebo		26	77.3	2.3	25 (92.6%)	6.1	2.8	0.5	11.6								
Nera 18mg		36	73.0	2.8	36 (85.7%)	2.1	2.3	-2.4	6.7	-3.9	3.7	-11.1	3.3	0.2860			
Week 44																	
Placebo		24	74.4	3.5	23 (85.2%)	3.2	2.9	-2.6	9.0								
Nera 18mg		37	73.2	2.3	36 (85.7%)	2.4	2.4	-2.3	7.0	-0.8	3.8	-8.2	6.6	0.8277			
Week 52																	
Placebo		25	74.0	2.5	24 (88.9%)	2.7	3.3	-3.9	9.2								
Nera 18mg		36	69.2	3.4	36 (85.7%)	-2.3	2.7	-7.7	3.1	-5.0	4.3	-13.5	3.5	0.2498			
Week 64																	
Placebo		21	77.5	2.7	21 (77.8%)	5.4	3.2	-0.9	11.6								
Nera 18mg		33	73.1	3.0	33 (78.6%)	-0.1	2.5	-5.1	4.9	-5.5	4.0	-13.5	2.5	0.1747			
Week 76																	
Placebo		16	80.1	2.9	16 (59.3%)												
Nera 18mg		19	77.1	3.3	19 (45.2%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 88																	
Placebo		6	82.5	5.9	6 (22.2%)												
Nera 18mg		5	81.0	6.6	5 (11.9%)												
Week 100																	
Placebo		4	82.5	5.2	4 (14.8%)												
Nera 18mg		2	93.0	1.0	2 (4.8%)												
Week 112																	
Placebo		2	82.5	2.5	2 (7.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other ILD																	
Baseline																	
Placebo	24	23	70.3	3.1	22 (100.0%)												
Nera 18mg	25	23	72.8	3.1	22 (100.0%)												
Week 6																	
Placebo		22	70.0	4.0	21 (95.5%)	0.9	2.8	-4.6	6.5								
Nera 18mg		23	78.0	3.2	21 (95.5%)	3.8	2.8	-1.7	9.4	2.9	4.0	-5.0	10.7	0.4748			
Week 12																	
Placebo		22	63.0	3.5	21 (95.5%)	-5.8	2.9	-11.5	-0.1								
Nera 18mg		24	69.4	2.9	22 (100.0%)	-2.9	2.9	-8.6	2.7	2.8	4.1	-5.2	10.9	0.4844			
Week 18																	
Placebo		23	67.2	3.6	22 (100.0%)	-2.4	3.0	-8.2	3.4								
Nera 18mg		24	69.5	3.7	22 (100.0%)	-3.5	3.0	-9.4	2.3	-1.1	4.2	-9.4	7.2	0.7910			
Week 26																	
Placebo		21	60.2	4.0	20 (90.9%)	-8.5	3.0	-14.5	-2.5								
Nera 18mg		23	68.1	3.3	21 (95.5%)	-6.0	3.0	-11.9	-0.1	2.5	4.3	-5.9	11.0	0.5556			
Week 36																	
Placebo		20	63.6	4.6	19 (86.4%)	-6.1	3.2	-12.4	0.2								
Nera 18mg		23	67.8	3.9	22 (100.0%)	-4.6	3.1	-10.6	1.5	1.5	4.4	-7.2	10.3	0.7283			
Week 44																	
Placebo		21	62.4	4.5	20 (90.9%)	-8.0	3.2	-14.3	-1.6								
Nera 18mg		21	64.7	3.7	20 (90.9%)	-8.8	3.2	-15.1	-2.5	-0.8	4.5	-9.8	8.1	0.8520			
Week 52																	
Placebo		21	62.7	4.4	20 (90.9%)	-7.2	3.7	-14.5	0.1								
Nera 18mg		22	65.2	4.0	21 (95.5%)	-7.9	3.6	-15.0	-0.7	-0.7	5.2	-10.9	9.6	0.8962			
Week 64																	
Placebo		19	63.1	4.2	18 (81.8%)	-6.9	3.5	-13.7	-0.1								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		19	63.9	4.1	18 (81.8%)	-10.7	3.5	-17.5	-3.9	-3.9	4.9	-13.5	5.8	0.4313			
Week 76																	
Placebo		13	68.3	4.3	12 (54.5%)												
Nera 18mg		17	63.1	5.1	16 (72.7%)												
Week 88																	
Placebo		5	59.0	6.4	4 (18.2%)												
Nera 18mg		8	44.8	9.9	8 (36.4%)												
Week 100																	
Placebo		2	60.0	0.0	2 (9.1%)												
Nera 18mg		2	73.5	18.5	2 (9.1%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Region																	
Test for homogeneity (H0)^																	
Week 6														0.1085			
Week 12														0.0095			
Week 18														0.4172			
Week 26														0.0639			
Week 36														0.3379			
Week 44														0.8032			
Week 52														0.4407			
Week 64														0.2239			
Europe																	
Baseline																	
Placebo	78	76	67.8	1.9	76 (100.0%)												
Nera 18mg	67	63	67.9	2.1	62 (100.0%)												
Week 6																	
Placebo		76	68.3	1.9	74 (97.4%)	-0.6	1.5	-3.5	2.3								
Nera 18mg		64	68.2	2.1	60 (96.8%)	-1.6	1.6	-4.8	1.6	-1.0	2.2	-5.3	3.3	0.6405			
Week 12																	
Placebo		75	64.0	2.1	73 (96.1%)	-5.7	1.6	-8.7	-2.6								
Nera 18mg		59	68.8	2.1	57 (91.9%)	-1.4	1.7	-4.8	2.1	4.3	2.3	-0.2	8.9	0.0637			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 18																	
Placebo		74	65.0	2.0	72 (94.7%)	-4.8	1.6	-8.0	-1.7								
Nera 18mg		58	65.6	2.4	55 (88.7%)	-4.6	1.8	-8.1	-1.0	0.3	2.4	-4.4	5.0	0.9041			
Week 26																	
Placebo		73	61.9	2.4	71 (93.4%)	-7.5	1.6	-10.7	-4.3								
Nera 18mg		55	66.0	2.3	52 (83.9%)	-4.3	1.9	-7.9	-0.6	3.2	2.5	-1.6	8.1	0.1885			
Week 36																	
Placebo		68	64.9	2.2	66 (86.8%)	-5.4	1.7	-8.9	-2.0								
Nera 18mg		53	65.0	2.6	52 (83.9%)	-4.3	1.9	-8.2	-0.5	1.1	2.6	-4.0	6.2	0.6725			
Week 44																	
Placebo		68	65.3	2.3	66 (86.8%)	-5.0	1.8	-8.5	-1.4								
Nera 18mg		53	65.9	2.5	51 (82.3%)	-3.9	2.0	-7.9	0.1	1.0	2.7	-4.3	6.4	0.7013			
Week 52																	
Placebo		69	63.6	2.5	67 (88.2%)	-7.0	2.0	-11.0	-3.0								
Nera 18mg		53	65.1	2.7	52 (83.9%)	-4.4	2.3	-8.9	0.1	2.6	3.1	-3.5	8.6	0.4025			
Week 64																	
Placebo		63	65.0	2.4	62 (81.6%)	-6.6	1.9	-10.3	-2.8								
Nera 18mg		52	64.9	2.7	51 (82.3%)	-5.1	2.1	-9.3	-0.9	1.5	2.8	-4.1	7.1	0.5951			
Week 76																	
Placebo		38	65.1	3.0	37 (48.7%)												
Nera 18mg		30	64.2	3.8	29 (46.8%)												
Week 88																	
Placebo		15	62.3	3.8	14 (18.4%)												
Nera 18mg		8	66.1	7.7	8 (12.9%)												
Week 100																	
Placebo		3	73.3	6.7	3 (3.9%)												
Nera 18mg		2	57.5	2.5	2 (3.2%)												
Week 112																	
Placebo		1	85.0	NC	1 (1.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Asia																	
Baseline																	
Placebo	45	45	73.5	2.5	43 (100.0%)												
Nera 18mg	41	41	69.3	2.9	40 (100.0%)												
Week 6																	
Placebo		43	82.0	2.2	43 (100.0%)	9.2	1.9	5.4	13.0								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg		40	74.3	3.1	40 (100.0%)	4.3	2.0	0.3	8.2	-4.9	2.8	-10.4	0.5	0.0774			
Week 12																	
Placebo		41	74.9	2.2	41 (95.3%)	1.9	2.1	-2.2	5.9								
Nera 18mg		39	70.3	2.5	39 (97.5%)	-0.3	2.1	-4.5	3.9	-2.2	3.0	-8.0	3.7	0.4652			
Week 18																	
Placebo		42	76.7	2.0	42 (97.7%)	3.7	2.1	-0.4	7.8								
Nera 18mg		39	73.2	2.8	39 (97.5%)	2.7	2.2	-1.5	7.0	-0.9	3.0	-6.8	5.0	0.7569			
Week 26																	
Placebo		42	73.0	2.5	42 (97.7%)	-0.1	2.1	-4.3	4.0								
Nera 18mg		36	72.1	2.5	36 (90.0%)	1.0	2.3	-3.5	5.4	1.1	3.1	-5.0	7.2	0.7231			
Week 36																	
Placebo		41	74.1	2.8	41 (95.3%)	0.9	2.2	-3.5	5.3								
Nera 18mg		34	73.9	2.7	34 (85.0%)	3.3	2.4	-1.5	8.0	2.4	3.3	-4.1	8.8	0.4711			
Week 44																	
Placebo		38	73.8	3.0	38 (88.4%)	0.3	2.4	-4.4	4.9								
Nera 18mg		31	71.7	2.8	31 (77.5%)	1.5	2.6	-3.6	6.5	1.2	3.5	-5.7	8.0	0.7313			
Week 52																	
Placebo		39	72.3	2.8	39 (90.7%)	-1.5	2.7	-6.7	3.8								
Nera 18mg		32	69.9	3.5	32 (80.0%)	-1.6	2.9	-7.3	4.0	-0.2	3.9	-7.9	7.5	0.9630			
Week 64																	
Placebo		33	71.2	3.4	33 (76.7%)	-4.0	2.6	-9.0	1.0								
Nera 18mg		26	70.8	3.6	26 (65.0%)	-2.7	2.8	-8.2	2.8	1.3	3.8	-6.1	8.7	0.7308			
Week 76																	
Placebo		25	77.8	2.4	25 (58.1%)												
Nera 18mg		19	73.1	4.4	19 (47.5%)												
Week 88																	
Placebo		13	71.6	5.3	13 (30.2%)												
Nera 18mg		9	70.0	10.1	9 (22.5%)												
Week 100																	
Placebo		5	69.0	7.5	5 (11.6%)												
Nera 18mg		4	87.8	3.2	4 (10.0%)												
Week 112																	
Placebo		1	80.0	NC	1 (2.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	
Baseline																	

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo	30	30	79.0	2.3	30 (100.0%)												
Nera 18mg	37	36	76.8	1.8	36 (100.0%)												
Week 6																	
Placebo		30	83.1	1.9	30 (100.0%)	7.7	2.3	3.1	12.3								
Nera 18mg		37	75.7	2.3	36 (100.0%)	0.9	2.1	-3.3	5.0	-6.8	3.1	-13.0	-0.7	0.0295	-0.53	-1.02	-0.04
Week 12																	
Placebo		28	78.0	2.4	28 (93.3%)	3.3	2.5	-1.7	8.2								
Nera 18mg		37	70.8	2.7	36 (100.0%)	-3.2	2.2	-7.6	1.2	-6.5	3.3	-13.0	0.1	0.0525			
Week 18																	
Placebo		29	79.9	2.5	29 (96.7%)	4.3	2.5	-0.7	9.3								
Nera 18mg		36	77.0	1.9	35 (97.2%)	3.0	2.3	-1.5	7.5	-1.3	3.4	-8.0	5.3	0.6992			
Week 26																	
Placebo		26	78.0	2.2	26 (86.7%)	3.6	2.7	-1.7	8.8								
Nera 18mg		34	75.5	2.1	33 (91.7%)	0.7	2.4	-4.0	5.4	-2.9	3.5	-9.8	4.0	0.4099			
Week 36																	
Placebo		26	79.7	2.3	26 (86.7%)	5.0	2.8	-0.4	10.5								
Nera 18mg		33	74.9	2.1	32 (88.9%)	0.3	2.5	-4.6	5.3	-4.7	3.7	-12.0	2.6	0.2035			
Week 44																	
Placebo		27	76.9	2.8	27 (90.0%)	1.3	2.9	-4.4	6.9								
Nera 18mg		33	74.3	2.4	32 (88.9%)	-0.2	2.6	-5.4	4.9	-1.5	3.8	-9.0	6.0	0.6973			
Week 52																	
Placebo		26	76.0	3.2	26 (86.7%)	-0.0	3.3	-6.5	6.5								
Nera 18mg		33	73.7	2.5	32 (88.9%)	-0.7	3.0	-6.5	5.1	-0.7	4.4	-9.3	7.9	0.8767			
Week 64																	
Placebo		21	76.8	3.2	21 (70.0%)	-0.6	3.2	-6.9	5.7								
Nera 18mg		27	70.4	2.5	26 (72.2%)	-4.8	2.9	-10.4	0.9	-4.2	4.2	-12.6	4.1	0.3210			
Week 76																	
Placebo		17	73.6	4.6	17 (56.7%)												
Nera 18mg		20	71.0	3.3	19 (52.8%)												
Week 88																	
Placebo		9	71.9	7.0	9 (30.0%)												
Nera 18mg		11	61.5	6.1	11 (30.6%)												
Week 100																	
Placebo		3	88.3	3.3	3 (10.0%)												
Nera 18mg		3	66.7	18.8	3 (8.3%)												
Week 112																	

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		2	90.0	5.0	2 (6.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Rest of the World																	
Baseline																	
Placebo	16	16	61.7	4.6	14 (100.0%)												
Nera 18mg	25	25	72.6	3.1	25 (100.0%)												
Week 6																	
Placebo		14	74.6	4.8	14 (100.0%)	7.4	3.4	0.8	14.1								
Nera 18mg		25	73.8	2.5	25 (100.0%)	1.9	2.5	-3.1	6.9	-5.5	4.2	-13.8	2.8	0.1924			
Week 12																	
Placebo		14	67.9	5.2	14 (100.0%)	0.6	3.6	-6.4	7.6								
Nera 18mg		23	68.5	2.7	23 (92.0%)	-2.4	2.7	-7.7	3.0	-2.9	4.5	-11.7	5.9	0.5146			
Week 18																	
Placebo		14	70.6	5.5	14 (100.0%)	3.2	3.6	-4.0	10.3								
Nera 18mg		24	70.2	3.6	24 (96.0%)	-1.5	2.8	-6.9	3.9	-4.7	4.5	-13.6	4.3	0.3030			
Week 26																	
Placebo		14	69.9	4.0	14 (100.0%)	2.5	3.7	-4.8	9.7								
Nera 18mg		24	67.2	3.5	24 (96.0%)	-4.4	2.8	-9.9	1.2	-6.8	4.6	-15.9	2.3	0.1415			
Week 36																	
Placebo		14	68.9	4.6	14 (100.0%)	1.3	3.8	-6.3	8.9								
Nera 18mg		23	68.7	3.4	23 (92.0%)	-3.1	3.0	-8.9	2.8	-4.3	4.9	-13.9	5.2	0.3736			
Week 44																	
Placebo		14	64.9	5.1	14 (100.0%)	-2.4	4.0	-10.2	5.5								
Nera 18mg		22	70.4	4.0	22 (88.0%)	-1.7	3.1	-7.8	4.4	0.7	5.1	-9.3	10.7	0.8904			
Week 52																	
Placebo		14	61.7	7.0	14 (100.0%)	-5.5	4.6	-14.5	3.5								
Nera 18mg		18	65.9	5.0	18 (72.0%)	-6.5	3.7	-13.8	0.8	-1.0	5.9	-12.6	10.6	0.8671			
Week 64																	
Placebo		11	75.5	4.5	11 (78.6%)	2.9	4.4	-5.9	11.6								
Nera 18mg		16	71.8	3.5	16 (64.0%)	-3.9	3.5	-10.9	3.0	-6.8	5.7	-18.0	4.4	0.2313			
Week 76																	
Placebo		8	74.9	8.6	8 (57.1%)												
Nera 18mg		11	75.5	4.2	11 (44.0%)												
Week 88																	
Placebo		1	90.0	NC	1 (7.1%)												
Nera 18mg		3	53.3	19.2	3 (12.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 7 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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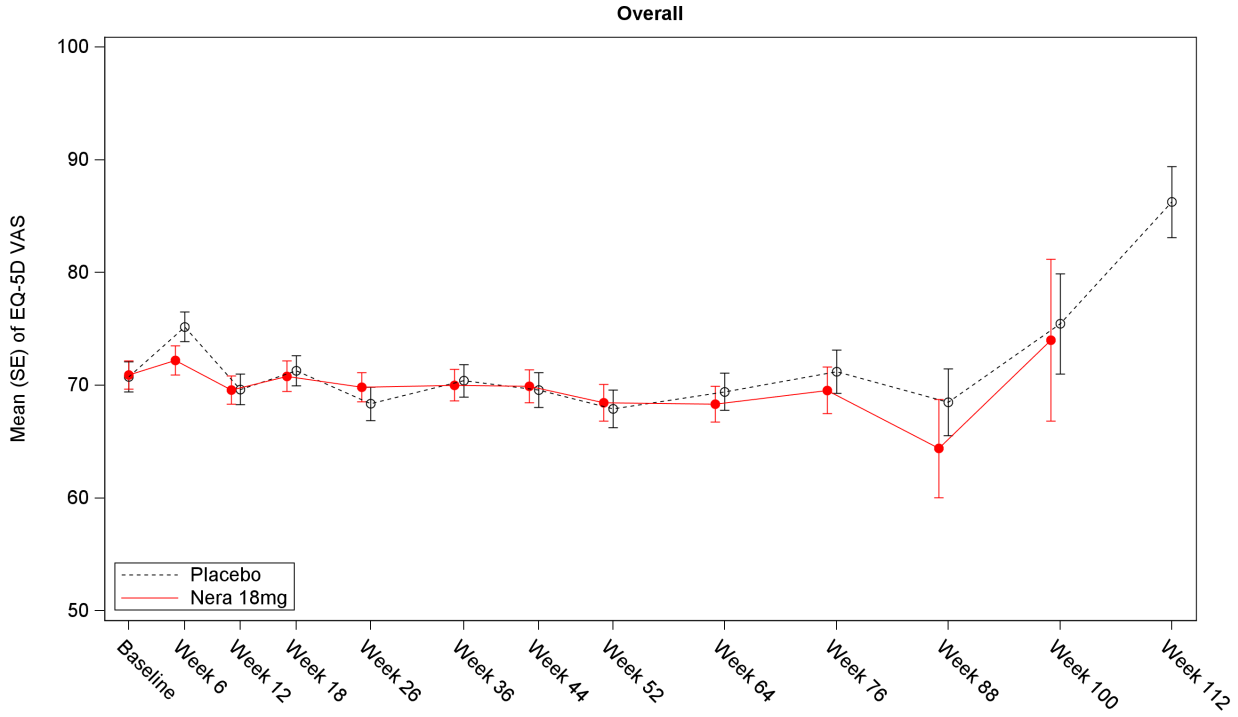

Number of patients

Placebo	167	163	158	159	155	149	147	148	128	88	38	11	4
Nera 18mg	165	166	158	157	149	143	139	136	121	80	31	9	0

Study: 1305-0023. Number of patients refers to the number of patients with observed data at visit.

Figure I.1.1.1.2.1: 7 Mean (SE) of EQ-5D VAS
over the whole trial - 18mg - FAS (NIN background)

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Boehringer Ingelheim
BI Trial No.: x1305p3.hta

Figure I.1.1.1.2.1: 7

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Overall																	
Baseline																	
Placebo	169	165	2.0	0.1	160 (100.0%)												
Nera 18mg	170	168	2.1	0.1	163 (100.0%)												
Week 12																	
Placebo		160	2.0	0.1	156 (97.5%)	-0.1	0.1	-0.2	0.1								
Nera 18mg		160	2.2	0.1	159 (97.5%)	0.1	0.1	-0.1	0.2	0.2	0.1	-0.1	0.4	0.1637			
Week 26																	
Placebo		155	2.1	0.1	151 (94.4%)	0.1	0.1	-0.1	0.3								
Nera 18mg		150	2.1	0.1	148 (90.8%)	0.1	0.1	-0.1	0.2	-0.1	0.1	-0.3	0.2	0.6842			
Week 36																	
Placebo		150	2.0	0.1	146 (91.3%)	0.0	0.1	-0.2	0.2								
Nera 18mg		146	2.1	0.1	144 (88.3%)	0.1	0.1	-0.1	0.2	0.0	0.1	-0.2	0.3	0.8088			
Week 44																	
Placebo		147	2.0	0.1	143 (89.4%)	-0.0	0.1	-0.2	0.2								
Nera 18mg		139	2.1	0.1	137 (84.0%)	0.1	0.1	-0.1	0.3	0.1	0.1	-0.2	0.3	0.4776			
Week 52																	
Placebo		147	2.0	0.1	143 (89.4%)	-0.0	0.1	-0.2	0.1								
Nera 18mg		138	2.2	0.1	136 (83.4%)	0.2	0.1	0.0	0.4	0.2	0.1	-0.0	0.5	0.0773			
Week 64																	
Placebo		128	2.0	0.1	125 (78.1%)	0.1	0.1	-0.1	0.3								
Nera 18mg		119	2.2	0.1	117 (71.8%)	0.2	0.1	-0.0	0.4	0.1	0.1	-0.2	0.4	0.5325			
Week 76																	
Placebo		88	2.0	0.1	85 (53.1%)												
Nera 18mg		80	2.3	0.2	78 (47.9%)												
Week 88																	
Placebo		38	2.1	0.2	37 (23.1%)												
Nera 18mg		30	2.5	0.2	30 (18.4%)												
Week 100																	
Placebo		11	1.5	0.3	11 (6.9%)												
Nera 18mg		9	2.7	0.3	9 (5.5%)												
Week 112																	
Placebo		4	1.8	0.3	4 (2.5%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Cough at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Age																	
Test for homogeneity (H0)^																	
Week 12														0.6068			
Week 26														0.3784			
Week 36														0.6534			
Week 44														0.9029			
Week 52														0.1171			
Week 64														0.2449			
<65 years																	
Baseline																	
Placebo	65	65	2.0	0.1	64 (100.0%)												
Nera 18mg	64	63	2.1	0.2	61 (100.0%)												
Week 12																	
Placebo		63	1.9	0.1	63 (98.4%)	-0.1	0.1	-0.3	0.2								
Nera 18mg		61	2.2	0.2	60 (98.4%)	0.1	0.1	-0.1	0.4	0.2	0.2	-0.1	0.6	0.2036			
Week 26																	
Placebo		62	2.2	0.2	62 (96.9%)	0.2	0.1	-0.1	0.4								
Nera 18mg		58	2.0	0.2	57 (93.4%)	-0.0	0.1	-0.3	0.3	-0.2	0.2	-0.6	0.2	0.3483			
Week 36																	
Placebo		61	2.1	0.2	61 (95.3%)	0.1	0.1	-0.2	0.3								
Nera 18mg		56	2.0	0.2	55 (90.2%)	0.0	0.1	-0.3	0.3	-0.0	0.2	-0.4	0.4	0.8462			
Week 44																	
Placebo		61	2.0	0.1	61 (95.3%)	0.0	0.1	-0.2	0.3								
Nera 18mg		52	2.1	0.2	51 (83.6%)	0.1	0.1	-0.2	0.4	0.1	0.2	-0.3	0.5	0.7095			
Week 52																	
Placebo		61	2.0	0.2	61 (95.3%)	0.0	0.1	-0.2	0.3								
Nera 18mg		52	2.0	0.2	51 (83.6%)	0.0	0.1	-0.3	0.3	-0.0	0.2	-0.4	0.4	0.9107			
Week 64																	
Placebo		57	2.2	0.2	57 (89.1%)	0.3	0.1	0.0	0.6								
Nera 18mg		45	2.1	0.2	44 (72.1%)	0.2	0.2	-0.1	0.5	-0.1	0.2	-0.5	0.3	0.6711			
Week 76																	
Placebo		37	2.2	0.2	37 (57.8%)												
Nera 18mg		34	2.1	0.2	33 (54.1%)												
Week 88																	
Placebo		15	2.5	0.3	15 (23.4%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Cough at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		7	3.3	0.4	7 (11.5%)												
Week 100																	
Placebo		4	1.5	0.5	4 (6.3%)												
Nera 18mg		1	2.0	NC	1 (1.6%)												
Week 112																	
Placebo		2	1.5	0.5	2 (3.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	104	100	2.0	0.1	96 (100.0%)												
Nera 18mg	106	105	2.1	0.1	102 (100.0%)												
Week 12																	
Placebo		97	2.0	0.1	93 (96.9%)	-0.1	0.1	-0.3	0.1								
Nera 18mg		99	2.1	0.1	99 (97.1%)	0.1	0.1	-0.2	0.3	0.1	0.1	-0.2	0.4	0.4440			
Week 26																	
Placebo		93	2.1	0.1	89 (92.7%)	0.1	0.1	-0.2	0.3								
Nera 18mg		92	2.2	0.1	91 (89.2%)	0.1	0.1	-0.1	0.3	0.0	0.2	-0.3	0.4	0.8091			
Week 36																	
Placebo		89	2.0	0.1	85 (88.5%)	-0.0	0.1	-0.2	0.2								
Nera 18mg		90	2.2	0.1	89 (87.3%)	0.1	0.1	-0.2	0.3	0.1	0.2	-0.2	0.4	0.6358			
Week 44																	
Placebo		86	2.0	0.1	82 (85.4%)	-0.1	0.1	-0.3	0.2								
Nera 18mg		87	2.2	0.1	86 (84.3%)	0.1	0.1	-0.2	0.3	0.1	0.2	-0.2	0.4	0.5152			
Week 52																	
Placebo		86	1.9	0.1	82 (85.4%)	-0.1	0.1	-0.3	0.1								
Nera 18mg		86	2.3	0.1	85 (83.3%)	0.3	0.1	0.1	0.5	0.4	0.2	0.1	0.7	0.0192	0.36	0.06	0.67
Week 64																	
Placebo		71	1.9	0.2	68 (70.8%)	-0.1	0.1	-0.3	0.2								
Nera 18mg		74	2.3	0.1	73 (71.6%)	0.2	0.1	-0.1	0.4	0.2	0.2	-0.1	0.6	0.1889			
Week 76																	
Placebo		51	1.8	0.2	48 (50.0%)												
Nera 18mg		46	2.4	0.2	45 (44.1%)												
Week 88																	
Placebo		23	1.8	0.3	22 (22.9%)												
Nera 18mg		23	2.3	0.2	23 (22.5%)												
Week 100																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Cough at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		7	1.4	0.4	7 (7.3%)												
Nera 18mg		8	2.8	0.4	8 (7.8%)												
Week 112																	
Placebo		2	2.0	0.0	2 (2.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Sex																	
Test for homogeneity (H0)^																	
Week 12														0.9416			
Week 26														0.5598			
Week 36														0.3149			
Week 44														0.4752			
Week 52														0.8016			
Week 64														0.3755			
Male																	
Baseline																	
Placebo	114	112	2.0	0.1	109 (100.0%)												
Nera 18mg	108	106	2.0	0.1	101 (100.0%)												
Week 12																	
Placebo		107	2.0	0.1	105 (96.3%)	-0.1	0.1	-0.3	0.1								
Nera 18mg		100	2.1	0.1	99 (98.0%)	0.1	0.1	-0.1	0.3	0.2	0.1	-0.1	0.5	0.2311			
Week 26																	
Placebo		103	2.2	0.1	101 (92.7%)	0.2	0.1	-0.1	0.4								
Nera 18mg		94	2.2	0.1	92 (91.1%)	0.2	0.1	-0.0	0.4	0.0	0.2	-0.3	0.3	0.9102			
Week 36																	
Placebo		99	2.1	0.1	97 (89.0%)	0.1	0.1	-0.1	0.3								
Nera 18mg		88	2.2	0.1	86 (85.1%)	0.2	0.1	0.0	0.5	0.1	0.2	-0.2	0.5	0.3536			
Week 44																	
Placebo		97	2.0	0.1	95 (87.2%)	-0.1	0.1	-0.3	0.2								
Nera 18mg		83	2.1	0.1	81 (80.2%)	0.1	0.1	-0.1	0.3	0.2	0.2	-0.2	0.5	0.3397			
Week 52																	
Placebo		96	2.0	0.1	94 (86.2%)	0.0	0.1	-0.2	0.3								
Nera 18mg		83	2.3	0.1	81 (80.2%)	0.3	0.1	0.1	0.5	0.3	0.2	-0.0	0.6	0.0989			
Week 64																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		82	2.0	0.1	81 (74.3%)	0.1	0.1	-0.1	0.4								
Nera 18mg		72	2.4	0.1	70 (69.3%)	0.3	0.1	0.1	0.6	0.2	0.2	-0.1	0.5	0.2633			
Week 76																	
Placebo		54	1.9	0.2	53 (48.6%)												
Nera 18mg		47	2.5	0.2	45 (44.6%)												
Week 88																	
Placebo		25	2.2	0.3	25 (22.9%)												
Nera 18mg		18	2.7	0.3	18 (17.8%)												
Week 100																	
Placebo		7	1.6	0.5	7 (6.4%)												
Nera 18mg		4	3.3	0.5	4 (4.0%)												
Week 112																	
Placebo		2	2.0	0.0	2 (1.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Female																	
Baseline																	
Placebo	55	53	2.0	0.2	51 (100.0%)												
Nera 18mg	62	62	2.3	0.1	62 (100.0%)												
Week 12																	
Placebo		53	1.9	0.2	51 (100.0%)	-0.1	0.1	-0.4	0.2								
Nera 18mg		60	2.2	0.2	60 (96.8%)	0.0	0.1	-0.2	0.3	0.2	0.2	-0.2	0.5	0.4331			
Week 26																	
Placebo		52	2.0	0.2	50 (98.0%)	-0.0	0.2	-0.3	0.3								
Nera 18mg		56	2.0	0.2	56 (90.3%)	-0.1	0.1	-0.4	0.1	-0.1	0.2	-0.5	0.3	0.5213			
Week 36																	
Placebo		51	2.0	0.2	49 (96.1%)	-0.1	0.2	-0.4	0.2								
Nera 18mg		58	1.9	0.2	58 (93.5%)	-0.2	0.1	-0.5	0.1	-0.1	0.2	-0.5	0.3	0.5743			
Week 44																	
Placebo		50	2.1	0.2	48 (94.1%)	0.1	0.2	-0.2	0.4								
Nera 18mg		56	2.2	0.2	56 (90.3%)	0.0	0.1	-0.2	0.3	-0.0	0.2	-0.5	0.4	0.8609			
Week 52																	
Placebo		51	1.9	0.2	49 (96.1%)	-0.2	0.2	-0.5	0.1								
Nera 18mg		55	2.1	0.2	55 (88.7%)	0.0	0.1	-0.3	0.3	0.2	0.2	-0.2	0.6	0.3520			
Week 64																	
Placebo		46	2.0	0.2	44 (86.3%)	-0.0	0.2	-0.3	0.3								
Nera 18mg		47	1.9	0.2	47 (75.8%)	-0.1	0.2	-0.4	0.3	-0.1	0.2	-0.5	0.4	0.7914			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 76																	
Placebo		34	2.1	0.2	32 (62.7%)												
Nera 18mg		33	2.0	0.2	33 (53.2%)												
Week 88																	
Placebo		13	1.8	0.3	12 (23.5%)												
Nera 18mg		12	2.3	0.4	12 (19.4%)												
Week 100																	
Placebo		4	1.3	0.3	4 (7.8%)												
Nera 18mg		5	2.2	0.4	5 (8.1%)												
Week 112																	
Placebo		2	1.5	0.5	2 (3.9%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 12														0.9642			
Week 26														0.7930			
Week 36														0.9206			
Week 44														0.4966			
Week 52														0.9426			
Week 64														0.8174			
<=70%																	
Baseline																	
Placebo	95	94	2.2	0.1	90 (100.0%)												
Nera 18mg	97	95	2.2	0.1	94 (100.0%)												
Week 12																	
Placebo		88	2.1	0.1	87 (96.7%)	0.0	0.1	-0.2	0.2								
Nera 18mg		92	2.3	0.1	91 (96.8%)	0.2	0.1	-0.0	0.4	0.2	0.2	-0.1	0.5	0.3184			
Week 26																	
Placebo		85	2.3	0.1	84 (93.3%)	0.2	0.1	-0.1	0.4								
Nera 18mg		85	2.3	0.1	83 (88.3%)	0.1	0.1	-0.1	0.4	-0.0	0.2	-0.3	0.3	0.8847			
Week 36																	
Placebo		82	2.1	0.1	81 (90.0%)	0.0	0.1	-0.2	0.3								
Nera 18mg		85	2.2	0.1	83 (88.3%)	0.1	0.1	-0.2	0.3	0.0	0.2	-0.3	0.4	0.9029			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Cough at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 44																	
Placebo		81	2.1	0.1	80 (88.9%)	0.0	0.1	-0.2	0.2								
Nera 18mg		79	2.3	0.1	77 (81.9%)	0.2	0.1	-0.1	0.4	0.2	0.2	-0.2	0.5	0.3328			
Week 52																	
Placebo		79	2.2	0.1	78 (86.7%)	0.1	0.1	-0.1	0.4								
Nera 18mg		79	2.4	0.1	77 (81.9%)	0.3	0.1	0.1	0.6	0.2	0.2	-0.1	0.5	0.2160			
Week 64																	
Placebo		70	2.2	0.2	69 (76.7%)	0.2	0.1	-0.0	0.5								
Nera 18mg		69	2.4	0.1	67 (71.3%)	0.3	0.1	0.0	0.6	0.1	0.2	-0.3	0.4	0.7732			
Week 76																	
Placebo		45	2.0	0.2	44 (48.9%)												
Nera 18mg		44	2.5	0.2	42 (44.7%)												
Week 88																	
Placebo		20	1.9	0.3	20 (22.2%)												
Nera 18mg		19	2.8	0.3	19 (20.2%)												
Week 100																	
Placebo		5	1.8	0.4	5 (5.6%)												
Nera 18mg		5	2.6	0.4	5 (5.3%)												
Week 112																	
Placebo		3	1.7	0.3	3 (3.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	74	71	1.8	0.1	70 (100.0%)												
Nera 18mg	73	73	1.9	0.1	69 (100.0%)												
Week 12																	
Placebo		72	1.8	0.1	69 (98.6%)	-0.2	0.1	-0.4	0.1								
Nera 18mg		68	1.9	0.2	68 (98.6%)	-0.0	0.1	-0.3	0.2	0.2	0.2	-0.2	0.5	0.3515			
Week 26																	
Placebo		70	2.0	0.1	67 (95.7%)	0.0	0.1	-0.2	0.3								
Nera 18mg		65	1.9	0.2	65 (94.2%)	-0.1	0.1	-0.3	0.2	-0.1	0.2	-0.5	0.3	0.6329			
Week 36																	
Placebo		68	2.0	0.2	65 (92.9%)	-0.0	0.1	-0.3	0.3								
Nera 18mg		61	2.0	0.2	61 (88.4%)	0.0	0.1	-0.2	0.3	0.0	0.2	-0.3	0.4	0.8108			
Week 44																	
Placebo		66	1.9	0.2	63 (90.0%)	-0.0	0.1	-0.3	0.2								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Cough at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		60	2.0	0.2	60 (87.0%)	-0.1	0.1	-0.3	0.2	-0.0	0.2	-0.4	0.4	0.9594			
Week 52																	
Placebo		68	1.8	0.2	65 (92.9%)	-0.2	0.1	-0.5	0.0								
Nera 18mg		59	1.9	0.2	59 (85.5%)	-0.0	0.1	-0.3	0.3	0.2	0.2	-0.1	0.6	0.2332			
Week 64																	
Placebo		58	1.9	0.2	56 (80.0%)	-0.1	0.1	-0.4	0.2								
Nera 18mg		50	1.9	0.2	50 (72.5%)	0.0	0.2	-0.3	0.3	0.1	0.2	-0.3	0.5	0.5748			
Week 76																	
Placebo		43	1.9	0.2	41 (58.6%)												
Nera 18mg		36	2.0	0.2	36 (52.2%)												
Week 88																	
Placebo		18	2.3	0.3	17 (24.3%)												
Nera 18mg		11	2.1	0.4	11 (15.9%)												
Week 100																	
Placebo		6	1.2	0.5	6 (8.6%)												
Nera 18mg		4	2.8	0.6	4 (5.8%)												
Week 112																	
Placebo		1	2.0	NC	1 (1.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline HRCT pattern																	
Test for homogeneity (H0)^																	
Week 12														0.6059			
Week 26														0.8400			
Week 36														0.0460			
Week 44														0.5038			
Week 52														0.6960			
Week 64														0.8165			
UIP-like																	
Baseline																	
Placebo	116	113	2.0	0.1	110 (100.0%)												
Nera 18mg	121	121	2.0	0.1	118 (100.0%)												
Week 12																	
Placebo		110	1.9	0.1	107 (97.3%)	-0.1	0.1	-0.3	0.1								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Cough at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		116	2.2	0.1	116 (98.3%)	0.1	0.1	-0.1	0.3	0.2	0.1	-0.1	0.5	0.1472			
Week 26																	
Placebo		106	2.2	0.1	103 (93.6%)	0.1	0.1	-0.1	0.3								
Nera 18mg		108	2.1	0.1	108 (91.5%)	0.1	0.1	-0.1	0.3	-0.1	0.1	-0.4	0.2	0.6521			
Week 36																	
Placebo		102	2.0	0.1	99 (90.0%)	-0.1	0.1	-0.3	0.2								
Nera 18mg		104	2.2	0.1	104 (88.1%)	0.1	0.1	-0.1	0.3	0.2	0.2	-0.1	0.5	0.1931			
Week 44																	
Placebo		99	2.0	0.1	96 (87.3%)	0.0	0.1	-0.2	0.2								
Nera 18mg		100	2.2	0.1	100 (84.7%)	0.1	0.1	-0.1	0.4	0.1	0.2	-0.2	0.4	0.3342			
Week 52																	
Placebo		99	2.0	0.1	96 (87.3%)	-0.0	0.1	-0.2	0.2								
Nera 18mg		99	2.2	0.1	99 (83.9%)	0.2	0.1	0.0	0.4	0.3	0.1	-0.0	0.5	0.0898			
Week 64																	
Placebo		90	2.1	0.1	88 (80.0%)	0.2	0.1	-0.1	0.4								
Nera 18mg		85	2.2	0.1	85 (72.0%)	0.3	0.1	0.0	0.5	0.1	0.2	-0.2	0.4	0.5083			
Week 76																	
Placebo		60	1.9	0.2	58 (52.7%)												
Nera 18mg		59	2.4	0.2	59 (50.0%)												
Week 88																	
Placebo		26	2.1	0.3	25 (22.7%)												
Nera 18mg		22	2.6	0.3	22 (18.6%)												
Week 100																	
Placebo		9	1.4	0.4	9 (8.2%)												
Nera 18mg		8	2.6	0.4	8 (6.8%)												
Week 112																	
Placebo		3	1.7	0.3	3 (2.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other fibrotic patterns																	
Baseline																	
Placebo	53	52	2.0	0.2	50 (100.0%)												
Nera 18mg	49	47	2.2	0.2	45 (100.0%)												
Week 12																	
Placebo		50	2.0	0.2	49 (98.0%)	0.0	0.1	-0.3	0.3								
Nera 18mg		44	2.1	0.2	43 (95.6%)	0.1	0.2	-0.2	0.4	0.1	0.2	-0.4	0.5	0.7495			
Week 26																	

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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Cough at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		49	2.1	0.2	48 (96.0%)	0.0	0.2	-0.3	0.4								
Nera 18mg		42	2.2	0.2	40 (88.9%)	0.0	0.2	-0.3	0.4	-0.0	0.2	-0.5	0.4	0.9601			
Week 36																	
Placebo		48	2.2	0.2	47 (94.0%)	0.2	0.2	-0.1	0.5								
Nera 18mg		42	1.9	0.2	40 (88.9%)	-0.2	0.2	-0.5	0.2	-0.4	0.2	-0.8	0.1	0.1241			
Week 44																	
Placebo		48	2.0	0.2	47 (94.0%)	-0.1	0.2	-0.4	0.3								
Nera 18mg		39	2.0	0.2	37 (82.2%)	-0.1	0.2	-0.4	0.2	-0.0	0.2	-0.5	0.4	0.8654			
Week 52																	
Placebo		48	1.9	0.2	47 (94.0%)	-0.1	0.2	-0.4	0.2								
Nera 18mg		39	2.2	0.2	37 (82.2%)	0.1	0.2	-0.3	0.4	0.1	0.2	-0.3	0.6	0.5236			
Week 64																	
Placebo		38	1.8	0.2	37 (74.0%)	-0.1	0.2	-0.4	0.3								
Nera 18mg		34	2.1	0.2	32 (71.1%)	-0.0	0.2	-0.4	0.4	0.0	0.3	-0.5	0.6	0.8836			
Week 76																	
Placebo		28	2.1	0.3	27 (54.0%)												
Nera 18mg		21	2.0	0.3	19 (42.2%)												
Week 88																	
Placebo		12	2.0	0.4	12 (24.0%)												
Nera 18mg		8	2.3	0.5	8 (17.8%)												
Week 100																	
Placebo		2	1.5	0.5	2 (4.0%)												
Nera 18mg		1	3.0	NC	1 (2.2%)												
Week 112																	
Placebo		1	2.0	NC	1 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Underlying ILD diagnosis																	
Test for homogeneity (H0)^																	
Week 12														0.9432			
Week 26														0.7213			
Week 36														0.6947			
Week 44														0.6281			
Week 52														0.7360			
Week 64														0.5569			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Cough at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
iNSIP																	
Baseline																	
Placebo	32	32	2.2	0.2	31 (100.0%)												
Nera 18mg	27	26	2.0	0.2	24 (100.0%)												
Week 12																	
Placebo		29	1.9	0.2	29 (93.5%)	-0.2	0.2	-0.6	0.2								
Nera 18mg		23	2.0	0.3	23 (95.8%)	-0.0	0.2	-0.4	0.4	0.2	0.3	-0.4	0.7	0.5483			
Week 26																	
Placebo		29	2.0	0.2	29 (93.5%)	-0.1	0.2	-0.5	0.3								
Nera 18mg		23	2.0	0.2	22 (91.7%)	-0.1	0.2	-0.5	0.4	0.0	0.3	-0.6	0.6	0.9212			
Week 36																	
Placebo		28	2.0	0.2	28 (90.3%)	-0.0	0.2	-0.4	0.4								
Nera 18mg		21	2.0	0.3	20 (83.3%)	-0.1	0.2	-0.6	0.4	-0.1	0.3	-0.7	0.5	0.8332			
Week 44																	
Placebo		28	2.0	0.2	28 (90.3%)	-0.0	0.2	-0.4	0.3								
Nera 18mg		19	2.2	0.4	18 (75.0%)	0.2	0.2	-0.3	0.7	0.3	0.3	-0.4	0.9	0.4171			
Week 52																	
Placebo		27	2.0	0.2	27 (87.1%)	-0.1	0.2	-0.5	0.3								
Nera 18mg		17	2.1	0.3	16 (66.7%)	0.2	0.2	-0.2	0.7	0.3	0.3	-0.3	0.9	0.2924			
Week 64																	
Placebo		23	2.0	0.3	23 (74.2%)	-0.1	0.2	-0.5	0.4								
Nera 18mg		16	2.3	0.3	15 (62.5%)	0.2	0.3	-0.3	0.8	0.3	0.4	-0.4	1.0	0.3662			
Week 76																	
Placebo		16	2.2	0.3	16 (51.6%)												
Nera 18mg		10	2.3	0.6	9 (37.5%)												
Week 88																	
Placebo		9	1.9	0.5	9 (29.0%)												
Nera 18mg		3	2.3	0.7	3 (12.5%)												
Week 100																	
Placebo		2	0.5	0.5	2 (6.5%)												
Nera 18mg		1	3.0	NC	1 (4.2%)												
Week 112																	
Placebo		2	2.0	0.0	2 (6.5%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Unclassifiable IIP																	

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n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Baseline																	
Placebo	46	46	2.1	0.2	44 (100.0%)												
Nera 18mg	32	32	2.1	0.2	32 (100.0%)												
Week 12																	
Placebo		44	2.0	0.2	44 (100.0%)	-0.1	0.2	-0.4	0.2								
Nera 18mg		32	2.3	0.2	32 (100.0%)	0.3	0.2	-0.1	0.6	0.4	0.2	-0.1	0.8	0.1447			
Week 26																	
Placebo		40	2.2	0.2	40 (90.9%)	0.1	0.2	-0.2	0.4								
Nera 18mg		28	2.1	0.2	28 (87.5%)	0.0	0.2	-0.3	0.4	-0.1	0.3	-0.6	0.5	0.8335			
Week 36																	
Placebo		38	2.1	0.2	38 (86.4%)	0.0	0.2	-0.3	0.4								
Nera 18mg		27	2.6	0.2	27 (84.4%)	0.5	0.2	0.1	0.9	0.5	0.3	-0.0	1.0	0.0758			
Week 44																	
Placebo		37	2.1	0.2	37 (84.1%)	0.1	0.2	-0.3	0.4								
Nera 18mg		27	2.1	0.2	27 (84.4%)	0.0	0.2	-0.4	0.4	-0.1	0.3	-0.6	0.4	0.7609			
Week 52																	
Placebo		38	1.9	0.2	38 (86.4%)	-0.1	0.2	-0.5	0.2								
Nera 18mg		28	2.2	0.2	28 (87.5%)	0.2	0.2	-0.2	0.6	0.3	0.3	-0.2	0.8	0.2122			
Week 64																	
Placebo		32	2.1	0.2	32 (72.7%)	0.2	0.2	-0.2	0.6								
Nera 18mg		23	2.2	0.3	23 (71.9%)	0.2	0.2	-0.3	0.6	-0.0	0.3	-0.6	0.6	0.9293			
Week 76																	
Placebo		25	1.8	0.2	25 (56.8%)												
Nera 18mg		17	2.1	0.3	17 (53.1%)												
Week 88																	
Placebo		10	2.5	0.5	10 (22.7%)												
Nera 18mg		10	2.3	0.5	10 (31.3%)												
Week 100																	
Placebo		2	2.5	0.5	2 (4.5%)												
Nera 18mg		3	2.3	0.7	3 (9.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
HP																	
Baseline																	
Placebo	38	37	1.8	0.2	37 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Cough at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg	43	43	2.3	0.2	41 (100.0%)												
Week 12																	
Placebo		37	1.8	0.2	36 (97.3%)	-0.0	0.2	-0.4	0.3								
Nera 18mg		39	2.6	0.2	39 (95.1%)	0.2	0.2	-0.1	0.6	0.2	0.2	-0.2	0.7	0.2978			
Week 26																	
Placebo		38	2.1	0.2	37 (100.0%)	0.2	0.2	-0.1	0.6								
Nera 18mg		36	2.4	0.2	36 (87.8%)	0.2	0.2	-0.1	0.6	-0.0	0.3	-0.5	0.5	0.9173			
Week 36																	
Placebo		37	2.1	0.2	36 (97.3%)	0.1	0.2	-0.3	0.4								
Nera 18mg		37	2.4	0.2	37 (90.2%)	0.3	0.2	-0.1	0.6	0.2	0.3	-0.3	0.7	0.4441			
Week 44																	
Placebo		37	1.8	0.2	36 (97.3%)	-0.0	0.2	-0.4	0.3								
Nera 18mg		34	2.5	0.2	34 (82.9%)	0.3	0.2	-0.1	0.6	0.3	0.3	-0.2	0.8	0.2127			
Week 52																	
Placebo		36	1.9	0.2	35 (94.6%)	0.0	0.2	-0.3	0.4								
Nera 18mg		35	2.5	0.2	35 (85.4%)	0.4	0.2	0.1	0.7	0.4	0.2	-0.1	0.9	0.1299			
Week 64																	
Placebo		33	2.2	0.2	32 (86.5%)	0.4	0.2	0.0	0.8								
Nera 18mg		29	2.5	0.2	29 (70.7%)	0.3	0.2	-0.1	0.7	-0.1	0.3	-0.7	0.4	0.6986			
Week 76																	
Placebo		18	2.0	0.3	17 (45.9%)												
Nera 18mg		17	2.6	0.3	17 (41.5%)												
Week 88																	
Placebo		8	2.1	0.5	8 (21.6%)												
Nera 18mg		5	2.8	0.5	5 (12.2%)												
Week 100																	
Placebo		1	0.0	NC	1 (2.7%)												
Nera 18mg		1	4.0	NC	1 (2.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Autoimmune ILD																	
Baseline																	
Placebo	29	28	2.1	0.2	27 (100.0%)												
Nera 18mg	43	43	2.0	0.2	43 (100.0%)												
Week 12																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Cough at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo		28	1.9	0.3	27 (100.0%)	-0.3	0.2	-0.6	0.1								
Nera 18mg		42	1.8	0.2	42 (97.7%)	-0.2	0.2	-0.5	0.2	0.1	0.3	-0.4	0.6	0.6770			
Week 26																	
Placebo		27	2.0	0.2	26 (96.3%)	-0.1	0.2	-0.6	0.3								
Nera 18mg		40	1.9	0.2	40 (93.0%)	-0.1	0.2	-0.4	0.2	0.0	0.3	-0.5	0.6	0.8559			
Week 36																	
Placebo		26	1.8	0.2	25 (92.6%)	-0.2	0.2	-0.7	0.2								
Nera 18mg		38	1.6	0.2	38 (88.4%)	-0.4	0.2	-0.8	-0.1	-0.2	0.3	-0.8	0.3	0.4345			
Week 44																	
Placebo		24	2.0	0.2	23 (85.2%)	-0.1	0.2	-0.6	0.3								
Nera 18mg		37	1.8	0.2	37 (86.0%)	-0.2	0.2	-0.6	0.1	-0.1	0.3	-0.7	0.4	0.6977			
Week 52																	
Placebo		25	2.0	0.2	24 (88.9%)	-0.1	0.2	-0.5	0.3								
Nera 18mg		36	1.7	0.2	36 (83.7%)	-0.3	0.2	-0.6	0.1	-0.1	0.3	-0.7	0.4	0.6015			
Week 64																	
Placebo		21	1.6	0.3	21 (77.8%)	-0.4	0.2	-0.9	0.0								
Nera 18mg		32	1.8	0.2	32 (74.4%)	-0.1	0.2	-0.4	0.3	0.4	0.3	-0.2	1.0	0.2306			
Week 76																	
Placebo		16	2.1	0.4	16 (59.3%)												
Nera 18mg		19	1.9	0.3	19 (44.2%)												
Week 88																	
Placebo		6	1.3	0.4	6 (22.2%)												
Nera 18mg		5	2.8	0.2	5 (11.6%)												
Week 100																	
Placebo		4	1.5	0.5	4 (14.8%)												
Nera 18mg		2	2.0	0.0	2 (4.7%)												
Week 112																	
Placebo		2	1.5	0.5	2 (7.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other ILD																	
Baseline																	
Placebo	24	22	2.0	0.3	21 (100.0%)												
Nera 18mg	25	24	2.0	0.2	23 (100.0%)												
Week 12																	
Placebo		22	2.2	0.3	20 (95.2%)	0.2	0.2	-0.2	0.7								
Nera 18mg		24	2.0	0.3	23 (100.0%)	0.1	0.2	-0.3	0.5	-0.1	0.3	-0.7	0.5	0.7318			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Cough at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 26																	
Placebo		21	2.4	0.3	19 (90.5%)	0.5	0.2	0.0	1.0								
Nera 18mg		23	2.3	0.2	22 (95.7%)	0.2	0.2	-0.3	0.6	-0.3	0.3	-1.0	0.3	0.3305			
Week 36																	
Placebo		21	2.2	0.3	19 (90.5%)	0.3	0.2	-0.2	0.8								
Nera 18mg		23	2.1	0.3	22 (95.7%)	0.1	0.2	-0.3	0.6	-0.2	0.3	-0.8	0.5	0.5930			
Week 44																	
Placebo		21	2.1	0.3	19 (90.5%)	0.1	0.2	-0.4	0.6								
Nera 18mg		22	2.3	0.3	21 (91.3%)	0.3	0.2	-0.1	0.8	0.2	0.3	-0.4	0.9	0.5017			
Week 52																	
Placebo		21	2.2	0.3	19 (90.5%)	0.3	0.2	-0.2	0.8								
Nera 18mg		22	2.5	0.2	21 (91.3%)	0.6	0.2	0.2	1.1	0.3	0.3	-0.3	0.9	0.3524			
Week 64																	
Placebo		19	2.1	0.3	17 (81.0%)	0.2	0.3	-0.3	0.7								
Nera 18mg		19	2.3	0.3	18 (78.3%)	0.4	0.3	-0.2	0.9	0.1	0.4	-0.6	0.9	0.7086			
Week 76																	
Placebo		13	1.8	0.4	11 (52.4%)												
Nera 18mg		17	2.5	0.3	16 (69.6%)												
Week 88																	
Placebo		5	2.4	0.4	4 (19.0%)												
Nera 18mg		7	2.6	0.5	7 (30.4%)												
Week 100																	
Placebo		2	2.0	0.0	2 (9.5%)												
Nera 18mg		2	3.0	1.0	2 (8.7%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Region																	
Test for homogeneity (H0)^																	
Week 12														0.8365			
Week 26														0.8968			
Week 36														0.0331			
Week 44														0.1247			
Week 52														0.1663			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 64														0.5488			
Europe																	
Baseline																	
Placebo	78	74	2.2	0.2	73 (100.0%)												
Nera 18mg	67	66	2.1	0.2	64 (100.0%)												
Week 12																	
Placebo		76	2.1	0.2	72 (98.6%)	0.0	0.1	-0.2	0.2								
Nera 18mg		61	2.2	0.2	61 (95.3%)	0.2	0.1	-0.1	0.5	0.2	0.2	-0.2	0.5	0.2912			
Week 26																	
Placebo		73	2.3	0.2	69 (94.5%)	0.2	0.1	-0.1	0.4								
Nera 18mg		56	2.2	0.1	55 (85.9%)	0.1	0.1	-0.2	0.4	-0.1	0.2	-0.5	0.3	0.6270			
Week 36																	
Placebo		68	2.1	0.2	64 (87.7%)	-0.1	0.1	-0.3	0.2								
Nera 18mg		55	2.4	0.2	54 (84.4%)	0.3	0.1	0.0	0.6	0.3	0.2	-0.0	0.7	0.0860			
Week 44																	
Placebo		68	2.0	0.2	64 (87.7%)	-0.1	0.1	-0.4	0.2								
Nera 18mg		54	2.3	0.2	53 (82.8%)	0.2	0.1	-0.1	0.5	0.3	0.2	-0.1	0.7	0.1059			
Week 52																	
Placebo		69	2.0	0.2	65 (89.0%)	-0.1	0.1	-0.3	0.2								
Nera 18mg		53	2.4	0.2	52 (81.3%)	0.3	0.1	0.1	0.6	0.4	0.2	0.0	0.8	0.0350	0.39	0.02	0.76
Week 64																	
Placebo		63	2.2	0.2	60 (82.2%)	0.2	0.1	-0.1	0.5								
Nera 18mg		51	2.5	0.2	50 (78.1%)	0.4	0.2	0.1	0.7	0.2	0.2	-0.2	0.6	0.3242			
Week 76																	
Placebo		38	1.8	0.2	35 (47.9%)												
Nera 18mg		30	2.8	0.2	29 (45.3%)												
Week 88																	
Placebo		15	2.1	0.4	14 (19.2%)												
Nera 18mg		8	2.8	0.3	8 (12.5%)												
Week 100																	
Placebo		3	1.0	0.6	3 (4.1%)												
Nera 18mg		2	3.5	0.5	2 (3.1%)												
Week 112																	
Placebo		1	2.0	NC	1 (1.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Asia																	
Baseline																	
Placebo	45	45	1.9	0.1	43 (100.0%)												
Nera 18mg	41	41	2.1	0.2	39 (100.0%)												
Week 12																	
Placebo		42	1.6	0.2	42 (97.7%)	-0.3	0.2	-0.6	0.0								
Nera 18mg		39	1.9	0.2	39 (100.0%)	-0.2	0.2	-0.5	0.1	0.1	0.2	-0.3	0.6	0.6544			
Week 26																	
Placebo		42	1.9	0.2	42 (97.7%)	-0.0	0.2	-0.4	0.3								
Nera 18mg		36	2.2	0.2	36 (92.3%)	0.1	0.2	-0.2	0.5	0.2	0.2	-0.3	0.6	0.5374			
Week 36																	
Placebo		41	1.9	0.2	41 (95.3%)	-0.0	0.2	-0.4	0.3								
Nera 18mg		34	1.9	0.2	34 (87.2%)	-0.2	0.2	-0.6	0.2	-0.1	0.3	-0.6	0.3	0.5513			
Week 44																	
Placebo		38	1.9	0.2	38 (88.4%)	0.0	0.2	-0.3	0.4								
Nera 18mg		31	2.1	0.2	31 (79.5%)	-0.1	0.2	-0.5	0.3	-0.1	0.3	-0.6	0.4	0.6323			
Week 52																	
Placebo		39	1.8	0.2	39 (90.7%)	-0.1	0.2	-0.4	0.2								
Nera 18mg		32	1.9	0.2	32 (82.1%)	-0.1	0.2	-0.5	0.2	-0.0	0.2	-0.5	0.4	0.8576			
Week 64																	
Placebo		33	1.8	0.2	33 (76.7%)	-0.0	0.2	-0.4	0.4								
Nera 18mg		26	1.8	0.3	26 (66.7%)	-0.1	0.2	-0.5	0.3	-0.1	0.3	-0.7	0.5	0.7115			
Week 76																	
Placebo		25	1.9	0.2	25 (58.1%)												
Nera 18mg		19	1.9	0.3	19 (48.7%)												
Week 88																	
Placebo		13	1.8	0.3	13 (30.2%)												
Nera 18mg		9	2.7	0.5	9 (23.1%)												
Week 100																	
Placebo		5	1.4	0.5	5 (11.6%)												
Nera 18mg		4	2.0	0.4	4 (10.3%)												
Week 112																	
Placebo		1	1.0	NC	1 (2.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	
Baseline																	

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo	30	30	1.6	0.2	30 (100.0%)												
Nera 18mg	37	36	2.0	0.2	36 (100.0%)												
Week 12																	
Placebo		28	1.9	0.2	28 (93.3%)	0.0	0.2	-0.4	0.4								
Nera 18mg		37	2.1	0.2	36 (100.0%)	0.2	0.2	-0.2	0.5	0.1	0.3	-0.4	0.7	0.5682			
Week 26																	
Placebo		26	1.9	0.2	26 (86.7%)	0.1	0.2	-0.4	0.5								
Nera 18mg		34	2.0	0.2	33 (91.7%)	0.0	0.2	-0.4	0.4	-0.0	0.3	-0.6	0.5	0.8846			
Week 36																	
Placebo		27	1.9	0.2	27 (90.0%)	0.1	0.2	-0.3	0.5								
Nera 18mg		34	1.9	0.2	33 (91.7%)	-0.0	0.2	-0.4	0.4	-0.1	0.3	-0.7	0.4	0.6360			
Week 44																	
Placebo		27	1.8	0.2	27 (90.0%)	0.0	0.2	-0.4	0.4								
Nera 18mg		33	1.9	0.2	32 (88.9%)	0.0	0.2	-0.3	0.4	0.0	0.3	-0.5	0.6	0.9669			
Week 52																	
Placebo		25	1.8	0.3	25 (83.3%)	0.1	0.2	-0.3	0.5								
Nera 18mg		33	2.2	0.2	32 (88.9%)	0.4	0.2	0.1	0.8	0.3	0.3	-0.3	0.8	0.2921			
Week 64																	
Placebo		21	2.0	0.3	21 (70.0%)	0.2	0.2	-0.3	0.6								
Nera 18mg		26	2.2	0.2	25 (69.4%)	0.3	0.2	-0.1	0.8	0.2	0.3	-0.5	0.8	0.5845			
Week 76																	
Placebo		17	2.3	0.3	17 (56.7%)												
Nera 18mg		20	2.4	0.3	19 (52.8%)												
Week 88																	
Placebo		9	2.3	0.4	9 (30.0%)												
Nera 18mg		10	2.3	0.4	10 (27.8%)												
Week 100																	
Placebo		3	2.0	0.6	3 (10.0%)												
Nera 18mg		3	3.0	0.6	3 (8.3%)												
Week 112																	
Placebo		2	2.0	0.0	2 (6.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Rest of the World																	
Baseline																	
Placebo	16	16	2.5	0.2	14 (100.0%)												
Nera 18mg	25	25	2.2	0.3	24 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 8 Adjusted mean (SE) of absolute change from baseline in PGI-S for Cough (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 12																	
Placebo		14	2.3	0.3	14 (100.0%)	-0.1	0.3	-0.6	0.5								
Nera 18mg		23	2.4	0.3	23 (95.8%)	0.1	0.2	-0.3	0.5	0.2	0.3	-0.5	0.8	0.6348			
Week 26																	
Placebo		14	2.5	0.3	14 (100.0%)	0.2	0.3	-0.3	0.8								
Nera 18mg		24	2.1	0.3	24 (100.0%)	-0.1	0.2	-0.5	0.4	-0.3	0.4	-1.0	0.4	0.4252			
Week 36																	
Placebo		14	2.6	0.3	14 (100.0%)	0.4	0.3	-0.2	0.9								
Nera 18mg		23	2.1	0.4	23 (95.8%)	-0.0	0.2	-0.5	0.4	-0.4	0.4	-1.1	0.3	0.2869			
Week 44																	
Placebo		14	2.5	0.2	14 (100.0%)	0.2	0.3	-0.3	0.8								
Nera 18mg		21	2.2	0.2	21 (87.5%)	0.1	0.2	-0.4	0.5	-0.1	0.4	-0.9	0.6	0.6832			
Week 52																	
Placebo		14	2.4	0.2	14 (100.0%)	0.1	0.3	-0.5	0.6								
Nera 18mg		20	2.1	0.3	20 (83.3%)	-0.0	0.2	-0.5	0.4	-0.1	0.4	-0.8	0.6	0.7792			
Week 64																	
Placebo		11	2.0	0.3	11 (78.6%)	-0.2	0.3	-0.8	0.5								
Nera 18mg		16	1.9	0.3	16 (66.7%)	-0.1	0.3	-0.7	0.4	0.0	0.4	-0.8	0.9	0.9345			
Week 76																	
Placebo		8	2.1	0.5	8 (57.1%)												
Nera 18mg		11	1.2	0.4	11 (45.8%)												
Week 88																	
Placebo		1	3.0	NC	1 (7.1%)												
Nera 18mg		3	2.3	0.7	3 (12.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Cough at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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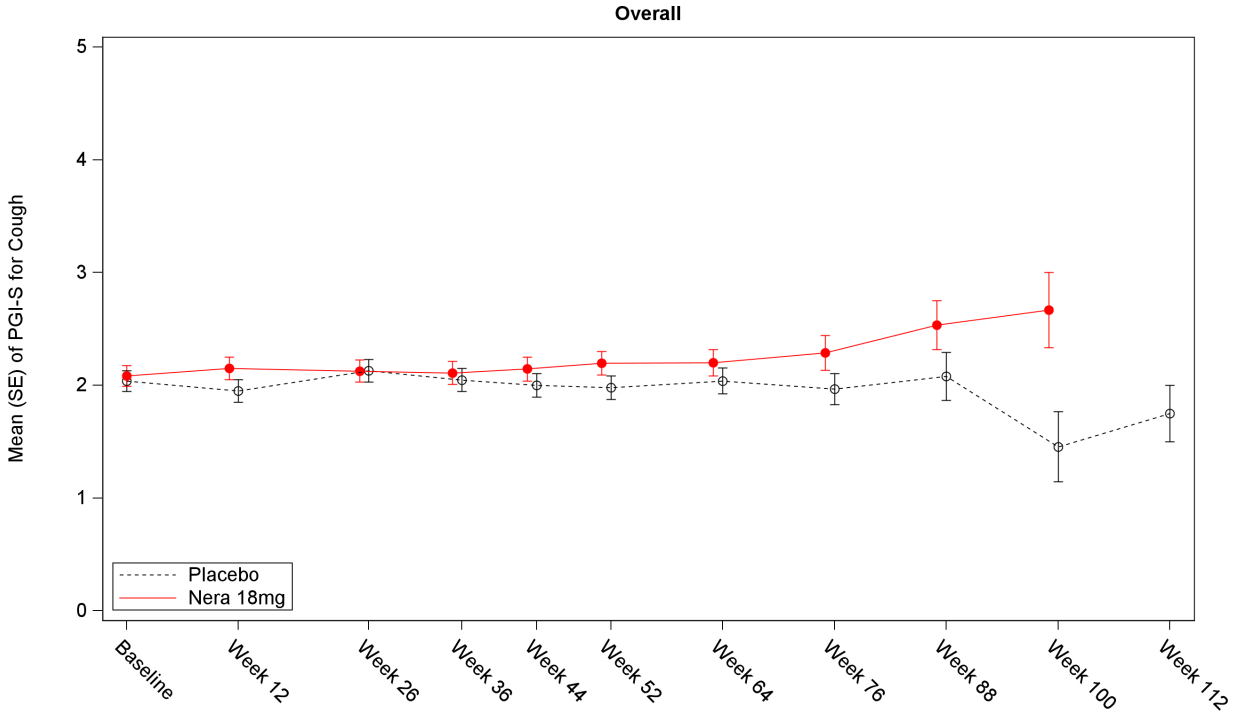

Number of patients

Placebo	165	160	155	150	147	147	128	88	38	11	4
Nera 18mg	168	160	150	146	139	138	119	80	30	9	0

Study: 1305-0023. Number of patients refers to the number of patients with observed data at visit.

Figure I.1.1.1.2.1: 8 Mean (SE) of PGI-S for Cough
over the whole trial - 18mg - FAS (NIN background)

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Boehringer Ingelheim
BI Trial No.: x1305p3.hta

Figure I.1.1.1.2.1: 8

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Overall																	
Baseline																	
Placebo	169	167	2.3	0.1	162 (100.0%)												
Nera 18mg	170	168	2.4	0.1	163 (100.0%)												
Week 12																	
Placebo		160	2.3	0.1	158 (97.5%)	-0.1	0.1	-0.2	0.1								
Nera 18mg		159	2.3	0.1	158 (96.9%)	-0.0	0.1	-0.2	0.1	0.0	0.1	-0.2	0.3	0.6798			
Week 26																	
Placebo		153	2.3	0.1	151 (93.2%)	0.0	0.1	-0.1	0.2								
Nera 18mg		150	2.3	0.1	148 (90.8%)	-0.1	0.1	-0.2	0.1	-0.1	0.1	-0.3	0.1	0.4525			
Week 36																	
Placebo		150	2.3	0.1	148 (91.4%)	0.0	0.1	-0.2	0.2								
Nera 18mg		146	2.2	0.1	144 (88.3%)	-0.1	0.1	-0.3	0.0	-0.1	0.1	-0.4	0.1	0.2718			
Week 44																	
Placebo		147	2.3	0.1	145 (89.5%)	0.0	0.1	-0.1	0.2								
Nera 18mg		139	2.3	0.1	137 (84.0%)	0.0	0.1	-0.2	0.2	-0.0	0.1	-0.2	0.2	0.8574			
Week 52																	
Placebo		148	2.3	0.1	146 (90.1%)	0.1	0.1	-0.1	0.2								
Nera 18mg		138	2.3	0.1	136 (83.4%)	0.0	0.1	-0.2	0.2	-0.1	0.1	-0.3	0.2	0.6464			
Week 64																	
Placebo		128	2.3	0.1	127 (78.4%)	0.1	0.1	-0.1	0.3								
Nera 18mg		120	2.3	0.1	118 (72.4%)	0.1	0.1	-0.0	0.3	0.0	0.1	-0.2	0.2	0.9189			
Week 76																	
Placebo		88	2.1	0.1	87 (53.7%)												
Nera 18mg		79	2.2	0.1	77 (47.2%)												
Week 88																	
Placebo		38	2.4	0.2	37 (22.8%)												
Nera 18mg		30	2.8	0.3	30 (18.4%)												
Week 100																	
Placebo		11	2.4	0.3	11 (6.8%)												
Nera 18mg		9	2.6	0.4	9 (5.5%)												
Week 112																	
Placebo		4	1.8	0.5	4 (2.5%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Age																	
Test for homogeneity (H0)^																	
Week 12														0.4719			
Week 26														0.9289			
Week 36														0.2167			
Week 44														0.9156			
Week 52														0.2199			
Week 64														0.9022			
<65 years																	
Baseline																	
Placebo	65	65	2.3	0.1	64 (100.0%)												
Nera 18mg	64	63	2.1	0.1	61 (100.0%)												
Week 12																	
Placebo		63	2.2	0.1	63 (98.4%)	-0.1	0.1	-0.4	0.1								
Nera 18mg		60	2.2	0.2	59 (96.7%)	0.0	0.1	-0.2	0.3	0.1	0.2	-0.2	0.5	0.4134			
Week 26																	
Placebo		61	2.2	0.2	61 (95.3%)	-0.0	0.1	-0.3	0.2								
Nera 18mg		58	2.1	0.1	57 (93.4%)	-0.1	0.1	-0.4	0.1	-0.1	0.2	-0.5	0.3	0.5844			
Week 36																	
Placebo		61	2.2	0.2	61 (95.3%)	-0.1	0.1	-0.4	0.2								
Nera 18mg		56	2.1	0.2	55 (90.2%)	-0.1	0.1	-0.3	0.2	0.1	0.2	-0.3	0.4	0.7935			
Week 44																	
Placebo		61	2.2	0.2	61 (95.3%)	-0.0	0.1	-0.3	0.2								
Nera 18mg		52	2.2	0.2	51 (83.6%)	-0.0	0.1	-0.3	0.2	-0.0	0.2	-0.4	0.3	0.9712			
Week 52																	
Placebo		62	2.1	0.2	62 (96.9%)	-0.2	0.1	-0.4	0.1								
Nera 18mg		52	2.2	0.2	51 (83.6%)	-0.0	0.1	-0.3	0.3	0.1	0.2	-0.3	0.5	0.5370			
Week 64																	
Placebo		57	2.2	0.2	57 (89.1%)	0.0	0.1	-0.2	0.3								
Nera 18mg		45	2.0	0.2	44 (72.1%)	0.0	0.1	-0.3	0.3	-0.0	0.2	-0.4	0.4	0.9430			
Week 76																	
Placebo		37	2.1	0.2	37 (57.8%)												
Nera 18mg		34	2.1	0.2	33 (54.1%)												
Week 88																	
Placebo		15	2.6	0.3	15 (23.4%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		7	2.6	0.7	7 (11.5%)												
Week 100																	
Placebo		4	2.3	0.6	4 (6.3%)												
Nera 18mg		1	0.0	NC	1 (1.6%)												
Week 112																	
Placebo		2	1.5	0.5	2 (3.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	104	102	2.3	0.1	98 (100.0%)												
Nera 18mg	106	105	2.5	0.1	102 (100.0%)												
Week 12																	
Placebo		97	2.3	0.1	95 (96.9%)	-0.0	0.1	-0.2	0.2								
Nera 18mg		99	2.4	0.1	99 (97.1%)	-0.0	0.1	-0.2	0.2	-0.0	0.1	-0.3	0.3	0.8981			
Week 26																	
Placebo		92	2.4	0.1	90 (91.8%)	0.1	0.1	-0.1	0.3								
Nera 18mg		92	2.4	0.1	91 (89.2%)	-0.0	0.1	-0.2	0.2	-0.1	0.1	-0.4	0.2	0.5908			
Week 36																	
Placebo		89	2.4	0.1	87 (88.8%)	0.1	0.1	-0.1	0.3								
Nera 18mg		90	2.2	0.1	89 (87.3%)	-0.2	0.1	-0.4	0.1	-0.3	0.2	-0.6	0.0	0.1000			
Week 44																	
Placebo		86	2.3	0.1	84 (85.7%)	0.0	0.1	-0.2	0.3								
Nera 18mg		87	2.4	0.1	86 (84.3%)	0.0	0.1	-0.2	0.2	-0.0	0.1	-0.3	0.3	0.8304			
Week 52																	
Placebo		86	2.5	0.1	84 (85.7%)	0.2	0.1	-0.0	0.4								
Nera 18mg		86	2.4	0.1	85 (83.3%)	0.0	0.1	-0.2	0.2	-0.2	0.2	-0.5	0.1	0.2338			
Week 64																	
Placebo		71	2.4	0.2	70 (71.4%)	0.2	0.1	-0.0	0.4								
Nera 18mg		75	2.5	0.1	74 (72.5%)	0.2	0.1	-0.0	0.4	0.0	0.2	-0.3	0.3	0.9149			
Week 76																	
Placebo		51	2.1	0.2	50 (51.0%)												
Nera 18mg		45	2.4	0.2	44 (43.1%)												
Week 88																	
Placebo		23	2.3	0.2	22 (22.4%)												
Nera 18mg		23	2.8	0.3	23 (22.5%)												
Week 100																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		7	2.4	0.4	7 (7.1%)												
Nera 18mg		8	2.9	0.4	8 (7.8%)												
Week 112																	
Placebo		2	2.0	1.0	2 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Sex																	
Test for homogeneity (H0)^																	
Week 12														0.8112			
Week 26														0.5720			
Week 36														0.5409			
Week 44														0.6838			
Week 52														0.9083			
Week 64														0.9966			
Male																	
Baseline																	
Placebo	114	113	2.3	0.1	110 (100.0%)												
Nera 18mg	108	106	2.5	0.1	101 (100.0%)												
Week 12																	
Placebo		107	2.2	0.1	106 (96.4%)	-0.1	0.1	-0.3	0.1								
Nera 18mg		99	2.4	0.1	98 (97.0%)	-0.0	0.1	-0.2	0.2	0.1	0.1	-0.2	0.3	0.6584			
Week 26																	
Placebo		102	2.3	0.1	101 (91.8%)	0.0	0.1	-0.2	0.2								
Nera 18mg		94	2.4	0.1	92 (91.1%)	-0.0	0.1	-0.2	0.2	-0.0	0.1	-0.3	0.2	0.7934			
Week 36																	
Placebo		99	2.3	0.1	98 (89.1%)	0.0	0.1	-0.2	0.2								
Nera 18mg		88	2.3	0.1	86 (85.1%)	-0.0	0.1	-0.3	0.2	-0.1	0.2	-0.4	0.2	0.6425			
Week 44																	
Placebo		97	2.3	0.1	96 (87.3%)	0.1	0.1	-0.1	0.3								
Nera 18mg		83	2.4	0.1	81 (80.2%)	0.0	0.1	-0.2	0.2	-0.1	0.1	-0.3	0.2	0.7101			
Week 52																	
Placebo		97	2.4	0.1	96 (87.3%)	0.1	0.1	-0.1	0.4								
Nera 18mg		83	2.5	0.1	81 (80.2%)	0.1	0.1	-0.1	0.3	-0.0	0.2	-0.3	0.3	0.8382			
Week 64																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		82	2.3	0.1	82 (74.5%)	0.1	0.1	-0.1	0.3								
Nera 18mg		73	2.5	0.1	71 (70.3%)	0.1	0.1	-0.1	0.4	0.0	0.2	-0.3	0.3	0.9269			
Week 76																	
Placebo		54	2.1	0.2	54 (49.1%)												
Nera 18mg		47	2.4	0.2	45 (44.6%)												
Week 88																	
Placebo		25	2.6	0.2	25 (22.7%)												
Nera 18mg		18	3.1	0.4	18 (17.8%)												
Week 100																	
Placebo		7	2.6	0.5	7 (6.4%)												
Nera 18mg		4	3.3	0.3	4 (4.0%)												
Week 112																	
Placebo		2	2.0	1.0	2 (1.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Female																	
Baseline																	
Placebo	55	54	2.3	0.2	52 (100.0%)												
Nera 18mg	62	62	2.2	0.1	62 (100.0%)												
Week 12																	
Placebo		53	2.3	0.2	52 (100.0%)	0.0	0.1	-0.2	0.3								
Nera 18mg		60	2.2	0.1	60 (96.8%)	0.0	0.1	-0.2	0.3	0.0	0.2	-0.4	0.4	0.9775			
Week 26																	
Placebo		51	2.3	0.2	50 (96.2%)	0.1	0.1	-0.2	0.3								
Nera 18mg		56	2.1	0.2	56 (90.3%)	-0.1	0.1	-0.4	0.2	-0.2	0.2	-0.6	0.2	0.3701			
Week 36																	
Placebo		51	2.3	0.2	50 (96.2%)	-0.0	0.1	-0.3	0.3								
Nera 18mg		58	2.0	0.2	58 (93.5%)	-0.2	0.1	-0.5	0.0	-0.2	0.2	-0.6	0.2	0.2646			
Week 44																	
Placebo		50	2.2	0.2	49 (94.2%)	-0.1	0.1	-0.3	0.2								
Nera 18mg		56	2.2	0.1	56 (90.3%)	-0.0	0.1	-0.3	0.2	0.0	0.2	-0.3	0.4	0.8173			
Week 52																	
Placebo		51	2.2	0.2	50 (96.2%)	-0.1	0.2	-0.4	0.2								
Nera 18mg		55	2.0	0.2	55 (88.7%)	-0.1	0.1	-0.4	0.1	-0.1	0.2	-0.5	0.4	0.7649			
Week 64																	
Placebo		46	2.4	0.2	45 (86.5%)	0.1	0.1	-0.2	0.4								
Nera 18mg		47	2.1	0.2	47 (75.8%)	0.1	0.1	-0.2	0.4	0.0	0.2	-0.4	0.4	0.9485			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 76																	
Placebo		34	2.1	0.2	33 (63.5%)												
Nera 18mg		32	2.0	0.2	32 (51.6%)												
Week 88																	
Placebo		13	2.2	0.3	12 (23.1%)												
Nera 18mg		12	2.3	0.3	12 (19.4%)												
Week 100																	
Placebo		4	2.0	0.4	4 (7.7%)												
Nera 18mg		5	2.0	0.7	5 (8.1%)												
Week 112																	
Placebo		2	1.5	0.5	2 (3.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 12														0.9316			
Week 26														0.4453			
Week 36														0.7583			
Week 44														0.4677			
Week 52														0.7721			
Week 64														0.9100			
<=70%																	
Baseline																	
Placebo	95	95	2.4	0.1	91 (100.0%)												
Nera 18mg	97	95	2.5	0.1	94 (100.0%)												
Week 12																	
Placebo		88	2.4	0.1	88 (96.7%)	0.0	0.1	-0.2	0.2								
Nera 18mg		91	2.5	0.1	90 (95.7%)	0.1	0.1	-0.1	0.3	0.0	0.1	-0.2	0.3	0.8229			
Week 26																	
Placebo		84	2.5	0.1	84 (92.3%)	0.2	0.1	-0.0	0.4								
Nera 18mg		85	2.4	0.1	83 (88.3%)	0.0	0.1	-0.2	0.2	-0.2	0.2	-0.5	0.1	0.2703			
Week 36																	
Placebo		82	2.4	0.1	82 (90.1%)	0.1	0.1	-0.1	0.3								
Nera 18mg		85	2.3	0.1	83 (88.3%)	-0.1	0.1	-0.3	0.1	-0.2	0.2	-0.5	0.2	0.3036			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 44																	
Placebo		81	2.5	0.1	81 (89.0%)	0.2	0.1	-0.1	0.4								
Nera 18mg		79	2.6	0.1	77 (81.9%)	0.2	0.1	-0.0	0.4	0.0	0.1	-0.2	0.3	0.7496			
Week 52																	
Placebo		80	2.6	0.1	80 (87.9%)	0.3	0.1	0.0	0.5								
Nera 18mg		79	2.6	0.1	77 (81.9%)	0.2	0.1	0.0	0.5	-0.0	0.2	-0.4	0.3	0.8246			
Week 64																	
Placebo		70	2.5	0.2	70 (76.9%)	0.3	0.1	0.1	0.5								
Nera 18mg		70	2.6	0.1	68 (72.3%)	0.3	0.1	0.1	0.5	-0.0	0.2	-0.3	0.3	0.9651			
Week 76																	
Placebo		45	2.2	0.2	45 (49.5%)												
Nera 18mg		44	2.5	0.2	42 (44.7%)												
Week 88																	
Placebo		20	2.4	0.3	20 (22.0%)												
Nera 18mg		19	3.1	0.3	19 (20.2%)												
Week 100																	
Placebo		5	2.8	0.6	5 (5.5%)												
Nera 18mg		5	2.2	0.6	5 (5.3%)												
Week 112																	
Placebo		3	2.0	0.6	3 (3.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	74	72	2.2	0.1	71 (100.0%)												
Nera 18mg	73	73	2.1	0.1	69 (100.0%)												
Week 12																	
Placebo		72	2.1	0.1	70 (98.6%)	-0.2	0.1	-0.4	0.1								
Nera 18mg		68	2.1	0.1	68 (98.6%)	-0.1	0.1	-0.3	0.1	0.1	0.2	-0.3	0.4	0.7564			
Week 26																	
Placebo		69	2.1	0.1	67 (94.4%)	-0.2	0.1	-0.4	0.1								
Nera 18mg		65	2.1	0.2	65 (94.2%)	-0.2	0.1	-0.4	0.1	0.0	0.2	-0.3	0.4	0.9645			
Week 36																	
Placebo		68	2.2	0.1	66 (93.0%)	-0.1	0.1	-0.3	0.2								
Nera 18mg		61	2.0	0.2	61 (88.4%)	-0.2	0.1	-0.4	0.1	-0.1	0.2	-0.5	0.3	0.6222			
Week 44																	
Placebo		66	2.1	0.1	64 (90.1%)	-0.1	0.1	-0.4	0.1								

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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg		60	2.0	0.1	60 (87.0%)	-0.3	0.1	-0.5	-0.0	-0.1	0.2	-0.4	0.2	0.4926			
Week 52																	
Placebo		68	2.0	0.1	66 (93.0%)	-0.2	0.1	-0.5	0.1								
Nera 18mg		59	1.9	0.1	59 (85.5%)	-0.3	0.1	-0.6	-0.0	-0.1	0.2	-0.5	0.3	0.5604			
Week 64																	
Placebo		58	2.1	0.1	57 (80.3%)	-0.1	0.1	-0.3	0.1								
Nera 18mg		50	2.0	0.2	50 (72.5%)	-0.1	0.1	-0.3	0.2	0.0	0.2	-0.3	0.4	0.9108			
Week 76																	
Placebo		43	2.1	0.2	42 (59.2%)												
Nera 18mg		35	1.9	0.2	35 (50.7%)												
Week 88																	
Placebo		18	2.5	0.2	17 (23.9%)												
Nera 18mg		11	2.3	0.4	11 (15.9%)												
Week 100																	
Placebo		6	2.0	0.4	6 (8.5%)												
Nera 18mg		4	3.0	0.7	4 (5.8%)												
Week 112																	
Placebo		1	1.0	NC	1 (1.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline HRCT pattern																	
Test for homogeneity (H0)^																	
Week 12														0.4482			
Week 26														0.9925			
Week 36														0.9713			
Week 44														0.9682			
Week 52														0.7435			
Week 64														0.9575			
UIP-like																	
Baseline																	
Placebo	116	114	2.3	0.1	111 (100.0%)												
Nera 18mg	121	121	2.4	0.1	118 (100.0%)												
Week 12																	
Placebo		110	2.2	0.1	108 (97.3%)	-0.0	0.1	-0.2	0.2								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg		115	2.3	0.1	115 (97.5%)	-0.0	0.1	-0.2	0.1	-0.0	0.1	-0.3	0.2	0.9473			
Week 26																	
Placebo		106	2.3	0.1	104 (93.7%)	0.0	0.1	-0.2	0.2								
Nera 18mg		108	2.3	0.1	108 (91.5%)	-0.1	0.1	-0.3	0.1	-0.1	0.1	-0.4	0.2	0.5236			
Week 36																	
Placebo		102	2.2	0.1	100 (90.1%)	-0.0	0.1	-0.2	0.2								
Nera 18mg		104	2.2	0.1	104 (88.1%)	-0.1	0.1	-0.3	0.1	-0.1	0.1	-0.4	0.1	0.3491			
Week 44																	
Placebo		99	2.2	0.1	97 (87.4%)	0.0	0.1	-0.1	0.2								
Nera 18mg		100	2.4	0.1	100 (84.7%)	0.0	0.1	-0.2	0.2	-0.0	0.1	-0.3	0.2	0.8640			
Week 52																	
Placebo		100	2.3	0.1	98 (88.3%)	0.1	0.1	-0.1	0.3								
Nera 18mg		99	2.3	0.1	99 (83.9%)	-0.0	0.1	-0.2	0.2	-0.1	0.2	-0.4	0.2	0.5739			
Week 64																	
Placebo		90	2.2	0.1	89 (80.2%)	0.1	0.1	-0.1	0.3								
Nera 18mg		85	2.3	0.1	85 (72.0%)	0.1	0.1	-0.1	0.3	0.0	0.1	-0.3	0.3	0.9567			
Week 76																	
Placebo		60	2.0	0.2	59 (53.2%)												
Nera 18mg		58	2.2	0.2	58 (49.2%)												
Week 88																	
Placebo		26	2.4	0.2	25 (22.5%)												
Nera 18mg		22	2.7	0.3	22 (18.6%)												
Week 100																	
Placebo		9	2.3	0.4	9 (8.1%)												
Nera 18mg		8	2.5	0.5	8 (6.8%)												
Week 112																	
Placebo		3	1.7	0.7	3 (2.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other fibrotic patterns																	
Baseline																	
Placebo	53	53	2.5	0.2	51 (100.0%)												
Nera 18mg	49	47	2.2	0.2	45 (100.0%)												
Week 12																	
Placebo		50	2.3	0.2	50 (98.0%)	-0.1	0.1	-0.4	0.1								
Nera 18mg		44	2.3	0.1	43 (95.6%)	0.0	0.1	-0.2	0.3	0.2	0.2	-0.2	0.6	0.3889			
Week 26																	

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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		47	2.5	0.2	47 (92.2%)	0.1	0.1	-0.2	0.4								
Nera 18mg		42	2.2	0.2	40 (88.9%)	-0.0	0.2	-0.3	0.3	-0.1	0.2	-0.5	0.3	0.6908			
Week 36																	
Placebo		48	2.5	0.2	48 (94.1%)	0.1	0.2	-0.2	0.4								
Nera 18mg		42	2.2	0.2	40 (88.9%)	-0.1	0.2	-0.4	0.3	-0.1	0.2	-0.6	0.3	0.5707			
Week 44																	
Placebo		48	2.4	0.2	48 (94.1%)	-0.0	0.1	-0.3	0.3								
Nera 18mg		39	2.3	0.2	37 (82.2%)	-0.0	0.2	-0.3	0.3	-0.0	0.2	-0.4	0.4	0.9493			
Week 52																	
Placebo		48	2.4	0.2	48 (94.1%)	0.0	0.2	-0.3	0.3								
Nera 18mg		39	2.3	0.2	37 (82.2%)	0.0	0.2	-0.3	0.4	0.0	0.2	-0.5	0.5	0.9793			
Week 64																	
Placebo		38	2.4	0.2	38 (74.5%)	0.2	0.2	-0.1	0.5								
Nera 18mg		35	2.3	0.2	33 (73.3%)	0.2	0.2	-0.1	0.5	0.0	0.2	-0.4	0.5	0.9218			
Week 76																	
Placebo		28	2.4	0.2	28 (54.9%)												
Nera 18mg		21	2.4	0.3	19 (42.2%)												
Week 88																	
Placebo		12	2.4	0.3	12 (23.5%)												
Nera 18mg		8	2.9	0.6	8 (17.8%)												
Week 100																	
Placebo		2	2.5	0.5	2 (3.9%)												
Nera 18mg		1	3.0	NC	1 (2.2%)												
Week 112																	
Placebo		1	2.0	NC	1 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Underlying ILD diagnosis																	
Test for homogeneity (H0)^																	
Week 12														0.7140			
Week 26														0.2370			
Week 36														0.2561			
Week 44														0.3957			
Week 52														0.1270			
Week 64														0.3470			

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
iNSIP																	
Baseline																	
Placebo	32	32	2.2	0.2	31 (100.0%)												
Nera 18mg	27	26	2.5	0.2	24 (100.0%)												
Week 12																	
Placebo		29	2.0	0.3	29 (93.5%)	-0.2	0.2	-0.5	0.2								
Nera 18mg		23	2.2	0.2	23 (95.8%)	-0.2	0.2	-0.6	0.2	-0.0	0.3	-0.5	0.5	0.9439			
Week 26																	
Placebo		29	2.1	0.2	29 (93.5%)	-0.1	0.2	-0.5	0.3								
Nera 18mg		23	2.6	0.2	22 (91.7%)	0.2	0.2	-0.3	0.6	0.3	0.3	-0.3	0.8	0.3456			
Week 36																	
Placebo		28	2.0	0.2	28 (90.3%)	-0.1	0.2	-0.5	0.3								
Nera 18mg		21	2.5	0.2	20 (83.3%)	0.1	0.2	-0.3	0.6	0.2	0.3	-0.4	0.8	0.4765			
Week 44																	
Placebo		28	1.9	0.3	28 (90.3%)	-0.2	0.2	-0.6	0.1								
Nera 18mg		19	2.3	0.3	18 (75.0%)	-0.0	0.2	-0.5	0.4	0.2	0.3	-0.3	0.8	0.4645			
Week 52																	
Placebo		27	2.0	0.3	27 (87.1%)	-0.1	0.2	-0.5	0.3								
Nera 18mg		17	2.7	0.3	16 (66.7%)	0.3	0.3	-0.2	0.8	0.4	0.3	-0.2	1.1	0.1852			
Week 64																	
Placebo		23	2.1	0.3	23 (74.2%)	0.1	0.2	-0.3	0.4								
Nera 18mg		17	2.7	0.2	16 (66.7%)	0.4	0.2	-0.1	0.8	0.3	0.3	-0.3	0.9	0.3005			
Week 76																	
Placebo		16	1.9	0.3	16 (51.6%)												
Nera 18mg		10	3.0	0.4	9 (37.5%)												
Week 88																	
Placebo		9	2.4	0.3	9 (29.0%)												
Nera 18mg		3	3.3	1.2	3 (12.5%)												
Week 100																	
Placebo		2	1.0	0.0	2 (6.5%)												
Nera 18mg		1	3.0	NC	1 (4.2%)												
Week 112																	
Placebo		2	2.0	1.0	2 (6.5%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Unclassifiable IIP																	

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Baseline																	
Placebo	46	46	2.5	0.2	44 (100.0%)												
Nera 18mg	32	32	2.2	0.2	32 (100.0%)												
Week 12																	
Placebo		44	2.4	0.2	44 (100.0%)	-0.0	0.1	-0.3	0.2								
Nera 18mg		32	2.2	0.2	32 (100.0%)	-0.0	0.2	-0.3	0.3	0.0	0.2	-0.4	0.5	0.8703			
Week 26																	
Placebo		40	2.6	0.2	40 (90.9%)	0.2	0.2	-0.1	0.5								
Nera 18mg		28	2.1	0.2	28 (87.5%)	-0.1	0.2	-0.5	0.2	-0.3	0.2	-0.8	0.2	0.2335			
Week 36																	
Placebo		38	2.4	0.2	38 (86.4%)	0.1	0.2	-0.2	0.4								
Nera 18mg		27	2.0	0.2	27 (84.4%)	-0.2	0.2	-0.6	0.2	-0.3	0.3	-0.8	0.2	0.2824			
Week 44																	
Placebo		37	2.5	0.2	37 (84.1%)	0.2	0.2	-0.1	0.5								
Nera 18mg		27	2.2	0.2	27 (84.4%)	-0.0	0.2	-0.4	0.3	-0.2	0.2	-0.7	0.2	0.3539			
Week 52																	
Placebo		38	2.4	0.2	38 (86.4%)	0.1	0.2	-0.2	0.5								
Nera 18mg		28	2.1	0.2	28 (87.5%)	-0.1	0.2	-0.5	0.3	-0.3	0.3	-0.8	0.3	0.3259			
Week 64																	
Placebo		32	2.4	0.2	32 (72.7%)	0.2	0.2	-0.1	0.5								
Nera 18mg		23	2.3	0.2	23 (71.9%)	0.2	0.2	-0.2	0.6	-0.0	0.3	-0.5	0.5	0.9192			
Week 76																	
Placebo		25	2.2	0.2	25 (56.8%)												
Nera 18mg		17	2.1	0.3	17 (53.1%)												
Week 88																	
Placebo		10	3.0	0.4	10 (22.7%)												
Nera 18mg		10	2.3	0.4	10 (31.3%)												
Week 100																	
Placebo		2	3.5	0.5	2 (4.5%)												
Nera 18mg		3	2.7	0.9	3 (9.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
HP																	
Baseline																	
Placebo	38	38	2.0	0.2	38 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg	43	43	2.7	0.2	41 (100.0%)												
Week 12																	
Placebo		37	2.2	0.2	37 (97.4%)	0.1	0.2	-0.2	0.4								
Nera 18mg		39	2.6	0.2	39 (95.1%)	0.1	0.2	-0.3	0.4	-0.0	0.2	-0.5	0.4	0.8285			
Week 26																	
Placebo		38	2.2	0.2	38 (100.0%)	0.1	0.2	-0.2	0.4								
Nera 18mg		36	2.3	0.2	36 (87.8%)	-0.2	0.2	-0.5	0.1	-0.3	0.2	-0.7	0.2	0.2578			
Week 36																	
Placebo		37	2.3	0.2	37 (97.4%)	0.1	0.2	-0.2	0.4								
Nera 18mg		37	2.5	0.2	37 (90.2%)	-0.0	0.2	-0.4	0.3	-0.1	0.2	-0.6	0.4	0.6169			
Week 44																	
Placebo		37	2.3	0.2	37 (97.4%)	0.2	0.2	-0.1	0.5								
Nera 18mg		34	2.7	0.2	34 (82.9%)	0.2	0.2	-0.1	0.5	-0.0	0.2	-0.4	0.4	0.9944			
Week 52																	
Placebo		37	2.4	0.2	37 (97.4%)	0.2	0.2	-0.1	0.6								
Nera 18mg		35	2.5	0.2	35 (85.4%)	0.1	0.2	-0.3	0.4	-0.1	0.3	-0.7	0.4	0.5603			
Week 64																	
Placebo		33	2.4	0.2	33 (86.8%)	0.4	0.2	0.1	0.7								
Nera 18mg		29	2.6	0.2	29 (70.7%)	0.2	0.2	-0.1	0.6	-0.2	0.2	-0.7	0.3	0.4826			
Week 76																	
Placebo		18	2.4	0.3	18 (47.4%)												
Nera 18mg		17	2.2	0.3	17 (41.5%)												
Week 88																	
Placebo		8	2.4	0.3	8 (21.1%)												
Nera 18mg		5	3.4	0.2	5 (12.2%)												
Week 100																	
Placebo		1	2.0	NC	1 (2.6%)												
Nera 18mg		1	4.0	NC	1 (2.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Autoimmune ILD																	
Baseline																	
Placebo	29	28	2.3	0.2	27 (100.0%)												
Nera 18mg	43	43	2.1	0.2	43 (100.0%)												
Week 12																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo		28	2.3	0.2	27 (100.0%)	-0.0	0.2	-0.4	0.3								
Nera 18mg		42	2.0	0.2	42 (97.7%)	-0.1	0.1	-0.4	0.2	-0.1	0.2	-0.5	0.4	0.7766			
Week 26																	
Placebo		26	2.2	0.2	25 (92.6%)	-0.0	0.2	-0.4	0.4								
Nera 18mg		40	2.0	0.2	40 (93.0%)	-0.2	0.2	-0.5	0.2	-0.2	0.3	-0.7	0.4	0.5582			
Week 36																	
Placebo		26	2.1	0.3	25 (92.6%)	-0.1	0.2	-0.5	0.3								
Nera 18mg		38	1.8	0.2	38 (88.4%)	-0.4	0.2	-0.7	-0.1	-0.3	0.3	-0.8	0.3	0.3102			
Week 44																	
Placebo		24	2.1	0.3	23 (85.2%)	-0.1	0.2	-0.5	0.2								
Nera 18mg		37	2.1	0.2	37 (86.0%)	-0.1	0.2	-0.4	0.2	0.1	0.2	-0.4	0.6	0.7906			
Week 52																	
Placebo		25	2.1	0.2	24 (88.9%)	-0.2	0.2	-0.6	0.3								
Nera 18mg		36	1.9	0.2	36 (83.7%)	-0.2	0.2	-0.6	0.1	-0.0	0.3	-0.6	0.5	0.8803			
Week 64																	
Placebo		21	2.0	0.3	21 (77.8%)	-0.1	0.2	-0.5	0.3								
Nera 18mg		32	2.1	0.2	32 (74.4%)	0.0	0.2	-0.3	0.4	0.2	0.3	-0.4	0.7	0.5400			
Week 76																	
Placebo		16	1.9	0.4	16 (59.3%)												
Nera 18mg		19	1.6	0.2	19 (44.2%)												
Week 88																	
Placebo		6	1.3	0.4	6 (22.2%)												
Nera 18mg		5	1.8	0.6	5 (11.6%)												
Week 100																	
Placebo		4	2.0	0.4	4 (14.8%)												
Nera 18mg		2	1.0	1.0	2 (4.7%)												
Week 112																	
Placebo		2	1.5	0.5	2 (7.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other ILD																	
Baseline																	
Placebo	24	23	2.7	0.2	22 (100.0%)												
Nera 18mg	25	24	2.3	0.2	23 (100.0%)												
Week 12																	
Placebo		22	2.4	0.3	21 (95.5%)	-0.2	0.2	-0.6	0.3								
Nera 18mg		23	2.6	0.2	22 (95.7%)	0.3	0.2	-0.1	0.7	0.4	0.3	-0.1	1.0	0.1385			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 26																	
Placebo		20	2.6	0.2	19 (86.4%)	-0.1	0.2	-0.6	0.3								
Nera 18mg		23	2.6	0.2	22 (95.7%)	0.2	0.2	-0.2	0.6	0.3	0.3	-0.3	0.9	0.3474			
Week 36																	
Placebo		21	2.7	0.3	20 (90.9%)	0.1	0.2	-0.4	0.5								
Nera 18mg		23	2.3	0.2	22 (95.7%)	0.1	0.2	-0.3	0.5	0.0	0.3	-0.6	0.7	0.9538			
Week 44																	
Placebo		21	2.6	0.2	20 (90.9%)	0.0	0.2	-0.4	0.4								
Nera 18mg		22	2.3	0.2	21 (91.3%)	-0.1	0.2	-0.5	0.3	-0.1	0.3	-0.7	0.5	0.8110			
Week 52																	
Placebo		21	2.8	0.2	20 (90.9%)	0.2	0.2	-0.3	0.7								
Nera 18mg		22	2.5	0.3	21 (91.3%)	0.2	0.2	-0.3	0.6	0.0	0.3	-0.7	0.7	0.9973			
Week 64																	
Placebo		19	2.5	0.2	18 (81.8%)	-0.2	0.2	-0.6	0.3								
Nera 18mg		19	2.1	0.3	18 (78.3%)	-0.2	0.2	-0.6	0.3	0.0	0.3	-0.6	0.7	0.8999			
Week 76																	
Placebo		13	2.2	0.3	12 (54.5%)												
Nera 18mg		16	2.7	0.3	15 (65.2%)												
Week 88																	
Placebo		5	2.6	0.5	4 (18.2%)												
Nera 18mg		7	3.4	0.5	7 (30.4%)												
Week 100																	
Placebo		2	3.5	0.5	2 (9.1%)												
Nera 18mg		2	3.0	0.0	2 (8.7%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Region																	
Test for homogeneity (H0)^																	
Week 12														0.8582			
Week 26														0.8019			
Week 36														0.3608			
Week 44														0.9708			
Week 52														0.4504			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 64														0.7827			
Europe																	
Baseline																	
Placebo	78	76	2.4	0.1	75 (100.0%)												
Nera 18mg	67	66	2.5	0.1	64 (100.0%)												
Week 12																	
Placebo		76	2.4	0.1	74 (98.7%)	0.1	0.1	-0.1	0.3								
Nera 18mg		60	2.5	0.1	60 (93.8%)	0.1	0.1	-0.1	0.4	0.0	0.2	-0.3	0.3	0.9059			
Week 26																	
Placebo		71	2.5	0.2	69 (92.0%)	0.1	0.1	-0.1	0.4								
Nera 18mg		56	2.4	0.2	55 (85.9%)	-0.0	0.1	-0.3	0.3	-0.1	0.2	-0.5	0.2	0.4621			
Week 36																	
Placebo		68	2.5	0.1	66 (88.0%)	0.1	0.1	-0.1	0.4								
Nera 18mg		55	2.5	0.1	54 (84.4%)	0.1	0.1	-0.2	0.4	-0.0	0.2	-0.4	0.3	0.8475			
Week 44																	
Placebo		68	2.5	0.1	66 (88.0%)	0.1	0.1	-0.1	0.4								
Nera 18mg		54	2.5	0.1	53 (82.8%)	0.1	0.1	-0.1	0.4	0.0	0.2	-0.3	0.4	0.9495			
Week 52																	
Placebo		69	2.5	0.1	67 (89.3%)	0.1	0.1	-0.1	0.4								
Nera 18mg		53	2.5	0.2	52 (81.3%)	0.1	0.1	-0.2	0.4	0.0	0.2	-0.4	0.4	0.9715			
Week 64																	
Placebo		63	2.4	0.2	62 (82.7%)	0.1	0.1	-0.1	0.4								
Nera 18mg		51	2.5	0.2	50 (78.1%)	0.1	0.1	-0.2	0.4	-0.0	0.2	-0.4	0.3	0.9288			
Week 76																	
Placebo		38	2.3	0.2	37 (49.3%)												
Nera 18mg		30	2.6	0.2	29 (45.3%)												
Week 88																	
Placebo		15	2.3	0.3	14 (18.7%)												
Nera 18mg		8	2.9	0.4	8 (12.5%)												
Week 100																	
Placebo		3	2.0	0.6	3 (4.0%)												
Nera 18mg		2	3.0	0.0	2 (3.1%)												
Week 112																	
Placebo		1	2.0	NC	1 (1.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Asia																	
Baseline																	
Placebo	45	45	2.2	0.2	43 (100.0%)												
Nera 18mg	41	41	2.0	0.2	39 (100.0%)												
Week 12																	
Placebo		42	1.9	0.2	42 (97.7%)	-0.3	0.1	-0.6	-0.1								
Nera 18mg		39	2.1	0.2	39 (100.0%)	-0.1	0.2	-0.4	0.2	0.3	0.2	-0.2	0.7	0.2148			
Week 26																	
Placebo		42	2.1	0.2	42 (97.7%)	-0.2	0.2	-0.5	0.1								
Nera 18mg		36	2.1	0.2	36 (92.3%)	-0.1	0.2	-0.4	0.2	0.0	0.2	-0.4	0.5	0.8288			
Week 36																	
Placebo		41	2.0	0.2	41 (95.3%)	-0.2	0.2	-0.6	0.1								
Nera 18mg		34	2.0	0.2	34 (87.2%)	-0.2	0.2	-0.5	0.2	0.1	0.2	-0.4	0.5	0.7815			
Week 44																	
Placebo		38	2.2	0.2	38 (88.4%)	0.0	0.2	-0.3	0.3								
Nera 18mg		31	2.1	0.2	31 (79.5%)	-0.1	0.2	-0.4	0.2	-0.1	0.2	-0.6	0.3	0.5616			
Week 52																	
Placebo		39	2.0	0.2	39 (90.7%)	-0.1	0.2	-0.5	0.2								
Nera 18mg		32	2.0	0.2	32 (82.1%)	-0.2	0.2	-0.5	0.2	-0.0	0.3	-0.5	0.5	0.9851			
Week 64																	
Placebo		33	2.1	0.2	33 (76.7%)	0.1	0.2	-0.2	0.4								
Nera 18mg		26	1.9	0.2	26 (66.7%)	-0.1	0.2	-0.4	0.3	-0.1	0.2	-0.6	0.3	0.5525			
Week 76																	
Placebo		25	1.8	0.3	25 (58.1%)												
Nera 18mg		19	1.9	0.3	19 (48.7%)												
Week 88																	
Placebo		13	2.3	0.4	13 (30.2%)												
Nera 18mg		9	2.3	0.6	9 (23.1%)												
Week 100																	
Placebo		5	2.6	0.6	5 (11.6%)												
Nera 18mg		4	1.8	0.9	4 (10.3%)												
Week 112																	
Placebo		1	1.0	NC	1 (2.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	
Baseline																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo	30	30	2.2	0.2	30 (100.0%)												
Nera 18mg	37	36	2.5	0.2	36 (100.0%)												
Week 12																	
Placebo		28	2.3	0.2	28 (93.3%)	-0.1	0.2	-0.4	0.3								
Nera 18mg		37	2.2	0.2	36 (100.0%)	-0.2	0.2	-0.5	0.1	-0.1	0.2	-0.6	0.3	0.5879			
Week 26																	
Placebo		26	2.3	0.2	26 (86.7%)	0.0	0.2	-0.3	0.4								
Nera 18mg		34	2.4	0.2	33 (91.7%)	0.0	0.2	-0.3	0.3	-0.0	0.3	-0.6	0.5	0.8568			
Week 36																	
Placebo		27	2.2	0.2	27 (90.0%)	-0.0	0.2	-0.4	0.4								
Nera 18mg		34	2.2	0.2	33 (91.7%)	-0.2	0.2	-0.5	0.2	-0.1	0.3	-0.7	0.4	0.5961			
Week 44																	
Placebo		27	2.1	0.2	27 (90.0%)	-0.0	0.2	-0.4	0.3								
Nera 18mg		33	2.5	0.2	32 (88.9%)	0.1	0.2	-0.3	0.4	0.1	0.2	-0.4	0.6	0.7097			
Week 52																	
Placebo		26	2.2	0.3	26 (86.7%)	-0.0	0.2	-0.4	0.4								
Nera 18mg		33	2.4	0.2	32 (88.9%)	0.0	0.2	-0.4	0.4	0.0	0.3	-0.5	0.6	0.9775			
Week 64																	
Placebo		21	2.2	0.2	21 (70.0%)	0.2	0.2	-0.3	0.6								
Nera 18mg		27	2.4	0.2	26 (72.2%)	0.3	0.2	-0.1	0.6	0.1	0.3	-0.4	0.7	0.6577			
Week 76																	
Placebo		17	2.4	0.3	17 (56.7%)												
Nera 18mg		19	2.4	0.3	18 (50.0%)												
Week 88																	
Placebo		9	2.8	0.3	9 (30.0%)												
Nera 18mg		10	3.0	0.4	10 (27.8%)												
Week 100																	
Placebo		3	2.3	0.7	3 (10.0%)												
Nera 18mg		3	3.3	0.3	3 (8.3%)												
Week 112																	
Placebo		2	2.0	1.0	2 (6.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Rest of the World																	
Baseline																	
Placebo	16	16	2.3	0.3	14 (100.0%)												
Nera 18mg	25	25	2.3	0.3	24 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 9 Adjusted mean (SE) of absolute change from baseline in PGI-S for Shortness of Breath (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 12																	
Placebo		14	2.2	0.4	14 (100.0%)	0.0	0.3	-0.5	0.5								
Nera 18mg		23	2.4	0.2	23 (95.8%)	0.1	0.2	-0.3	0.4	0.0	0.3	-0.6	0.7	0.8898			
Week 26																	
Placebo		14	2.2	0.3	14 (100.0%)	-0.0	0.3	-0.5	0.5								
Nera 18mg		24	2.1	0.3	24 (100.0%)	-0.2	0.2	-0.6	0.2	-0.2	0.3	-0.9	0.5	0.5247			
Week 36																	
Placebo		14	2.5	0.3	14 (100.0%)	0.3	0.3	-0.3	0.8								
Nera 18mg		23	1.8	0.3	23 (95.8%)	-0.5	0.2	-0.9	-0.0	-0.7	0.4	-1.4	-0.0	0.0416	-0.68	-1.35	-0.01
Week 44																	
Placebo		14	1.9	0.3	14 (100.0%)	-0.4	0.3	-0.9	0.1								
Nera 18mg		21	2.0	0.3	21 (87.5%)	-0.3	0.2	-0.7	0.1	0.1	0.3	-0.6	0.7	0.7693			
Week 52																	
Placebo		14	2.8	0.3	14 (100.0%)	0.6	0.3	-0.0	1.1								
Nera 18mg		20	2.2	0.3	20 (83.3%)	-0.0	0.2	-0.5	0.4	-0.6	0.4	-1.3	0.2	0.1204			
Week 64																	
Placebo		11	2.1	0.4	11 (78.6%)	0.1	0.3	-0.4	0.7								
Nera 18mg		16	2.3	0.3	16 (66.7%)	0.3	0.2	-0.2	0.8	0.2	0.4	-0.5	0.9	0.6181			
Week 76																	
Placebo		8	1.8	0.4	8 (57.1%)												
Nera 18mg		11	1.5	0.4	11 (45.8%)												
Week 88																	
Placebo		1	2.0	NC	1 (7.1%)												
Nera 18mg		3	3.0	0.6	3 (12.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline PGI-S for Shortness of Breath at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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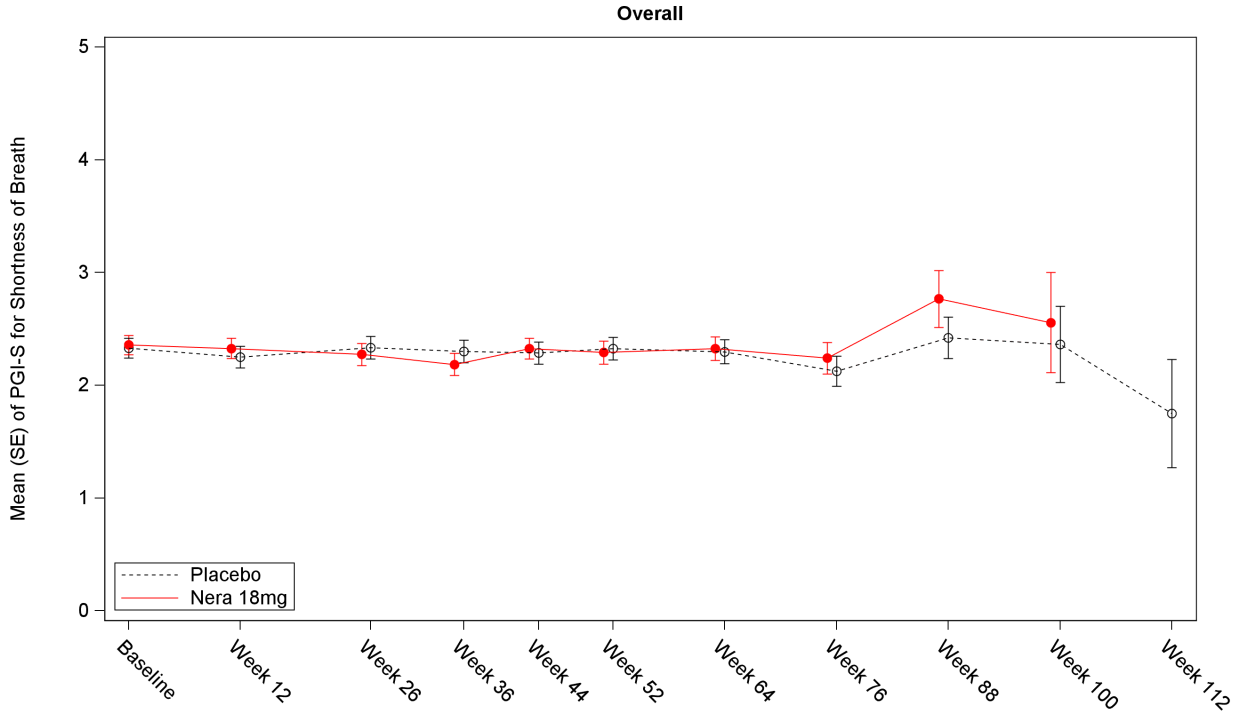

Number of patients

Placebo	167	160	153	150	147	148	128	88	38	11	4
Nera 18mg	168	159	150	146	139	138	120	79	30	9	0

Study: 1305-0023. Number of patients refers to the number of patients with observed data at visit.

Figure I.1.1.1.2.1: 9 Mean (SE) of PGI-S for Shortness of Breath over the whole trial - 18mg - FAS (NIN background)

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	95% CI upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	95% CI upper	p-value	Hedges'g value	95% CI lower	95% CI upper
Overall																	
Baseline																	
Placebo	169	75	1.6	0.1													
Nera 18mg	170	78	1.4	0.1													
Week 12																	
Placebo		116	1.6	0.1													
Nera 18mg		105	1.4	0.1													
Week 26																	
Placebo		141	1.5	0.1													
Nera 18mg		134	1.5	0.1													
Week 36																	
Placebo		144	1.4	0.1													
Nera 18mg		136	1.5	0.1													
Week 44																	
Placebo		145	1.4	0.1													
Nera 18mg		135	1.6	0.1													
Week 52																	
Placebo		148	1.4	0.1													
Nera 18mg		136	1.6	0.1													
Week 64																	
Placebo		127	1.4	0.1													
Nera 18mg		118	1.6	0.1													
Week 76																	
Placebo		86	1.3	0.1													
Nera 18mg		78	1.6	0.1													
Week 88																	
Placebo		38	1.4	0.1													
Nera 18mg		30	1.9	0.2													
Week 100																	
Placebo		11	1.3	0.1													
Nera 18mg		9	1.7	0.3													
Week 112																	
Placebo		4	1.0	0.0													
Nera 18mg		0	NC	NC													
Age																	
<65 years																	
Baseline																	
Placebo	65	31	1.5	0.1													
Nera 18mg	64	33	1.4	0.2													

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	95% CI upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	95% CI upper	p-value	Hedges'g value	95% CI lower	95% CI upper
Week 12																	
Placebo		45	1.5	0.1													
Nera 18mg		39	1.5	0.1													
Week 26																	
Placebo		56	1.4	0.1													
Nera 18mg		51	1.3	0.1													
Week 36																	
Placebo		59	1.4	0.1													
Nera 18mg		51	1.4	0.1													
Week 44																	
Placebo		61	1.4	0.1													
Nera 18mg		49	1.4	0.1													
Week 52																	
Placebo		62	1.4	0.1													
Nera 18mg		51	1.3	0.1													
Week 64																	
Placebo		57	1.3	0.1													
Nera 18mg		44	1.3	0.1													
Week 76																	
Placebo		35	1.3	0.1													
Nera 18mg		33	1.5	0.2													
Week 88																	
Placebo		15	1.4	0.2													
Nera 18mg		7	1.7	0.4													
Week 100																	
Placebo		4	1.3	0.3													
Nera 18mg		1	1.0	NC													
Week 112																	
Placebo		2	1.0	0.0													
Nera 18mg		0	NC	NC													
>=65 years																	
Baseline																	
Placebo	104	44	1.8	0.1													
Nera 18mg	106	45	1.4	0.1													
Week 12																	
Placebo		71	1.6	0.1													
Nera 18mg		66	1.4	0.1													
Week 26																	
Placebo		85	1.5	0.1													
Nera 18mg		83	1.6	0.1													
Week 36																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		85	1.5	0.1													
Nera 18mg		85	1.5	0.1													
Week 44																	
Placebo		84	1.5	0.1													
Nera 18mg		86	1.6	0.1													
Week 52																	
Placebo		86	1.5	0.1													
Nera 18mg		85	1.7	0.1													
Week 64																	
Placebo		70	1.5	0.1													
Nera 18mg		74	1.7	0.1													
Week 76																	
Placebo		51	1.3	0.1													
Nera 18mg		45	1.8	0.1													
Week 88																	
Placebo		23	1.5	0.2													
Nera 18mg		23	2.0	0.2													
Week 100																	
Placebo		7	1.3	0.2													
Nera 18mg		8	1.8	0.4													
Week 112																	
Placebo		2	1.0	0.0													
Nera 18mg		0	NC	NC													
Sex																	
Male																	
Baseline																	
Placebo	114	49	1.6	0.1													
Nera 18mg	108	52	1.4	0.1													
Week 12																	
Placebo		74	1.4	0.1													
Nera 18mg		69	1.4	0.1													
Week 26																	
Placebo		95	1.5	0.1													
Nera 18mg		84	1.5	0.1													
Week 36																	
Placebo		96	1.4	0.1													
Nera 18mg		81	1.5	0.1													
Week 44																	
Placebo		96	1.5	0.1													

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	95% CI upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	95% CI upper	p-value	Hedges'g value	95% CI lower	95% CI upper
Nera 18mg		80	1.6	0.1													
Week 52																	
Placebo		97	1.5	0.1													
Nera 18mg		82	1.6	0.1													
Week 64																	
Placebo		82	1.4	0.1													
Nera 18mg		72	1.7	0.1													
Week 76																	
Placebo		53	1.3	0.1													
Nera 18mg		46	1.8	0.1													
Week 88																	
Placebo		25	1.6	0.2													
Nera 18mg		18	2.1	0.3													
Week 100																	
Placebo		7	1.4	0.2													
Nera 18mg		4	2.3	0.5													
Week 112																	
Placebo		2	1.0	0.0													
Nera 18mg		0	NC	NC													
Female																	
Baseline																	
Placebo	55	26	1.7	0.2													
Nera 18mg	62	26	1.4	0.2													
Week 12																	
Placebo		42	1.8	0.1													
Nera 18mg		36	1.5	0.1													
Week 26																	
Placebo		46	1.6	0.1													
Nera 18mg		50	1.3	0.1													
Week 36																	
Placebo		48	1.5	0.1													
Nera 18mg		55	1.4	0.1													
Week 44																	
Placebo		49	1.4	0.1													
Nera 18mg		55	1.5	0.1													
Week 52																	
Placebo		51	1.4	0.1													
Nera 18mg		54	1.4	0.1													
Week 64																	
Placebo		45	1.6	0.1													
Nera 18mg		46	1.3	0.1													

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 76																	
Placebo		33	1.2	0.1													
Nera 18mg		32	1.4	0.1													
Week 88																	
Placebo		13	1.2	0.3													
Nera 18mg		12	1.6	0.3													
Week 100																	
Placebo		4	1.0	0.0													
Nera 18mg		5	1.2	0.4													
Week 112																	
Placebo		2	1.0	0.0													
Nera 18mg		0	NC	NC													
Baseline FVC percent predicted																	
<=70%																	
Baseline																	
Placebo	95	42	1.6	0.1													
Nera 18mg	97	43	1.5	0.1													
Week 12																	
Placebo		61	1.7	0.1													
Nera 18mg		60	1.7	0.1													
Week 26																	
Placebo		79	1.5	0.1													
Nera 18mg		77	1.5	0.1													
Week 36																	
Placebo		79	1.5	0.1													
Nera 18mg		79	1.6	0.1													
Week 44																	
Placebo		81	1.5	0.1													
Nera 18mg		78	1.7	0.1													
Week 52																	
Placebo		80	1.6	0.1													
Nera 18mg		78	1.7	0.1													
Week 64																	
Placebo		70	1.5	0.1													
Nera 18mg		69	1.7	0.1													
Week 76																	
Placebo		44	1.4	0.1													
Nera 18mg		44	1.8	0.2													
Week 88																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		20	1.3	0.2													
Nera 18mg		19	2.1	0.3													
Week 100																	
Placebo		5	1.4	0.2													
Nera 18mg		5	1.6	0.6													
Week 112																	
Placebo		3	1.0	0.0													
Nera 18mg		0	NC	NC													
>70%																	
Baseline																	
Placebo	74	33	1.6	0.1													
Nera 18mg	73	35	1.2	0.1													
Week 12																	
Placebo		55	1.5	0.1													
Nera 18mg		45	1.2	0.1													
Week 26																	
Placebo		62	1.5	0.1													
Nera 18mg		57	1.4	0.1													
Week 36																	
Placebo		65	1.4	0.1													
Nera 18mg		57	1.3	0.1													
Week 44																	
Placebo		64	1.3	0.1													
Nera 18mg		57	1.4	0.1													
Week 52																	
Placebo		68	1.3	0.1													
Nera 18mg		58	1.3	0.1													
Week 64																	
Placebo		57	1.4	0.1													
Nera 18mg		49	1.4	0.1													
Week 76																	
Placebo		42	1.1	0.1													
Nera 18mg		34	1.4	0.1													
Week 88																	
Placebo		18	1.6	0.2													
Nera 18mg		11	1.6	0.3													
Week 100																	
Placebo		6	1.2	0.2													
Nera 18mg		4	1.8	0.3													
Week 112																	
Placebo		1	1.0	NC													

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		0	NC	NC													
Baseline HRCT pattern																	
UIP-like																	
Baseline																	
Placebo	116	48	1.7	0.1													
Nera 18mg	121	55	1.4	0.1													
Week 12																	
Placebo		80	1.6	0.1													
Nera 18mg		75	1.4	0.1													
Week 26																	
Placebo		97	1.4	0.1													
Nera 18mg		96	1.4	0.1													
Week 36																	
Placebo		99	1.4	0.1													
Nera 18mg		96	1.4	0.1													
Week 44																	
Placebo		98	1.4	0.1													
Nera 18mg		96	1.5	0.1													
Week 52																	
Placebo		100	1.4	0.1													
Nera 18mg		97	1.5	0.1													
Week 64																	
Placebo		90	1.4	0.1													
Nera 18mg		83	1.6	0.1													
Week 76																	
Placebo		58	1.2	0.1													
Nera 18mg		57	1.6	0.1													
Week 88																	
Placebo		26	1.3	0.1													
Nera 18mg		22	1.9	0.2													
Week 100																	
Placebo		9	1.3	0.2													
Nera 18mg		8	1.5	0.3													
Week 112																	
Placebo		3	1.0	0.0													
Nera 18mg		0	NC	NC													
Other fibrotic patterns																	
Baseline																	
Placebo	53	27	1.6	0.2													

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	95% CI upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	95% CI upper	p-value	Hedges'g value	95% CI lower	95% CI upper
Nera 18mg	49	23	1.3	0.2													
Week 12																	
Placebo		36	1.6	0.1													
Nera 18mg		30	1.6	0.1													
Week 26																	
Placebo		44	1.7	0.1													
Nera 18mg		38	1.6	0.1													
Week 36																	
Placebo		45	1.5	0.1													
Nera 18mg		40	1.6	0.1													
Week 44																	
Placebo		47	1.5	0.1													
Nera 18mg		39	1.6	0.1													
Week 52																	
Placebo		48	1.6	0.1													
Nera 18mg		39	1.7	0.1													
Week 64																	
Placebo		37	1.5	0.1													
Nera 18mg		35	1.7	0.1													
Week 76																	
Placebo		28	1.5	0.1													
Nera 18mg		21	1.7	0.2													
Week 88																	
Placebo		12	1.8	0.4													
Nera 18mg		8	2.0	0.4													
Week 100																	
Placebo		2	1.0	0.0													
Nera 18mg		1	3.0	NC													
Week 112																	
Placebo		1	1.0	NC													
Nera 18mg		0	NC	NC													
Underlying ILD diagnosis																	
iNSIP																	
Baseline																	
Placebo	32	11	1.5	0.3													
Nera 18mg	27	9	1.7	0.2													
Week 12																	
Placebo		21	1.3	0.2													
Nera 18mg		13	1.5	0.2													

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 26																	
Placebo		26	1.2	0.1													
Nera 18mg		17	1.9	0.2													
Week 36																	
Placebo		27	1.2	0.1													
Nera 18mg		17	1.6	0.2													
Week 44																	
Placebo		27	1.3	0.2													
Nera 18mg		18	1.8	0.3													
Week 52																	
Placebo		27	1.1	0.2													
Nera 18mg		17	1.8	0.2													
Week 64																	
Placebo		23	1.3	0.2													
Nera 18mg		17	1.9	0.2													
Week 76																	
Placebo		15	1.6	0.2													
Nera 18mg		10	2.4	0.3													
Week 88																	
Placebo		9	1.4	0.2													
Nera 18mg		3	3.3	0.7													
Week 100																	
Placebo		2	1.0	0.0													
Nera 18mg		1	3.0	NC													
Week 112																	
Placebo		2	1.0	0.0													
Nera 18mg		0	NC	NC													
Unclassifiable IIP																	
Baseline																	
Placebo	46	21	1.8	0.2													
Nera 18mg	32	14	1.3	0.2													
Week 12																	
Placebo		34	1.7	0.2													
Nera 18mg		21	1.5	0.2													
Week 26																	
Placebo		38	1.6	0.1													
Nera 18mg		26	1.3	0.1													
Week 36																	
Placebo		36	1.4	0.1													
Nera 18mg		26	1.3	0.2													
Week 44																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		37	1.5	0.2													
Nera 18mg		26	1.4	0.2													
Week 52																	
Placebo		38	1.6	0.2													
Nera 18mg		27	1.3	0.2													
Week 64																	
Placebo		32	1.6	0.2													
Nera 18mg		22	1.5	0.2													
Week 76																	
Placebo		25	1.4	0.1													
Nera 18mg		16	1.3	0.2													
Week 88																	
Placebo		10	2.2	0.3													
Nera 18mg		10	1.5	0.3													
Week 100																	
Placebo		2	1.5	0.5													
Nera 18mg		3	1.7	0.3													
Week 112																	
Placebo		0	NC	NC													
Nera 18mg		0	NC	NC													
HP																	
Baseline																	
Placebo	38	20	1.4	0.2													
Nera 18mg	43	25	1.7	0.2													
Week 12																	
Placebo		26	1.3	0.2													
Nera 18mg		27	1.7	0.1													
Week 26																	
Placebo		35	1.3	0.2													
Nera 18mg		33	1.7	0.2													
Week 36																	
Placebo		35	1.4	0.1													
Nera 18mg		37	1.7	0.1													
Week 44																	
Placebo		36	1.3	0.1													
Nera 18mg		35	1.9	0.1													
Week 52																	
Placebo		37	1.4	0.2													
Nera 18mg		35	1.8	0.2													
Week 64																	
Placebo		32	1.3	0.2													

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		29	1.9	0.1													
Week 76																	
Placebo		18	1.1	0.2													
Nera 18mg		17	1.8	0.2													
Week 88																	
Placebo		8	0.8	0.3													
Nera 18mg		5	2.6	0.2													
Week 100																	
Placebo		1	1.0	NC													
Nera 18mg		1	2.0	NC													
Week 112																	
Placebo		0	NC	NC													
Nera 18mg		0	NC	NC													
Autoimmune ILD																	
Baseline																	
Placebo	29	16	1.7	0.2													
Nera 18mg	43	20	1.2	0.2													
Week 12																	
Placebo		23	1.7	0.2													
Nera 18mg		29	1.2	0.1													
Week 26																	
Placebo		24	1.5	0.2													
Nera 18mg		36	1.2	0.1													
Week 36																	
Placebo		25	1.5	0.2													
Nera 18mg		35	1.3	0.1													
Week 44																	
Placebo		24	1.5	0.2													
Nera 18mg		35	1.3	0.1													
Week 52																	
Placebo		25	1.5	0.2													
Nera 18mg		35	1.3	0.1													
Week 64																	
Placebo		21	1.3	0.2													
Nera 18mg		31	1.2	0.1													
Week 76																	
Placebo		16	1.1	0.2													
Nera 18mg		18	1.2	0.2													
Week 88																	
Placebo		6	1.0	0.3													
Nera 18mg		5	1.2	0.5													

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 100																	
Placebo		4	1.3	0.3													
Nera 18mg		2	0.5	0.5													
Week 112																	
Placebo		2	1.0	0.0													
Nera 18mg		0	NC	NC													
Other ILD																	
Baseline																	
Placebo	24	7	2.0	0.2													
Nera 18mg	25	10	0.9	0.2													
Week 12																	
Placebo		12	1.9	0.2													
Nera 18mg		15	1.3	0.2													
Week 26																	
Placebo		18	2.0	0.2													
Nera 18mg		22	1.4	0.1													
Week 36																	
Placebo		21	1.8	0.2													
Nera 18mg		21	1.4	0.2													
Week 44																	
Placebo		21	1.6	0.2													
Nera 18mg		21	1.3	0.2													
Week 52																	
Placebo		21	1.7	0.2													
Nera 18mg		22	1.5	0.1													
Week 64																	
Placebo		19	1.6	0.2													
Nera 18mg		19	1.6	0.2													
Week 76																	
Placebo		12	1.2	0.2													
Nera 18mg		17	1.8	0.2													
Week 88																	
Placebo		5	1.6	0.4													
Nera 18mg		7	1.9	0.4													
Week 100																	
Placebo		2	1.5	0.5													
Nera 18mg		2	2.0	1.0													
Week 112																	
Placebo		0	NC	NC													
Nera 18mg		0	NC	NC													

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Region																	
Europe																	
Baseline																	
Placebo	78	40	1.7	0.1													
Nera 18mg	67	39	1.4	0.1													
Week 12																	
Placebo		56	1.8	0.1													
Nera 18mg		43	1.5	0.1													
Week 26																	
Placebo		66	1.6	0.1													
Nera 18mg		54	1.6	0.1													
Week 36																	
Placebo		67	1.6	0.1													
Nera 18mg		52	1.7	0.1													
Week 44																	
Placebo		68	1.5	0.1													
Nera 18mg		53	1.7	0.1													
Week 52																	
Placebo		69	1.6	0.1													
Nera 18mg		52	1.8	0.1													
Week 64																	
Placebo		63	1.7	0.1													
Nera 18mg		50	1.8	0.1													
Week 76																	
Placebo		36	1.3	0.1													
Nera 18mg		28	1.9	0.1													
Week 88																	
Placebo		15	1.5	0.3													
Nera 18mg		8	1.9	0.4													
Week 100																	
Placebo		3	1.0	0.0													
Nera 18mg		2	2.5	0.5													
Week 112																	
Placebo		1	1.0	NC													
Nera 18mg		0	NC	NC													
Asia																	
Baseline																	
Placebo	45	18	1.2	0.2													
Nera 18mg	41	10	0.7	0.2													
Week 12																	
Placebo		31	1.3	0.2													

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		21	0.9	0.2													
Week 26																	
Placebo		40	1.2	0.1													
Nera 18mg		33	1.0	0.1													
Week 36																	
Placebo		40	1.1	0.1													
Nera 18mg		33	1.1	0.1													
Week 44																	
Placebo		38	1.2	0.2													
Nera 18mg		31	1.1	0.2													
Week 52																	
Placebo		39	1.3	0.1													
Nera 18mg		32	1.3	0.1													
Week 64																	
Placebo		33	1.2	0.1													
Nera 18mg		26	1.2	0.2													
Week 76																	
Placebo		25	1.0	0.2													
Nera 18mg		19	1.3	0.2													
Week 88																	
Placebo		13	1.2	0.2													
Nera 18mg		9	1.2	0.4													
Week 100																	
Placebo		5	1.4	0.2													
Nera 18mg		4	1.0	0.4													
Week 112																	
Placebo		1	1.0	NC													
Nera 18mg		0	NC	NC													
Canada and USA																	
Baseline																	
Placebo	30	12	1.9	0.2													
Nera 18mg	37	19	1.5	0.2													
Week 12																	
Placebo		20	1.6	0.2													
Nera 18mg		26	1.7	0.1													
Week 26																	
Placebo		23	1.6	0.1													
Nera 18mg		30	1.6	0.1													
Week 36																	
Placebo		25	1.4	0.1													
Nera 18mg		31	1.5	0.1													

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 44																	
Placebo		26	1.3	0.2													
Nera 18mg		32	1.6	0.2													
Week 52																	
Placebo		26	1.3	0.2													
Nera 18mg		33	1.5	0.2													
Week 64																	
Placebo		21	1.2	0.2													
Nera 18mg		27	1.7	0.1													
Week 76																	
Placebo		17	1.5	0.2													
Nera 18mg		20	1.9	0.2													
Week 88																	
Placebo		9	1.8	0.3													
Nera 18mg		10	2.4	0.3													
Week 100																	
Placebo		3	1.3	0.3													
Nera 18mg		3	2.0	0.6													
Week 112																	
Placebo		2	1.0	0.0													
Nera 18mg		0	NC	NC													
Rest of the World																	
Baseline																	
Placebo	16	5	2.0	0.3													
Nera 18mg	25	10	1.8	0.3													
Week 12																	
Placebo		9	1.6	0.3													
Nera 18mg		15	1.7	0.2													
Week 26																	
Placebo		12	1.6	0.3													
Nera 18mg		17	1.6	0.2													
Week 36																	
Placebo		12	1.7	0.2													
Nera 18mg		20	1.6	0.2													
Week 44																	
Placebo		13	1.8	0.2													
Nera 18mg		19	1.8	0.2													
Week 52																	
Placebo		14	1.6	0.3													
Nera 18mg		19	1.6	0.2													
Week 64																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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Table I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		10	1.3	0.3													
Nera 18mg		15	1.3	0.2													
Week 76																	
Placebo		8	1.6	0.3													
Nera 18mg		11	1.3	0.3													
Week 88																	
Placebo		1	1.0	NC													
Nera 18mg		3	2.3	0.3													
Week 100																	
Placebo		0	NC	NC													
Nera 18mg		0	NC	NC													
Week 112																	
Placebo		0	NC	NC													
Nera 18mg		0	NC	NC													

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit
Only descriptive statistics are presented due to low number of available baseline values.

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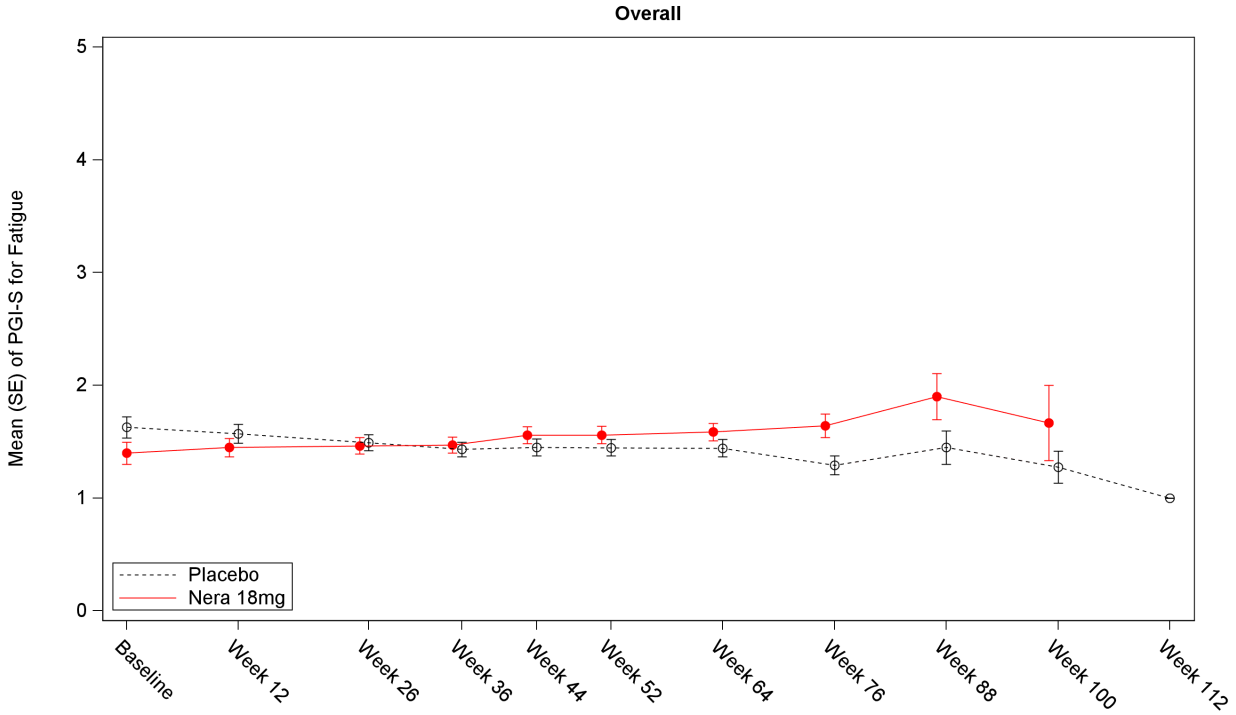

Number of patients

Placebo	75	116	141	144	145	148	127	86	38	11	4
Nera 18mg	78	105	134	136	135	136	118	78	30	9	0

Study: 1305-0023. Number of patients refers to the number of patients with observed data at visit.

Figure I.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (NIN background)

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BI Trial No.: x1305p3.hta

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Overall																	
Baseline																	
Placebo	169	169	2472.2	60.6	166 (100.0%)												
Nera 18mg	170	170	2419.7	56.3	169 (100.0%)												
Week 2																	
Placebo		159	2489.4	62.5	159 (95.8%)	7.5	12.7	-17.6	32.6								
Nera 18mg		164	2425.1	56.7	164 (97.0%)	8.4	12.6	-16.3	33.2	0.9	17.9	-34.3	36.2	0.9578			
Week 6																	
Placebo		158	2468.7	64.7	158 (95.2%)	-33.3	12.9	-58.7	-7.8								
Nera 18mg		165	2416.5	55.3	165 (97.6%)	-1.0	12.8	-26.1	24.1	32.2	18.2	-3.5	68.0	0.0772			
Week 12																	
Placebo		158	2439.2	63.8	158 (95.2%)	-52.9	15.1	-82.7	-23.1								
Nera 18mg		156	2411.4	56.8	156 (92.3%)	-0.4	15.1	-30.2	29.4	52.5	21.4	10.3	94.7	0.0148	0.28	0.05	0.50
Week 18																	
Placebo		152	2442.3	65.4	152 (91.6%)	-76.4	15.3	-106.6	-46.3								
Nera 18mg		150	2409.6	59.4	150 (88.8%)	-15.6	15.3	-45.7	14.6	60.9	21.7	18.2	103.6	0.0054	0.32	0.10	0.55
Week 26																	
Placebo		153	2414.6	64.7	153 (92.2%)	-91.1	16.3	-123.1	-59.0								
Nera 18mg		146	2379.7	60.8	146 (86.4%)	-33.8	16.4	-66.0	-1.5	57.3	23.1	11.8	102.8	0.0138	0.29	0.06	0.51
Week 36																	
Placebo		146	2381.5	65.4	146 (88.0%)	-127.8	16.7	-160.6	-94.9								
Nera 18mg		142	2371.6	61.6	142 (84.0%)	-45.5	16.8	-78.5	-12.5	82.2	23.7	35.6	128.9	0.0006	0.41	0.18	0.64
Week 44																	
Placebo		142	2384.9	67.8	142 (85.5%)	-159.0	19.6	-197.7	-120.4								
Nera 18mg		137	2343.6	61.7	137 (81.1%)	-77.3	19.8	-116.3	-38.3	81.7	27.9	26.7	136.7	0.0037	0.35	0.11	0.59
Week 52																	
Placebo		145	2377.2	67.9	145 (87.3%)	-181.4	22.0	-224.6	-138.1								
Nera 18mg		137	2308.9	63.0	137 (81.1%)	-98.4	22.2	-142.2	-54.7	82.9	31.3	21.3	144.6	0.0086	0.32	0.08	0.55
Week 64																	
Placebo		127	2367.1	75.1	127 (76.5%)	-222.0	22.5	-266.3	-177.7								
Nera 18mg		119	2332.7	66.3	119 (70.4%)	-132.1	22.8	-177.0	-87.1	89.9	32.1	26.8	153.1	0.0055	0.36	0.11	0.61
Week 76																	
Placebo		84	2323.2	91.9	84 (50.6%)												
Nera 18mg		80	2304.7	83.1	80 (47.3%)												
Week 88																	
Placebo		38	2357.5	150.7	38 (22.9%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		30	2185.8	127.1	30 (17.8%)												
Week 100																	
Placebo		10	2404.0	288.6	10 (6.0%)												
Nera 18mg		9	1920.0	239.2	9 (5.3%)												
Week 112																	
Placebo		4	2229.0	356.5	4 (2.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Age																	
Test for homogeneity (H0)^																	
Week 6														0.8451			
Week 12														0.5845			
Week 18														0.6128			
Week 26														0.6291			
Week 36														0.7021			
Week 44														0.5934			
Week 52														0.4223			
Week 64														0.9807			
<65 years																	
Baseline																	
Placebo	65	65	2602.5	114.8	65 (100.0%)												
Nera 18mg	64	64	2556.0	98.8	64 (100.0%)												
Week 2																	
Placebo		62	2606.4	118.6	62 (95.4%)	16.5	20.5	-23.9	56.8								
Nera 18mg		62	2573.2	99.8	62 (96.9%)	21.9	20.5	-18.5	62.3	5.4	28.9	-51.4	62.3	0.8509			
Week 6																	
Placebo		64	2608.4	120.1	64 (98.5%)	-9.3	20.5	-49.6	30.9								
Nera 18mg		63	2567.7	98.0	63 (98.4%)	35.5	20.6	-4.9	76.0	44.9	28.9	-12.0	101.7	0.1217			
Week 12																	
Placebo		62	2629.1	122.2	62 (95.4%)	-11.2	24.1	-58.7	36.3								
Nera 18mg		58	2558.5	101.2	58 (90.6%)	28.0	24.5	-20.1	76.2	39.3	34.3	-28.2	106.7	0.2526			
Week 18																	
Placebo		62	2589.6	121.2	62 (95.4%)	-51.6	24.5	-99.7	-3.4								
Nera 18mg		58	2542.8	101.7	58 (90.6%)	-3.9	24.8	-52.6	44.9	47.7	34.7	-20.6	116.0	0.1706			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 26																	
Placebo		61	2582.3	118.8	61 (93.8%)	-71.7	26.1	-123.0	-20.4								
Nera 18mg		55	2531.3	107.3	55 (85.9%)	-3.3	26.6	-55.6	49.0	68.4	37.1	-4.6	141.4	0.0662			
Week 36																	
Placebo		58	2529.1	120.8	58 (89.2%)	-86.6	26.5	-138.8	-34.4								
Nera 18mg		56	2498.3	104.4	56 (87.5%)	-19.8	26.9	-72.7	33.1	66.8	37.7	-7.3	141.0	0.0772			
Week 44																	
Placebo		59	2549.0	122.6	59 (90.8%)	-105.6	31.0	-166.7	-44.6								
Nera 18mg		52	2479.3	105.5	52 (81.3%)	-51.1	31.9	-113.9	11.6	54.5	44.3	-32.8	141.8	0.2202			
Week 52																	
Placebo		60	2521.1	124.5	60 (92.3%)	-137.6	34.7	-205.9	-69.3								
Nera 18mg		52	2448.6	104.5	52 (81.3%)	-55.4	35.9	-126.0	15.2	82.2	49.8	-15.8	180.2	0.0999			
Week 64																	
Placebo		57	2499.3	129.3	57 (87.7%)	-183.0	35.1	-252.3	-113.8								
Nera 18mg		43	2456.0	119.1	43 (67.2%)	-104.2	37.2	-177.5	-30.9	78.8	51.0	-21.7	179.4	0.1239			
Week 76																	
Placebo		36	2381.0	167.2	36 (55.4%)												
Nera 18mg		34	2501.2	126.5	34 (53.1%)												
Week 88																	
Placebo		15	2386.2	322.6	15 (23.1%)												
Nera 18mg		6	2239.3	177.5	6 (9.4%)												
Week 100																	
Placebo		3	2157.0	282.9	3 (4.6%)												
Nera 18mg		1	1516.0	NC	1 (1.6%)												
Week 112																	
Placebo		2	2091.0	462.0	2 (3.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	104	104	2390.7	66.8	101 (100.0%)												
Nera 18mg	106	106	2337.4	66.9	105 (100.0%)												
Week 2																	
Placebo		97	2414.6	68.4	97 (96.0%)	1.8	16.4	-30.4	34.0								
Nera 18mg		102	2335.1	66.9	102 (97.1%)	0.0	16.1	-31.6	31.7	-1.8	22.9	-46.8	43.3	0.9385			
Week 6																	
Placebo		94	2373.5	70.6	94 (93.1%)	-48.5	16.5	-81.0	-16.0								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		102	2323.2	64.6	102 (97.1%)	-23.9	16.2	-55.7	7.9	24.6	23.1	-20.8	70.0	0.2875			
Week 12																	
Placebo		96	2316.5	67.0	96 (95.0%)	-79.1	19.2	-117.0	-41.3								
Nera 18mg		98	2324.3	66.6	98 (93.3%)	-17.7	19.1	-55.4	19.9	61.4	27.1	8.1	114.7	0.0241	0.32	0.04	0.61
Week 18																	
Placebo		90	2340.8	71.0	90 (89.1%)	-91.8	19.7	-130.6	-53.1								
Nera 18mg		92	2325.6	71.6	92 (87.6%)	-22.7	19.6	-61.2	15.8	69.1	27.7	14.6	123.7	0.0132	0.37	0.08	0.66
Week 26																	
Placebo		92	2303.3	71.5	92 (91.1%)	-102.6	20.8	-143.7	-61.6								
Nera 18mg		91	2288.0	71.6	91 (86.7%)	-52.4	20.9	-93.5	-11.3	50.3	29.5	-7.7	108.3	0.0891			
Week 36																	
Placebo		88	2284.3	72.5	88 (87.1%)	-153.9	21.3	-195.8	-111.9								
Nera 18mg		86	2289.1	74.9	86 (81.9%)	-61.3	21.4	-103.4	-19.2	92.6	30.2	33.2	152.0	0.0023	0.46	0.16	0.76
Week 44																	
Placebo		83	2268.2	74.5	83 (82.2%)	-193.8	25.2	-243.3	-144.2								
Nera 18mg		85	2260.5	74.7	85 (81.0%)	-93.6	25.2	-143.2	-44.0	100.2	35.6	30.2	170.2	0.0052	0.43	0.13	0.74
Week 52																	
Placebo		85	2275.6	74.1	85 (84.2%)	-208.8	28.2	-264.3	-153.3								
Nera 18mg		85	2223.5	77.8	85 (81.0%)	-125.1	28.3	-180.8	-69.4	83.7	39.9	5.1	162.4	0.0369	0.32	0.02	0.62
Week 64																	
Placebo		70	2259.4	85.3	70 (69.3%)	-245.9	29.2	-303.5	-188.3								
Nera 18mg		76	2263.0	78.4	76 (72.4%)	-149.8	28.9	-206.7	-92.8	96.1	41.1	15.1	177.1	0.0202	0.38	0.06	0.71
Week 76																	
Placebo		48	2279.8	102.0	48 (47.5%)												
Nera 18mg		46	2159.4	106.2	46 (43.8%)												
Week 88																	
Placebo		23	2338.7	141.0	23 (22.8%)												
Nera 18mg		24	2172.5	154.0	24 (22.9%)												
Week 100																	
Placebo		7	2509.9	401.1	7 (6.9%)												
Nera 18mg		8	1970.5	265.1	8 (7.6%)												
Week 112																	
Placebo		2	2367.0	715.0	2 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Sex																	
Test for homogeneity (H0)^																	
Week 6														0.7496			
Week 12														0.9998			
Week 18														0.7966			
Week 26														0.8597			
Week 36														0.9211			
Week 44														0.9513			
Week 52														0.6868			
Week 64														0.8093			
Male																	
Baseline																	
Placebo	114	114	2742.4	72.5	112 (100.0%)												
Nera 18mg	108	108	2712.6	66.5	107 (100.0%)												
Week 2																	
Placebo		110	2745.2	74.2	110 (98.2%)	13.0	15.9	-18.3	44.3								
Nera 18mg		105	2714.3	67.8	105 (98.1%)	10.4	16.1	-21.3	42.2	-2.6	22.1	-46.0	40.8	0.9071			
Week 6																	
Placebo		108	2721.1	78.9	108 (96.4%)	-36.3	16.3	-68.3	-4.3								
Nera 18mg		106	2687.9	65.3	106 (99.1%)	-4.2	16.3	-36.3	27.9	32.1	22.4	-12.0	76.3	0.1530			
Week 12																	
Placebo		107	2691.0	77.8	107 (95.5%)	-62.0	19.0	-99.5	-24.5								
Nera 18mg		98	2689.9	68.0	98 (91.6%)	-5.8	19.4	-44.1	32.5	56.2	26.5	4.0	108.3	0.0348	0.29	0.01	0.56
Week 18																	
Placebo		103	2698.0	80.6	103 (92.0%)	-88.2	19.3	-126.2	-50.3								
Nera 18mg		94	2698.6	71.6	94 (87.9%)	-30.9	19.7	-69.6	7.8	57.3	26.8	4.6	110.0	0.0331	0.30	0.02	0.58
Week 26																	
Placebo		101	2689.1	79.3	101 (90.2%)	-107.2	20.6	-147.7	-66.7								
Nera 18mg		89	2681.7	75.0	89 (83.2%)	-52.6	21.2	-94.3	-10.9	54.6	28.7	-1.8	111.0	0.0579			
Week 36																	
Placebo		96	2642.5	81.9	96 (85.7%)	-151.0	21.1	-192.5	-109.6								
Nera 18mg		85	2683.2	76.6	85 (79.4%)	-71.2	21.7	-114.0	-28.4	79.9	29.4	22.1	137.6	0.0069	0.39	0.10	0.68
Week 44																	
Placebo		95	2628.5	85.6	95 (84.8%)	-193.0	24.6	-241.5	-144.6								
Nera 18mg		81	2630.7	80.7	81 (75.7%)	-122.2	25.6	-172.5	-71.9	70.8	34.4	3.1	138.6	0.0403	0.30	0.00	0.60

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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 52																	
Placebo		97	2606.2	87.2	97 (86.6%)	-236.0	27.1	-289.4	-182.6								
Nera 18mg		81	2576.5	84.4	81 (75.7%)	-162.5	28.2	-218.0	-106.9	73.5	38.0	-1.2	148.3	0.0537			
Week 64																	
Placebo		82	2659.8	95.5	82 (73.2%)	-264.1	28.1	-319.5	-208.7								
Nera 18mg		71	2589.0	87.5	71 (66.4%)	-199.0	29.2	-256.5	-141.6	65.1	39.2	-12.2	142.3	0.0984			
Week 76																	
Placebo		53	2586.8	123.9	53 (47.3%)												
Nera 18mg		45	2612.6	114.0	45 (42.1%)												
Week 88																	
Placebo		25	2642.4	195.0	25 (22.3%)												
Nera 18mg		17	2515.0	163.5	17 (15.9%)												
Week 100																	
Placebo		6	2576.3	468.0	6 (5.4%)												
Nera 18mg		4	2488.3	375.0	4 (3.7%)												
Week 112																	
Placebo		2	2367.0	715.0	2 (1.8%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Female																	
Baseline																	
Placebo	55	55	1912.1	60.9	54 (100.0%)												
Nera 18mg	62	62	1909.5	62.1	62 (100.0%)												
Week 2																	
Placebo		49	1915.3	61.2	49 (90.7%)	-5.1	24.1	-52.5	42.3								
Nera 18mg		59	1910.5	57.5	59 (95.2%)	4.5	22.4	-39.5	48.5	9.6	31.1	-51.6	70.8	0.7574			
Week 6																	
Placebo		50	1923.3	64.6	50 (92.6%)	-27.1	24.1	-74.5	20.3								
Nera 18mg		59	1929.1	62.7	59 (95.2%)	5.0	22.7	-39.6	49.6	32.1	31.4	-29.6	93.8	0.3066			
Week 12																	
Placebo		51	1910.9	66.6	51 (94.4%)	-34.2	28.1	-89.5	21.1								
Nera 18mg		58	1940.8	64.2	58 (93.5%)	10.3	26.6	-42.0	62.7	44.5	36.6	-27.6	116.6	0.2254			
Week 18																	
Placebo		49	1904.6	62.1	49 (90.7%)	-53.0	28.3	-108.8	2.8								
Nera 18mg		56	1924.4	64.9	56 (90.3%)	12.4	26.9	-40.5	65.3	65.4	37.0	-7.5	138.3	0.0783			
Week 26																	
Placebo		52	1881.3	65.5	52 (96.3%)	-59.7	29.8	-118.3	-1.0								

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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		57	1908.0	64.6	57 (91.9%)	-0.3	28.4	-56.2	55.7	59.4	38.9	-17.2	136.0	0.1280			
Week 36																	
Placebo		50	1880.6	65.1	50 (92.6%)	-83.3	30.3	-143.0	-23.5								
Nera 18mg		57	1907.0	65.1	57 (91.9%)	-0.4	28.8	-57.1	56.3	82.9	39.5	5.0	160.7	0.0370	0.38	0.00	0.76
Week 44																	
Placebo		47	1892.6	66.3	47 (87.0%)	-94.9	35.4	-164.6	-25.1								
Nera 18mg		56	1928.2	63.5	56 (90.3%)	-0.8	33.6	-66.8	65.3	94.1	46.2	3.2	185.1	0.0426	0.38	-0.01	0.77
Week 52																	
Placebo		48	1914.4	67.0	48 (88.9%)	-79.0	39.0	-155.7	-2.3								
Nera 18mg		56	1922.0	66.4	56 (90.3%)	9.9	37.0	-63.0	82.8	88.9	50.9	-11.4	189.2	0.0820			
Week 64																	
Placebo		45	1833.6	70.8	45 (83.3%)	-142.7	39.8	-221.0	-64.3								
Nera 18mg		48	1953.7	73.1	48 (77.4%)	-20.4	38.0	-95.3	54.4	122.3	52.2	19.4	225.1	0.0201	0.46	0.05	0.87
Week 76																	
Placebo		31	1872.5	84.5	31 (57.4%)												
Nera 18mg		35	1908.8	82.5	35 (56.5%)												
Week 88																	
Placebo		13	1809.5	142.8	13 (24.1%)												
Nera 18mg		13	1755.4	127.4	13 (21.0%)												
Week 100																	
Placebo		4	2145.5	200.4	4 (7.4%)												
Nera 18mg		5	1465.4	73.2	5 (8.1%)												
Week 112																	
Placebo		2	2091.0	462.0	2 (3.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 6														0.5173			
Week 12														0.0329			
Week 18														0.3414			
Week 26														0.1638			
Week 36														0.1363			
Week 44														0.2407			
Week 52														0.4371			

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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 64														0.3644			
<=70%																	
Baseline																	
Placebo	95	95	2105.6	50.9	93 (100.0%)												
Nera 18mg	97	97	2117.8	56.7	97 (100.0%)												
Week 2																	
Placebo		91	2144.8	52.6	91 (97.8%)	7.1	17.6	-27.4	41.7								
Nera 18mg		93	2139.3	57.8	93 (95.9%)	18.2	17.4	-15.9	52.4	11.1	23.8	-35.7	57.9	0.6406			
Week 6																	
Placebo		89	2094.5	53.9	89 (95.7%)	-30.4	17.7	-65.3	4.4								
Nera 18mg		95	2157.5	59.6	95 (97.9%)	35.9	17.3	1.9	69.9	66.3	23.8	19.5	113.2	0.0056	0.39	0.10	0.68
Week 12																	
Placebo		88	2088.7	55.2	88 (94.6%)	-47.6	21.0	-89.0	-6.2								
Nera 18mg		90	2158.3	60.9	90 (92.8%)	23.0	20.7	-17.7	63.7	70.6	28.4	14.8	126.5	0.0134	0.36	0.06	0.65
Week 18																	
Placebo		83	2058.3	55.0	83 (89.2%)	-88.7	21.4	-130.9	-46.6								
Nera 18mg		84	2122.2	63.2	84 (86.6%)	-1.4	21.1	-42.9	40.1	87.3	28.9	30.3	144.2	0.0028	0.45	0.14	0.75
Week 26																	
Placebo		83	2041.4	55.4	83 (89.2%)	-107.1	22.8	-152.0	-62.3								
Nera 18mg		84	2088.7	59.4	84 (86.6%)	-19.4	22.5	-63.7	24.9	87.8	30.8	27.2	148.4	0.0047	0.42	0.12	0.73
Week 36																	
Placebo		80	2015.3	58.1	80 (86.0%)	-140.4	23.4	-186.4	-94.4								
Nera 18mg		82	2076.0	58.9	82 (84.5%)	-33.7	23.1	-79.1	11.7	106.7	31.6	44.6	168.8	0.0008	0.51	0.20	0.82
Week 44																	
Placebo		77	2002.2	59.3	77 (82.8%)	-170.2	27.6	-224.5	-115.9								
Nera 18mg		79	2047.2	58.2	79 (81.4%)	-69.5	27.3	-123.2	-15.7	100.7	37.3	27.2	174.2	0.0074	0.41	0.10	0.73
Week 52																	
Placebo		77	1995.9	60.1	77 (82.8%)	-206.0	30.8	-266.6	-145.3								
Nera 18mg		79	1995.8	57.7	79 (81.4%)	-98.1	30.7	-158.5	-37.8	107.8	41.8	25.5	190.1	0.0104	0.40	0.08	0.71
Week 64																	
Placebo		69	1976.1	63.4	69 (74.2%)	-242.1	31.5	-304.1	-180.0								
Nera 18mg		67	2020.0	62.6	67 (69.1%)	-117.4	31.5	-179.5	-55.3	124.7	42.9	40.2	209.2	0.0040	0.48	0.14	0.82
Week 76																	
Placebo		44	1909.9	73.8	44 (47.3%)												
Nera 18mg		44	1963.3	74.4	44 (45.4%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 88																	
Placebo		20	1997.5	128.4	20 (21.5%)												
Nera 18mg		18	1909.9	122.0	18 (18.6%)												
Week 100																	
Placebo		4	1815.3	295.4	4 (4.3%)												
Nera 18mg		5	1856.8	268.1	5 (5.2%)												
Week 112																	
Placebo		3	1944.7	304.2	3 (3.2%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	74	74	2942.7	98.2	73 (100.0%)												
Nera 18mg	73	73	2820.8	87.9	72 (100.0%)												
Week 2																	
Placebo		68	2950.6	105.0	68 (93.2%)	7.7	20.6	-32.8	48.3								
Nera 18mg		71	2799.5	89.5	71 (98.6%)	-4.7	19.9	-43.8	34.5	-12.4	27.4	-66.3	41.5	0.6512			
Week 6																	
Placebo		69	2951.3	105.8	69 (94.5%)	-38.2	20.5	-78.6	2.2								
Nera 18mg		70	2768.1	86.4	70 (97.2%)	-49.6	20.0	-88.9	-10.3	-11.4	27.4	-65.3	42.5	0.6773			
Week 12																	
Placebo		70	2879.7	105.1	70 (95.9%)	-60.2	24.1	-107.6	-12.8								
Nera 18mg		66	2756.5	89.9	66 (91.7%)	-30.7	23.9	-77.7	16.3	29.5	32.5	-34.6	93.6	0.3655			
Week 18																	
Placebo		69	2904.2	103.9	69 (94.5%)	-61.3	24.4	-109.4	-13.2								
Nera 18mg		66	2775.3	90.5	66 (91.7%)	-35.1	24.1	-82.7	12.4	26.2	32.9	-38.6	90.9	0.4267			
Week 26																	
Placebo		70	2857.0	103.0	70 (95.9%)	-71.5	25.8	-122.3	-20.7								
Nera 18mg		62	2773.8	98.8	62 (86.1%)	-53.4	26.0	-104.6	-2.2	18.1	35.1	-50.9	87.1	0.6060			
Week 36																	
Placebo		66	2825.5	103.0	66 (90.4%)	-112.1	26.5	-164.3	-60.0								
Nera 18mg		60	2775.6	100.9	60 (83.3%)	-61.6	26.7	-114.1	-9.1	50.5	36.0	-20.3	121.3	0.1613			
Week 44																	
Placebo		65	2838.3	106.0	65 (89.0%)	-145.2	31.2	-206.7	-83.8								
Nera 18mg		58	2747.2	100.9	58 (80.6%)	-88.4	31.6	-150.5	-26.3	56.8	42.4	-26.6	140.2	0.1808			
Week 52																	
Placebo		68	2808.9	106.1	68 (93.2%)	-150.8	34.7	-219.1	-82.4								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		58	2735.4	103.0	58 (80.6%)	-100.2	35.3	-169.6	-30.7	50.6	47.3	-42.5	143.6	0.2853			
Week 64																	
Placebo		58	2832.2	121.0	58 (79.5%)	-197.4	35.7	-267.8	-127.1								
Nera 18mg		52	2735.6	105.2	52 (72.2%)	-152.3	36.1	-223.4	-81.1	45.2	48.4	-50.2	140.6	0.3515			
Week 76																	
Placebo		40	2777.9	145.0	40 (54.8%)												
Nera 18mg		36	2722.0	131.4	36 (50.0%)												
Week 88																	
Placebo		18	2757.5	256.9	18 (24.7%)												
Nera 18mg		12	2599.8	214.5	12 (16.7%)												
Week 100																	
Placebo		6	2796.5	371.5	6 (8.2%)												
Nera 18mg		4	1999.0	468.8	4 (5.6%)												
Week 112																	
Placebo		1	3082.0	NC	1 (1.4%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline HRCT pattern																	
Test for homogeneity (H0)^																	
Week 6														0.3144			
Week 12														0.1124			
Week 18														0.3305			
Week 26														0.0613			
Week 36														0.0108			
Week 44														0.0827			
Week 52														0.0853			
Week 64														0.1214			
UIP-like																	
Baseline																	
Placebo	116	116	2547.4	71.3	113 (100.0%)												
Nera 18mg	121	121	2465.6	70.0	120 (100.0%)												
Week 2																	
Placebo		107	2567.7	73.5	107 (94.7%)	11.2	15.5	-19.4	41.8								
Nera 18mg		116	2452.9	70.9	116 (96.7%)	0.2	14.9	-29.1	29.6	-11.0	21.6	-53.4	31.5	0.6116			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 6																	
Placebo		109	2547.8	75.6	109 (96.5%)	-18.7	15.6	-49.4	12.0								
Nera 18mg		118	2450.1	68.1	118 (98.3%)	-5.4	15.0	-35.0	24.2	13.3	21.7	-29.4	55.9	0.5409			
Week 12																	
Placebo		109	2501.6	73.6	109 (96.5%)	-50.3	18.3	-86.4	-14.2								
Nera 18mg		113	2444.9	70.0	113 (94.2%)	-11.6	17.8	-46.7	23.5	38.7	25.6	-11.7	89.0	0.1315			
Week 18																	
Placebo		103	2537.9	75.2	103 (91.2%)	-64.5	18.5	-101.0	-28.0								
Nera 18mg		108	2432.4	73.6	108 (90.0%)	-30.2	18.0	-65.7	5.2	34.3	25.8	-16.6	85.1	0.1861			
Week 26																	
Placebo		106	2496.7	75.5	106 (93.8%)	-73.1	19.5	-111.6	-34.6								
Nera 18mg		106	2393.2	74.8	106 (88.3%)	-54.1	19.1	-91.7	-16.4	19.0	27.4	-34.8	72.9	0.4873			
Week 36																	
Placebo		101	2474.0	71.9	101 (89.4%)	-118.0	20.1	-157.6	-78.3								
Nera 18mg		102	2391.0	76.7	102 (85.0%)	-62.5	19.7	-101.4	-23.7	55.4	28.2	-0.1	110.9	0.0505			
Week 44																	
Placebo		96	2489.5	77.0	96 (85.0%)	-154.1	23.8	-201.0	-107.3								
Nera 18mg		97	2348.8	78.6	97 (80.8%)	-103.7	23.3	-149.6	-57.8	50.4	33.3	-15.2	116.1	0.1314			
Week 52																	
Placebo		99	2475.6	77.8	99 (87.6%)	-168.7	26.6	-221.1	-116.2								
Nera 18mg		98	2330.1	80.7	98 (81.7%)	-117.3	26.2	-168.8	-65.8	51.3	37.4	-22.2	124.9	0.1705			
Week 64																	
Placebo		89	2459.3	84.7	89 (78.8%)	-213.1	27.2	-266.6	-159.6								
Nera 18mg		84	2363.1	84.9	84 (70.0%)	-155.8	26.9	-208.8	-102.8	57.3	38.2	-18.0	132.7	0.1353			
Week 76																	
Placebo		58	2383.0	96.8	58 (51.3%)												
Nera 18mg		58	2296.2	102.0	58 (48.3%)												
Week 88																	
Placebo		26	2295.0	134.8	26 (23.0%)												
Nera 18mg		22	2164.0	154.8	22 (18.3%)												
Week 100																	
Placebo		8	2410.6	362.4	8 (7.1%)												
Nera 18mg		8	1880.3	267.5	8 (6.7%)												
Week 112																	
Placebo		3	2121.0	480.5	3 (2.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Other fibrotic patterns																	
Baseline																	
Placebo	53	53	2307.4	111.8	53 (100.0%)												
Nera 18mg	49	49	2306.2	89.9	49 (100.0%)												
Week 2																	
Placebo		52	2328.4	114.6	52 (98.1%)	-0.2	22.4	-44.3	43.9								
Nera 18mg		48	2358.0	90.5	48 (98.0%)	27.9	23.3	-17.9	73.8	28.1	32.3	-35.3	91.6	0.3837			
Week 6																	
Placebo		49	2292.6	120.9	49 (92.5%)	-65.7	23.1	-111.0	-20.3								
Nera 18mg		47	2332.2	91.9	47 (95.9%)	10.6	23.9	-36.3	57.5	76.2	33.1	11.1	141.4	0.0219	0.47	0.06	0.87
Week 12																	
Placebo		49	2300.3	123.4	49 (92.5%)	-57.4	27.1	-110.7	-4.1								
Nera 18mg		43	2323.1	92.6	43 (87.8%)	27.0	28.6	-29.3	83.3	84.4	39.3	7.0	161.7	0.0326	0.44	0.03	0.85
Week 18																	
Placebo		49	2241.2	123.6	49 (92.5%)	-101.9	27.1	-155.3	-48.4								
Nera 18mg		42	2350.9	96.2	42 (85.7%)	21.0	28.7	-35.6	77.5	122.8	39.4	45.2	200.5	0.0020	0.65	0.23	1.07
Week 26																	
Placebo		47	2229.2	120.9	47 (88.7%)	-129.8	28.9	-186.8	-72.9								
Nera 18mg		40	2343.8	100.7	40 (81.6%)	18.2	30.8	-42.4	78.8	148.0	42.2	65.0	230.9	0.0005	0.75	0.31	1.18
Week 36																	
Placebo		45	2174.1	134.1	45 (84.9%)	-148.0	29.8	-206.6	-89.3								
Nera 18mg		40	2322.1	99.0	40 (81.6%)	-2.7	31.5	-64.7	59.4	145.3	43.2	60.2	230.4	0.0009	0.72	0.29	1.16
Week 44																	
Placebo		46	2166.7	129.3	46 (86.8%)	-168.5	34.8	-237.0	-99.9								
Nera 18mg		40	2330.9	92.4	40 (81.6%)	-13.2	37.1	-86.2	59.9	155.3	50.8	55.4	255.2	0.0024	0.65	0.22	1.08
Week 52																	
Placebo		46	2165.4	129.0	46 (86.8%)	-208.0	39.0	-284.7	-131.3								
Nera 18mg		39	2255.7	89.3	39 (79.6%)	-50.8	41.8	-133.0	31.4	157.2	57.0	45.0	269.3	0.0062	0.59	0.16	1.03
Week 64																	
Placebo		38	2151.1	150.1	38 (71.7%)	-239.4	40.2	-318.7	-160.1								
Nera 18mg		35	2260.0	96.5	35 (71.4%)	-72.8	42.6	-156.9	11.2	166.6	58.5	51.3	281.8	0.0048	0.66	0.19	1.13
Week 76																	
Placebo		26	2189.7	204.7	26 (49.1%)												
Nera 18mg		22	2327.0	140.9	22 (44.9%)												
Week 88																	
Placebo		12	2492.9	387.3	12 (22.6%)												

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		8	2245.8	229.2	8 (16.3%)												
Week 100																	
Placebo		2	2377.5	266.5	2 (3.8%)												
Nera 18mg		1	2238.0	NC	1 (2.0%)												
Week 112																	
Placebo		1	2553.0	NC	1 (1.9%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Underlying ILD diagnosis																	
Test for homogeneity (H0)^																	
Week 6														0.5434			
Week 12														0.1528			
Week 18														0.1427			
Week 26														0.2030			
Week 36														0.6132			
Week 44														0.8750			
Week 52														0.4132			
Week 64														0.6105			
iNSIP																	
Baseline																	
Placebo	32	32	2671.6	172.0	32 (100.0%)												
Nera 18mg	27	27	2524.1	126.8	27 (100.0%)												
Week 2																	
Placebo		30	2714.9	176.7	30 (93.8%)	24.4	29.4	-33.5	82.3								
Nera 18mg		26	2519.3	132.7	26 (96.3%)	8.0	31.6	-54.2	70.2	-16.4	43.2	-101.4	68.7	0.7050			
Week 6																	
Placebo		30	2738.6	172.0	30 (93.8%)	2.1	29.8	-56.6	60.7								
Nera 18mg		27	2499.4	123.1	27 (100.0%)	-21.1	31.7	-83.4	41.2	-23.2	43.5	-108.8	62.4	0.5945			
Week 12																	
Placebo		28	2671.6	174.2	28 (87.5%)	-0.2	35.4	-69.8	69.4								
Nera 18mg		23	2509.3	117.3	23 (85.2%)	-16.1	38.4	-91.8	59.5	-15.9	52.2	-118.7	86.8	0.7604			
Week 18																	
Placebo		28	2653.5	175.9	28 (87.5%)	-61.6	35.5	-131.5	8.2								
Nera 18mg		25	2465.3	129.4	25 (92.6%)	-61.5	38.0	-136.3	13.3	0.1	52.0	-102.2	102.5	0.9978			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 26																	
Placebo		29	2586.7	175.4	29 (90.6%)	-87.5	37.6	-161.5	-13.5								
Nera 18mg		23	2507.6	129.4	23 (85.2%)	-50.7	41.3	-132.0	30.5	36.7	55.8	-73.1	146.6	0.5109			
Week 36																	
Placebo		27	2496.1	155.5	27 (84.4%)	-139.5	39.2	-216.6	-62.4								
Nera 18mg		21	2513.9	140.3	21 (77.8%)	-51.2	43.4	-136.7	34.3	88.3	58.5	-26.8	203.4	0.1320			
Week 44																	
Placebo		28	2558.9	162.5	28 (87.5%)	-160.7	45.8	-250.9	-70.5								
Nera 18mg		18	2583.8	151.4	18 (66.7%)	-27.2	52.5	-130.5	76.0	133.5	69.6	-3.5	270.5	0.0561			
Week 52																	
Placebo		27	2580.7	173.2	27 (84.4%)	-171.6	51.2	-272.4	-70.8								
Nera 18mg		17	2498.9	146.3	17 (63.0%)	-55.7	59.1	-172.1	60.7	115.9	78.2	-37.9	269.8	0.1392			
Week 64																	
Placebo		23	2624.8	203.3	23 (71.9%)	-200.6	52.3	-303.6	-97.6								
Nera 18mg		18	2405.8	130.1	18 (66.7%)	-152.5	58.9	-268.6	-36.5	48.1	78.7	-107.0	203.1	0.5419			
Week 76																	
Placebo		16	2340.3	260.1	16 (50.0%)												
Nera 18mg		11	2121.4	124.2	11 (40.7%)												
Week 88																	
Placebo		9	2352.2	349.3	9 (28.1%)												
Nera 18mg		3	2166.7	459.8	3 (11.1%)												
Week 100																	
Placebo		2	3811.0	692.0	2 (6.3%)												
Nera 18mg		1	2238.0	NC	1 (3.7%)												
Week 112																	
Placebo		2	2367.0	715.0	2 (6.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Unclassifiable IIP																	
Baseline																	
Placebo	46	46	2386.8	98.4	45 (100.0%)												
Nera 18mg	32	32	2429.8	146.7	32 (100.0%)												
Week 2																	
Placebo		45	2402.1	98.0	45 (100.0%)	2.6	24.1	-44.8	50.1								
Nera 18mg		32	2489.9	132.1	32 (100.0%)	60.4	28.7	4.0	116.8	57.8	37.5	-16.0	131.5	0.1243			
Week 6																	
Placebo		43	2319.2	103.5	43 (95.6%)	-61.1	24.7	-109.8	-12.4								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		32	2465.7	131.0	32 (100.0%)	33.3	29.1	-23.9	90.5	94.4	38.2	19.2	169.6	0.0140	0.57	0.11	1.03
Week 12																	
Placebo		45	2324.8	100.9	45 (100.0%)	-76.1	28.7	-132.6	-19.7								
Nera 18mg		30	2467.7	142.1	30 (93.8%)	34.1	34.5	-33.9	102.1	110.2	44.9	21.8	198.6	0.0148	0.57	0.10	1.04
Week 18																	
Placebo		41	2295.0	112.4	41 (91.1%)	-105.3	29.3	-163.0	-47.7								
Nera 18mg		27	2505.2	153.8	27 (84.4%)	22.3	35.4	-47.3	91.9	127.6	45.9	37.2	218.1	0.0059	0.68	0.18	1.17
Week 26																	
Placebo		39	2334.2	109.8	39 (86.7%)	-107.1	31.6	-169.3	-44.8								
Nera 18mg		27	2409.1	145.2	27 (84.4%)	20.0	37.9	-54.6	94.6	127.1	49.4	29.8	224.3	0.0106	0.64	0.14	1.13
Week 36																	
Placebo		37	2306.9	115.7	37 (82.2%)	-139.4	32.9	-204.1	-74.6								
Nera 18mg		27	2367.4	140.8	27 (84.4%)	-20.4	39.1	-97.4	56.6	119.0	51.2	18.3	219.7	0.0208	0.58	0.08	1.08
Week 44																	
Placebo		36	2259.4	125.0	36 (80.0%)	-177.5	38.6	-253.6	-101.4								
Nera 18mg		27	2336.4	144.8	27 (84.4%)	-53.7	45.9	-144.0	36.7	123.9	60.0	5.6	242.1	0.0401	0.52	0.02	1.02
Week 52																	
Placebo		39	2255.4	114.3	39 (86.7%)	-208.6	42.7	-292.6	-124.6								
Nera 18mg		27	2277.4	147.4	27 (84.4%)	-85.5	51.0	-185.9	14.9	123.1	66.6	-8.0	254.2	0.0655			
Week 64																	
Placebo		32	2200.5	125.5	32 (71.1%)	-244.7	43.7	-330.8	-158.6								
Nera 18mg		22	2331.3	172.4	22 (68.8%)	-106.6	52.3	-209.8	-3.5	138.1	68.2	3.6	272.5	0.0442	0.55	0.01	1.10
Week 76																	
Placebo		23	2179.5	134.0	23 (51.1%)												
Nera 18mg		17	2297.1	204.2	17 (53.1%)												
Week 88																	
Placebo		10	2161.2	144.6	10 (22.2%)												
Nera 18mg		10	2222.0	241.6	10 (31.3%)												
Week 100																	
Placebo		1	1709.0	NC	1 (2.2%)												
Nera 18mg		3	1532.7	67.4	3 (9.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
HP																	
Baseline																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo	38	38	2543.7	133.1	38 (100.0%)												
Nera 18mg	43	43	2402.9	98.8	42 (100.0%)												
Week 2																	
Placebo		37	2532.2	129.9	37 (97.4%)	38.4	26.6	-13.9	90.7								
Nera 18mg		41	2395.4	103.3	41 (97.6%)	-15.9	25.2	-65.5	33.7	-54.3	36.5	-126.2	17.6	0.1384			
Week 6																	
Placebo		35	2568.9	149.1	35 (92.1%)	8.8	27.4	-45.0	62.7								
Nera 18mg		39	2427.7	104.9	39 (92.9%)	4.5	26.0	-46.7	55.6	-4.4	37.6	-78.4	69.7	0.9077			
Week 12																	
Placebo		35	2523.3	142.9	35 (92.1%)	-60.6	32.0	-123.5	2.4								
Nera 18mg		37	2443.9	110.1	37 (88.1%)	21.4	30.8	-39.3	82.0	82.0	44.3	-5.2	169.1	0.0653			
Week 18																	
Placebo		36	2517.2	138.3	36 (94.7%)	-46.5	31.9	-109.3	16.3								
Nera 18mg		35	2445.6	116.1	35 (83.3%)	14.5	31.2	-46.8	75.9	61.0	44.5	-26.6	148.6	0.1713			
Week 26																	
Placebo		36	2522.0	139.3	36 (94.7%)	-69.0	33.8	-135.6	-2.4								
Nera 18mg		34	2388.9	121.9	34 (81.0%)	-12.8	33.4	-78.6	53.0	56.2	47.4	-37.2	149.6	0.2369			
Week 36																	
Placebo		36	2474.5	139.1	36 (94.7%)	-126.2	34.9	-194.8	-57.5								
Nera 18mg		35	2419.1	117.4	35 (83.3%)	-38.7	34.2	-106.1	28.7	87.4	48.7	-8.5	183.4	0.0740			
Week 44																	
Placebo		35	2462.0	142.9	35 (92.1%)	-165.5	40.8	-245.9	-85.1								
Nera 18mg		34	2341.5	113.9	34 (81.0%)	-94.6	40.3	-174.0	-15.2	71.0	57.3	-41.9	183.8	0.2167			
Week 52																	
Placebo		35	2440.6	146.8	35 (92.1%)	-206.5	45.5	-296.0	-116.9								
Nera 18mg		34	2271.1	122.3	34 (81.0%)	-148.0	45.0	-236.7	-59.3	58.5	63.9	-67.3	184.3	0.3607			
Week 64																	
Placebo		32	2424.8	160.1	32 (84.2%)	-256.7	45.9	-347.2	-166.2								
Nera 18mg		27	2379.0	138.1	27 (64.3%)	-118.6	46.6	-210.3	-26.9	138.1	65.2	9.5	266.6	0.0354	0.54	0.03	1.06
Week 76																	
Placebo		17	2414.8	190.5	17 (44.7%)												
Nera 18mg		16	2364.9	190.7	16 (38.1%)												
Week 88																	
Placebo		8	2493.4	240.1	8 (21.1%)												
Nera 18mg		5	2294.8	410.8	5 (11.9%)												
Week 100																	

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		1	2430.0	NC	1 (2.6%)												
Nera 18mg		1	3398.0	NC	1 (2.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Autoimmune ILD																	
Baseline																	
Placebo	29	29	2155.8	94.2	28 (100.0%)												
Nera 18mg	43	43	2146.0	96.7	43 (100.0%)												
Week 2																	
Placebo		25	2158.0	100.7	25 (89.3%)	-31.5	32.0	-94.5	31.5								
Nera 18mg		41	2113.9	98.4	41 (95.3%)	-10.2	25.5	-60.3	39.9	21.4	40.5	-58.3	101.0	0.5983			
Week 6																	
Placebo		27	2142.9	100.0	27 (96.4%)	-71.1	31.5	-133.2	-9.0								
Nera 18mg		43	2140.4	98.3	43 (100.0%)	-15.1	25.4	-65.0	34.9	56.0	40.1	-22.8	134.8	0.1627			
Week 12																	
Placebo		27	2119.4	107.5	27 (96.4%)	-68.9	37.0	-141.7	4.0								
Nera 18mg		42	2097.6	97.5	42 (97.7%)	-41.7	29.9	-100.5	17.2	27.2	47.0	-65.4	119.8	0.5635			
Week 18																	
Placebo		25	2183.8	97.9	25 (89.3%)	-85.4	37.6	-159.4	-11.4								
Nera 18mg		39	2087.3	99.1	39 (90.7%)	-37.0	30.4	-96.9	22.9	48.4	47.8	-45.8	142.5	0.3126			
Week 26																	
Placebo		27	2106.8	107.3	27 (96.4%)	-82.9	39.5	-160.8	-5.1								
Nera 18mg		40	2063.1	101.6	40 (93.0%)	-89.9	32.2	-153.3	-26.4	-6.9	50.4	-106.2	92.4	0.8911			
Week 36																	
Placebo		26	2113.3	105.2	26 (92.9%)	-110.4	41.0	-191.1	-29.8								
Nera 18mg		38	2057.9	101.5	38 (88.4%)	-52.3	33.6	-118.4	13.7	58.1	52.3	-44.9	161.1	0.2678			
Week 44																	
Placebo		23	2142.9	108.9	23 (82.1%)	-127.2	48.7	-223.1	-31.4								
Nera 18mg		36	2048.7	98.5	36 (83.7%)	-76.7	39.6	-154.7	1.3	50.5	62.0	-71.6	172.7	0.4159			
Week 52																	
Placebo		24	2169.2	109.1	24 (85.7%)	-114.5	54.1	-221.1	-7.9								
Nera 18mg		37	2097.7	105.6	37 (86.0%)	-45.5	44.1	-132.3	41.2	69.0	69.0	-66.9	204.9	0.3184			
Week 64																	
Placebo		21	2176.0	112.6	21 (75.0%)	-131.8	55.1	-240.4	-23.3								
Nera 18mg		33	2083.4	110.9	33 (76.7%)	-108.5	44.6	-196.4	-20.6	23.4	70.1	-114.9	161.6	0.7392			

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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 76																	
Placebo		15	2219.3	122.9	15 (53.6%)												
Nera 18mg		19	2146.3	154.7	19 (44.2%)												
Week 88																	
Placebo		6	2117.5	154.4	6 (21.4%)												
Nera 18mg		5	1835.0	203.7	5 (11.6%)												
Week 100																	
Placebo		4	2231.0	213.3	4 (14.3%)												
Nera 18mg		2	1364.5	151.5	2 (4.7%)												
Week 112																	
Placebo		2	2091.0	462.0	2 (7.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other ILD																	
Baseline																	
Placebo	24	24	2638.8	178.0	23 (100.0%)												
Nera 18mg	25	25	2793.6	168.4	25 (100.0%)												
Week 2																	
Placebo		22	2665.1	197.6	22 (95.7%)	-12.7	34.4	-80.4	55.0								
Nera 18mg		24	2819.3	168.6	24 (96.0%)	13.6	33.1	-51.5	78.7	26.3	47.6	-67.3	119.9	0.5804			
Week 6																	
Placebo		23	2625.7	190.3	23 (100.0%)	-46.5	34.4	-114.2	21.2								
Nera 18mg		24	2734.3	167.2	24 (96.0%)	-8.6	33.6	-74.6	57.4	37.9	47.9	-56.3	132.2	0.4292			
Week 12																	
Placebo		23	2627.1	197.0	23 (100.0%)	-44.8	40.3	-124.1	34.4								
Nera 18mg		24	2746.1	158.2	24 (96.0%)	11.1	39.3	-66.2	88.4	55.9	56.1	-54.5	166.4	0.3195			
Week 18																	
Placebo		22	2618.9	205.9	22 (95.7%)	-79.4	40.7	-159.7	0.8								
Nera 18mg		24	2715.0	164.2	24 (96.0%)	-21.9	39.5	-99.7	55.9	57.5	56.6	-53.9	169.0	0.3102			
Week 26																	
Placebo		22	2532.1	195.0	22 (95.7%)	-110.3	43.4	-195.7	-25.0								
Nera 18mg		22	2771.0	176.6	22 (88.0%)	-14.7	42.6	-98.6	69.2	95.6	60.6	-23.7	214.9	0.1159			
Week 36																	
Placebo		20	2546.5	234.7	20 (87.0%)	-114.1	45.4	-203.5	-24.7								
Nera 18mg		21	2723.1	195.9	21 (84.0%)	-66.0	44.3	-153.1	21.2	48.1	63.2	-76.4	172.6	0.4476			
Week 44																	
Placebo		20	2510.5	222.0	20 (87.0%)	-152.8	53.2	-257.6	-47.9								

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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		22	2641.3	187.6	22 (88.0%)	-115.6	51.6	-217.2	-14.0	37.2	73.9	-108.4	182.7	0.6156			
Week 52																	
Placebo		20	2478.7	232.4	20 (87.0%)	-188.8	59.4	-305.8	-71.8								
Nera 18mg		22	2614.6	190.5	22 (88.0%)	-151.1	57.4	-264.2	-37.9	37.8	82.4	-124.5	200.0	0.6472			
Week 64																	
Placebo		19	2449.7	239.6	19 (82.6%)	-252.1	59.6	-369.6	-134.7								
Nera 18mg		19	2632.5	190.8	19 (76.0%)	-187.3	58.4	-302.3	-72.2	64.9	83.1	-99.0	228.8	0.4361			
Week 76																	
Placebo		13	2556.3	349.4	13 (56.5%)												
Nera 18mg		17	2551.2	207.6	17 (68.0%)												
Week 88																	
Placebo		5	2830.0	875.4	5 (21.7%)												
Nera 18mg		7	2315.1	244.9	7 (28.0%)												
Week 100																	
Placebo		2	1677.5	433.5	2 (8.7%)												
Nera 18mg		2	2158.5	538.5	2 (8.0%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Region																	
Test for homogeneity (H0)^																	
Week 6														0.9558			
Week 12														0.3012			
Week 18														0.0438			
Week 26														0.2875			
Week 36														0.7391			
Week 44														0.8984			
Week 52														0.7281			
Week 64														0.6713			
Europe																	
Baseline																	
Placebo	78	78	2660.7	107.7	78 (100.0%)												
Nera 18mg	67	67	2527.4	78.9	67 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 2																	
Placebo		76	2640.3	109.9	76 (97.4%)	6.2	18.7	-30.7	43.1								
Nera 18mg		63	2525.4	83.6	63 (94.0%)	6.2	20.4	-33.9	46.2	-0.0	27.6	-54.3	54.3	0.9988			
Week 6																	
Placebo		75	2667.9	112.5	75 (96.2%)	-17.2	18.8	-54.2	19.8								
Nera 18mg		64	2557.4	76.7	64 (95.5%)	36.3	20.2	-3.5	76.1	53.5	27.6	-0.7	107.7	0.0530			
Week 12																	
Placebo		74	2593.1	113.5	74 (94.9%)	-64.3	22.3	-108.1	-20.5								
Nera 18mg		60	2579.7	81.6	60 (89.6%)	40.0	24.3	-7.9	87.9	104.2	32.9	39.5	169.0	0.0017	0.55	0.20	0.89
Week 18																	
Placebo		72	2590.8	116.4	72 (92.3%)	-72.0	22.5	-116.3	-27.7								
Nera 18mg		54	2591.2	89.9	54 (80.6%)	16.2	25.0	-33.0	65.3	88.2	33.5	22.2	154.2	0.0090	0.47	0.11	0.82
Week 26																	
Placebo		72	2566.2	114.4	72 (92.3%)	-81.0	23.9	-128.1	-33.9								
Nera 18mg		56	2516.2	90.5	56 (83.6%)	-12.9	26.5	-65.0	39.2	68.1	35.6	-2.0	138.2	0.0569			
Week 36																	
Placebo		68	2529.5	115.6	68 (87.2%)	-117.3	24.7	-165.8	-68.7								
Nera 18mg		54	2546.2	90.6	54 (80.6%)	-28.5	27.3	-82.2	25.2	88.8	36.7	16.6	161.0	0.0161	0.44	0.08	0.80
Week 44																	
Placebo		66	2539.8	120.1	66 (84.6%)	-152.4	28.9	-209.4	-95.5								
Nera 18mg		53	2522.3	92.4	53 (79.1%)	-52.6	32.1	-115.7	10.6	99.9	43.0	15.1	184.6	0.0211	0.42	0.06	0.79
Week 52																	
Placebo		69	2538.5	117.9	69 (88.5%)	-168.1	32.0	-231.0	-105.1								
Nera 18mg		53	2495.3	99.2	53 (79.1%)	-54.7	35.7	-125.0	15.5	113.3	47.8	19.3	207.4	0.0184	0.43	0.07	0.79
Week 64																	
Placebo		63	2503.2	128.1	63 (80.8%)	-230.6	32.2	-294.1	-167.1								
Nera 18mg		49	2516.0	96.6	49 (73.1%)	-63.0	35.9	-133.8	7.8	167.6	48.1	72.8	262.4	0.0006	0.66	0.28	1.04
Week 76																	
Placebo		36	2531.6	170.1	36 (46.2%)												
Nera 18mg		30	2416.4	126.5	30 (44.8%)												
Week 88																	
Placebo		15	2797.9	298.6	15 (19.2%)												
Nera 18mg		8	2412.4	237.6	8 (11.9%)												
Week 100																	
Placebo		3	3086.0	725.0	3 (3.8%)												
Nera 18mg		2	2150.5	546.5	2 (3.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline FVC [mL] at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 112																	
Placebo		1	2553.0	NC	1 (1.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Asia																	
Baseline																	
Placebo	45	45	2267.1	91.4	43 (100.0%)												
Nera 18mg	41	41	2235.8	127.3	40 (100.0%)												
Week 2																	
Placebo		39	2310.1	98.1	39 (90.7%)	20.6	25.8	-30.2	71.3								
Nera 18mg		40	2216.1	121.9	40 (100.0%)	0.2	26.1	-51.1	51.5	-20.4	36.4	-92.0	51.3	0.5768			
Week 6																	
Placebo		40	2216.8	101.5	40 (93.0%)	-62.7	25.4	-112.6	-12.9								
Nera 18mg		40	2184.9	118.9	40 (100.0%)	-34.9	26.0	-86.1	16.3	27.9	36.1	-43.1	98.8	0.4408			
Week 12																	
Placebo		40	2243.4	101.9	40 (93.0%)	-51.4	30.0	-110.5	7.6								
Nera 18mg		36	2176.7	126.5	36 (90.0%)	-28.1	31.5	-90.0	33.9	23.4	43.2	-61.6	108.3	0.5888			
Week 18																	
Placebo		38	2295.2	100.9	38 (88.4%)	-90.3	30.4	-150.2	-30.4								
Nera 18mg		38	2175.3	122.1	38 (95.0%)	-16.6	31.4	-78.5	45.3	73.7	43.4	-11.8	159.2	0.0910			
Week 26																	
Placebo		41	2213.7	99.9	41 (95.3%)	-105.7	32.0	-168.7	-42.8								
Nera 18mg		34	2146.8	136.9	34 (85.0%)	-66.0	34.1	-133.0	1.0	39.7	46.4	-51.6	131.0	0.3924			
Week 36																	
Placebo		37	2230.9	104.2	37 (86.0%)	-126.1	33.2	-191.5	-60.7								
Nera 18mg		33	2137.8	142.2	33 (82.5%)	-52.5	35.0	-121.4	16.4	73.6	47.9	-20.7	167.9	0.1254			
Week 44																	
Placebo		35	2248.0	107.6	35 (81.4%)	-157.6	39.1	-234.6	-80.6								
Nera 18mg		30	2103.2	141.9	30 (75.0%)	-95.9	41.4	-177.5	-14.4	61.7	56.5	-49.6	172.9	0.2764			
Week 52																	
Placebo		36	2247.0	103.4	36 (83.7%)	-169.7	43.4	-255.2	-84.2								
Nera 18mg		32	2109.0	138.3	32 (80.0%)	-126.6	45.8	-216.7	-36.4	43.1	62.7	-80.2	166.5	0.4918			
Week 64																	
Placebo		32	2174.7	117.0	32 (74.4%)	-213.2	44.0	-299.9	-126.4								
Nera 18mg		27	2142.3	153.8	27 (67.5%)	-198.5	46.7	-290.5	-106.5	14.7	63.8	-111.0	140.4	0.8181			
Week 76																	
Placebo		24	1995.9	124.4	24 (55.8%)												

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		19	2112.5	186.9	19 (47.5%)												
Week 88																	
Placebo		13	1877.7	138.3	13 (30.2%)												
Nera 18mg		8	1962.3	274.0	8 (20.0%)												
Week 100																	
Placebo		4	1875.3	263.6	4 (9.3%)												
Nera 18mg		4	1430.8	83.2	4 (10.0%)												
Week 112																	
Placebo		1	1629.0	NC	1 (2.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	
Baseline																	
Placebo	30	30	2421.2	96.6	30 (100.0%)												
Nera 18mg	37	37	2536.2	126.8	37 (100.0%)												
Week 2																	
Placebo		29	2459.6	92.6	29 (96.7%)	0.4	30.2	-59.0	59.9								
Nera 18mg		37	2564.6	119.9	37 (100.0%)	29.7	26.8	-23.1	82.5	29.3	40.3	-50.0	108.6	0.4679			
Week 6																	
Placebo		29	2393.4	101.4	29 (96.7%)	-29.6	30.1	-88.8	29.6								
Nera 18mg		36	2577.1	124.4	36 (97.3%)	16.4	27.0	-36.7	69.6	46.0	40.3	-33.3	125.4	0.2543			
Week 12																	
Placebo		30	2399.6	98.8	30 (100.0%)	-25.7	35.4	-95.4	43.9								
Nera 18mg		37	2533.1	116.5	37 (100.0%)	-1.4	31.7	-63.8	61.1	24.3	47.4	-68.9	117.6	0.6076			
Week 18																	
Placebo		28	2363.5	106.5	28 (93.3%)	-64.1	36.1	-135.2	7.1								
Nera 18mg		35	2505.7	124.9	35 (94.6%)	-31.6	32.3	-95.2	32.0	32.4	48.3	-62.7	127.5	0.5025			
Week 26																	
Placebo		27	2382.7	105.7	27 (90.0%)	-86.1	38.8	-162.4	-9.7								
Nera 18mg		34	2486.3	121.0	34 (91.9%)	-24.3	34.6	-92.5	43.8	61.7	51.7	-40.1	163.6	0.2339			
Week 36																	
Placebo		27	2332.3	112.7	27 (90.0%)	-138.3	39.7	-216.4	-60.2								
Nera 18mg		34	2473.7	118.7	34 (91.9%)	-37.4	35.4	-107.0	32.3	100.9	52.9	-3.2	205.1	0.0575			
Week 44																	
Placebo		27	2341.5	114.1	27 (90.0%)	-133.3	46.3	-224.5	-42.1								
Nera 18mg		33	2442.2	119.0	33 (89.2%)	-62.3	41.5	-144.0	19.4	71.0	61.9	-50.9	192.9	0.2526			
Week 52																	

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo		26	2335.1	120.1	26 (86.7%)	-152.5	51.7	-254.2	-50.7								
Nera 18mg		33	2402.1	120.5	33 (89.2%)	-101.0	46.1	-191.8	-10.3	51.4	68.9	-84.3	187.1	0.4562			
Week 64																	
Placebo		21	2386.2	136.4	21 (70.0%)	-173.7	53.1	-278.4	-69.1								
Nera 18mg		27	2455.2	132.8	27 (73.0%)	-162.7	47.2	-255.8	-69.6	11.0	70.7	-128.3	150.3	0.8762			
Week 76																	
Placebo		16	2471.3	170.3	16 (53.3%)												
Nera 18mg		20	2482.6	153.8	20 (54.1%)												
Week 88																	
Placebo		9	2293.8	242.8	9 (30.0%)												
Nera 18mg		11	2351.3	196.8	11 (29.7%)												
Week 100																	
Placebo		3	2427.0	407.2	3 (10.0%)												
Nera 18mg		3	2418.7	521.2	3 (8.1%)												
Week 112																	
Placebo		2	2367.0	715.0	2 (6.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Rest of the World																	
Baseline																	
Placebo	16	16	2225.0	135.0	15 (100.0%)												
Nera 18mg	25	25	2260.0	143.4	25 (100.0%)												
Week 2																	
Placebo		15	2248.9	141.8	15 (100.0%)	-3.6	42.2	-86.5	79.4								
Nera 18mg		24	2295.4	152.3	24 (96.0%)	-6.4	33.1	-71.5	58.7	-2.8	53.5	-108.1	102.4	0.9578			
Week 6																	
Placebo		14	2276.9	129.1	14 (93.3%)	-39.5	43.2	-124.5	45.4								
Nera 18mg		25	2195.5	141.4	25 (100.0%)	-69.5	32.6	-133.7	-5.3	-29.9	54.0	-136.2	76.3	0.5796			
Week 12																	
Placebo		14	2269.1	130.5	14 (93.3%)	-51.8	51.1	-152.3	48.7								
Nera 18mg		23	2143.9	142.7	23 (92.0%)	-58.0	39.4	-135.6	19.5	-6.2	64.4	-132.9	120.4	0.9229			
Week 18																	
Placebo		14	2234.9	126.1	14 (93.3%)	-85.6	51.5	-187.1	15.9								
Nera 18mg		23	2223.7	148.2	23 (92.0%)	-72.3	39.6	-150.3	5.8	13.4	64.9	-114.4	141.1	0.8370			
Week 26																	
Placebo		13	2274.4	130.9	13 (86.7%)	-107.3	55.2	-216.1	1.4								
Nera 18mg		22	2227.3	159.2	22 (88.0%)	-52.9	42.5	-136.6	30.7	54.4	69.6	-82.5	191.3	0.4347			

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Table I.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 36																	
Placebo		14	2156.1	133.9	14 (93.3%)	-164.0	55.7	-273.8	-54.3								
Nera 18mg		21	2124.7	156.3	21 (84.0%)	-91.2	43.8	-177.4	-5.0	72.8	70.7	-66.4	212.1	0.3040			
Week 44																	
Placebo		14	2080.4	139.6	14 (93.3%)	-243.2	64.9	-370.9	-115.4								
Nera 18mg		21	2080.8	151.9	21 (84.0%)	-136.9	51.3	-237.9	-35.9	106.2	82.5	-56.3	268.7	0.1991			
Week 52																	
Placebo		14	1995.1	142.7	14 (93.3%)	-325.9	71.9	-467.6	-184.2								
Nera 18mg		19	1964.0	140.8	19 (76.0%)	-162.8	57.9	-276.9	-48.8	163.1	92.1	-18.3	344.5	0.0779			
Week 64																	
Placebo		11	2110.4	125.8	11 (73.3%)	-272.0	74.1	-418.0	-126.0								
Nera 18mg		16	1886.2	136.8	16 (64.0%)	-163.6	59.8	-281.3	-45.9	108.4	94.9	-78.5	295.4	0.2544			
Week 76																	
Placebo		8	2071.4	186.2	8 (53.3%)												
Nera 18mg		11	2008.5	235.2	11 (44.0%)												
Week 88																	
Placebo		1	2561.0	NC	1 (6.7%)												
Nera 18mg		3	1571.3	174.4	3 (12.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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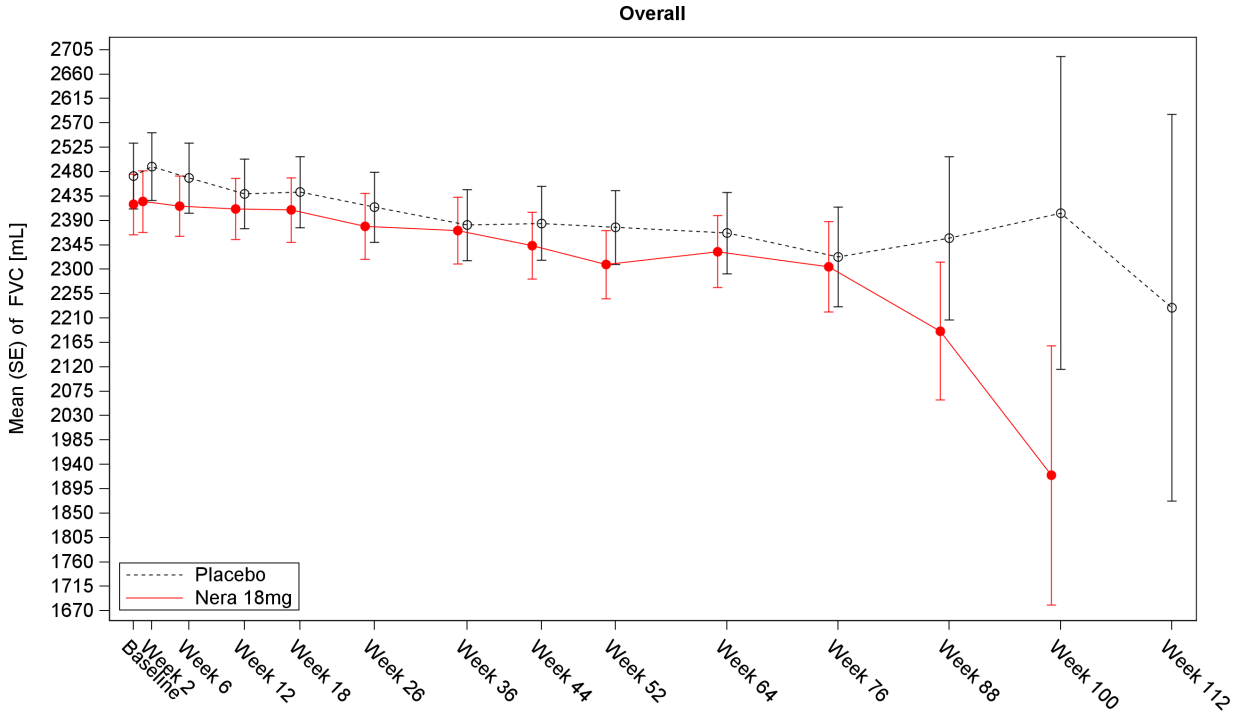

Number of patients

Placebo	169	159	158	158	152	153	146	142	145	127	84	38	10	4
Nera 18mg	170	164	165	156	150	146	142	137	137	119	80	30	9	0

Study: 1305-0023. Number of patients refers to the number of patients with observed data at visit.

Figure I.1.1.1.2.1: 11 Mean (SE) of FVC [mL]
over the whole trial - 18mg - FAS (NIN background)

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BI Trial No.: x1305p3.hta

Figure I.1.1.1.2.1: 11

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I.1.1.2 Safety analysis

I.1.1.2.1 Safety analysis over the whole trial

I.1.1.2.1.1 Adverse events overall over the whole trial

Table I.1.1.2.1.1: 1 Proportion of patients with any adverse events over the whole trial - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	163	96.4	170	162	95.3	0.5929	0.99 (0.95, 1.03)	0.75 (0.25, 2.20)	-1.16 (-5.87, 3.44)	
Age											0.7449
<65 years	65	60	92.3	64	59	92.2	0.9796	1.00 (0.90, 1.10)	0.98 (0.27, 3.57)	-0.12 (-10.31, 9.99)	
>=65 years	104	103	99.0	106	103	97.2	0.3219	0.98 (0.94, 1.02)	0.33 (0.03, 3.26)	-1.87 (-7.09, 2.80)	
Sex											0.5786
Male	114	110	96.5	108	104	96.3	0.9379	1.00 (0.95, 1.05)	0.95 (0.23, 3.88)	-0.19 (-6.03, 5.44)	
Female	55	53	96.4	62	58	93.5	0.4908	0.97 (0.89, 1.05)	0.55 (0.10, 3.11)	-2.82 (-12.19, 6.71)	
Baseline FVC percent predicted											0.5004
<=70%	95	90	94.7	97	92	94.8	0.9730	1.00 (0.94, 1.07)	1.02 (0.29, 3.65)	0.11 (-6.91, 7.21)	
>70%	74	73	98.6	73	70	95.9	0.3041	0.97 (0.92, 1.03)	0.32 (0.03, 3.15)	-2.76 (-10.13, 3.74)	
Baseline HRCT pattern											0.8408
UIP-like	116	113	97.4	121	116	95.9	0.5100	0.98 (0.94, 1.03)	0.62 (0.14, 2.64)	-1.55 (-7.00, 3.75)	
Other fibrotic patterns	53	50	94.3	49	46	93.9	0.9211	1.00 (0.90, 1.10)	0.92 (0.18, 4.79)	-0.46 (-11.50, 10.05)	
Underlying ILD diagnosis											0.3905
iNSIP	32	30	93.8	27	25	92.6	0.8602	0.99 (0.86, 1.14)	0.83 (0.11, 6.35)	-1.16 (-17.75, 13.73)	
Unclassifiable IIP	46	44	95.7	32	32	100.0	0.2321	1.05 (0.98, 1.11)	NC (NC, NC)	4.35 (-6.82, 14.53)	
HP	38	37	97.4	43	42	97.7	0.9294	1.00 (0.94, 1.08)	1.14 (0.07, 18.79)	0.31 (-9.67, 11.34)	
Autoimmune ILD	29	28	96.6	43	39	90.7	0.3379	0.94 (0.83, 1.06)	0.35 (0.04, 3.29)	-5.85 (-18.48, 8.98)	
Other ILD	24	24	100.0	25	24	96.0	0.3222	0.96 (0.89, 1.04)	0.00 (NC, NC)	-4.00 (-19.54, 10.18)	
Region											0.8962
Europe	78	76	97.4	67	64	95.5	0.5290	0.98 (0.92, 1.04)	0.56 (0.09, 3.46)	-1.91 (-10.01, 5.05)	
Asia	45	42	93.3	41	37	90.2	0.6008	0.97 (0.85, 1.10)	0.66 (0.14, 3.15)	-3.09 (-16.61, 9.56)	
Canada and USA	30	30	100.0	37	37	100.0	0.9182	1.00 (0.95, 1.06)	NC (NC, NC)	0.00 (NC, NC)	
Rest of the World	16	15	93.8	25	24	96.0	0.7442	1.02 (0.88, 1.19)	1.60 (0.09, 27.55)	2.25 (-14.12, 24.57)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.1.2.1.1: 2 Proportion of patients with any adverse events (excluding disease-related events) over the whole trial - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	163	96.4	170	161	94.7	0.4350	0.98 (0.94, 1.03)	0.66 (0.23, 1.89)	-1.74 (-6.60, 2.95)	
Age											0.9909
<65 years	65	60	92.3	64	58	90.6	0.7322	0.98 (0.88, 1.09)	0.81 (0.23, 2.79)	-1.68 (-12.23, 8.69)	
>=65 years	104	103	99.0	106	103	97.2	0.3219	0.98 (0.94, 1.02)	0.33 (0.03, 3.26)	-1.87 (-7.09, 2.80)	
Sex											0.7229
Male	114	110	96.5	108	103	95.4	0.6721	0.99 (0.94, 1.04)	0.75 (0.20, 2.87)	-1.12 (-7.26, 4.68)	
Female	55	53	96.4	62	58	93.5	0.4908	0.97 (0.89, 1.05)	0.55 (0.10, 3.11)	-2.82 (-12.19, 6.71)	
Baseline FVC percent predicted											0.3409
<=70%	95	90	94.7	97	92	94.8	0.9730	1.00 (0.94, 1.07)	1.02 (0.29, 3.65)	0.11 (-6.91, 7.21)	
>70%	74	73	98.6	73	69	94.5	0.1674	0.96 (0.90, 1.02)	0.24 (0.03, 2.17)	-4.13 (-11.99, 2.66)	
Baseline HRCT pattern											0.7238
UIP-like	116	113	97.4	121	115	95.0	0.3395	0.98 (0.93, 1.03)	0.51 (0.12, 2.08)	-2.37 (-8.07, 3.07)	
Other fibrotic patterns	53	50	94.3	49	46	93.9	0.9211	1.00 (0.90, 1.10)	0.92 (0.18, 4.79)	-0.46 (-11.50, 10.05)	
Underlying ILD diagnosis											0.2759
iNSIP	32	30	93.8	27	25	92.6	0.8602	0.99 (0.86, 1.14)	0.83 (0.11, 6.35)	-1.16 (-17.75, 13.73)	
Unclassifiable IIP	46	44	95.7	32	32	100.0	0.2321	1.05 (0.98, 1.11)	NC (NC, NC)	4.35 (-6.82, 14.53)	
HP	38	37	97.4	43	42	97.7	0.9294	1.00 (0.94, 1.08)	1.14 (0.07, 18.79)	0.31 (-9.67, 11.34)	
Autoimmune ILD	29	28	96.6	43	39	90.7	0.3379	0.94 (0.83, 1.06)	0.35 (0.04, 3.29)	-5.85 (-18.48, 8.98)	
Other ILD	24	24	100.0	25	23	92.0	0.1571	0.92 (0.82, 1.03)	0.00 (NC, NC)	-8.00 (-24.97, 6.96)	
Region											0.7967
Europe	78	76	97.4	67	63	94.0	0.3046	0.97 (0.90, 1.04)	0.41 (0.07, 2.34)	-3.41 (-12.01, 3.87)	
Asia	45	42	93.3	41	37	90.2	0.6008	0.97 (0.85, 1.10)	0.66 (0.14, 3.15)	-3.09 (-16.61, 9.56)	
Canada and USA	30	30	100.0	37	37	100.0	0.9182	1.00 (0.95, 1.06)	NC (NC, NC)	0.00 (NC, NC)	
Rest of the World	16	15	93.8	25	24	96.0	0.7442	1.02 (0.88, 1.19)	1.60 (0.09, 27.55)	2.25 (-14.12, 24.57)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.1.2.1.1: 3 Proportion of patients with serious adverse events over the whole trial - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	82	48.5	170	86	50.6	0.7034	1.04 (0.84, 1.29)	1.09 (0.71, 1.66)	2.07 (-8.49, 12.56)	
Age											0.2976
<65 years	65	29	44.6	64	25	39.1	0.5227	0.88 (0.58, 1.32)	0.80 (0.39, 1.60)	-5.55 (-21.87, 11.21)	
>=65 years	104	53	51.0	106	61	57.5	0.3381	1.13 (0.88, 1.45)	1.30 (0.76, 2.25)	6.59 (-6.79, 19.64)	
Sex											0.9787
Male	114	60	52.6	108	60	55.6	0.6622	1.06 (0.83, 1.35)	1.13 (0.66, 1.91)	2.92 (-10.04, 15.74)	
Female	55	22	40.0	62	26	41.9	0.8318	1.05 (0.68, 1.62)	1.08 (0.52, 2.27)	1.94 (-15.53, 19.11)	
Baseline FVC percent predicted											0.0285
<=70%	95	54	56.8	97	47	48.5	0.2445	0.85 (0.65, 1.12)	0.71 (0.40, 1.26)	-8.39 (-21.96, 5.65)	
>70%	74	28	37.8	73	39	53.4	0.0578	1.41 (0.98, 2.03)	1.88 (0.98, 3.64)	15.59 (-0.48, 30.57)	
Baseline HRCT pattern											0.4659
UIP-like	116	57	49.1	121	65	53.7	0.4806	1.09 (0.85, 1.40)	1.20 (0.72, 2.00)	4.58 (-8.03, 17.00)	
Other fibrotic patterns	53	25	47.2	49	21	42.9	0.6619	0.91 (0.59, 1.40)	0.84 (0.38, 1.84)	-4.31 (-22.70, 14.55)	
Underlying ILD diagnosis											0.1122
iNSIP	32	12	37.5	27	14	51.9	0.2686	1.38 (0.78, 2.46)	1.79 (0.63, 5.08)	14.35 (-10.48, 37.05)	
Unclassifiable IIP	46	31	67.4	32	15	46.9	0.0700	0.70 (0.46, 1.06)	0.43 (0.17, 1.08)	-20.52 (-40.37, 1.53)	
HP	38	13	34.2	43	24	55.8	0.0514	1.63 (0.97, 2.73)	2.43 (0.99, 5.98)	21.60 (-0.05, 40.53)	
Autoimmune ILD	29	14	48.3	43	20	46.5	0.8831	0.96 (0.59, 1.58)	0.93 (0.36, 2.39)	-1.76 (-24.01, 20.54)	
Other ILD	24	12	50.0	25	13	52.0	0.8887	1.04 (0.60, 1.80)	1.08 (0.35, 3.32)	2.00 (-24.22, 27.84)	
Region											0.9885
Europe	78	37	47.4	67	33	49.3	0.8271	1.04 (0.74, 1.45)	1.08 (0.56, 2.07)	1.82 (-14.13, 17.66)	
Asia	45	28	62.2	41	27	65.9	0.7261	1.06 (0.77, 1.45)	1.17 (0.48, 2.83)	3.63 (-16.24, 22.90)	
Canada and USA	30	10	33.3	37	13	35.1	0.8772	1.05 (0.54, 2.06)	1.08 (0.39, 2.99)	1.80 (-20.49, 23.21)	
Rest of the World	16	7	43.8	25	13	52.0	0.6062	1.19 (0.61, 2.33)	1.39 (0.39, 4.92)	8.25 (-21.32, 35.62)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.1.2.1.1: 4 Proportion of patients with serious adverse events (excluding disease-related events) over the whole trial - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	77	45.6	170	82	48.2	0.6219	1.06 (0.84, 1.33)	1.11 (0.73, 1.71)	2.67 (-7.87, 13.13)	
Age											0.1153
<65 years	65	29	44.6	64	23	35.9	0.3151	0.81 (0.53, 1.23)	0.70 (0.34, 1.41)	-8.68 (-24.76, 8.08)	
>=65 years	104	48	46.2	106	59	55.7	0.1683	1.21 (0.92, 1.58)	1.46 (0.85, 2.52)	9.51 (-3.95, 22.49)	
Sex											0.9239
Male	114	55	48.2	108	56	51.9	0.5912	1.07 (0.83, 1.40)	1.16 (0.68, 1.96)	3.61 (-9.41, 16.45)	
Female	55	22	40.0	62	26	41.9	0.8318	1.05 (0.68, 1.62)	1.08 (0.52, 2.27)	1.94 (-15.53, 19.11)	
Baseline FVC percent predicted											0.0962
<=70%	95	49	51.6	97	45	46.4	0.4722	0.90 (0.67, 1.20)	0.81 (0.46, 1.43)	-5.19 (-18.90, 8.80)	
>70%	74	28	37.8	73	37	50.7	0.1169	1.34 (0.93, 1.94)	1.69 (0.88, 3.26)	12.85 (-3.14, 27.95)	
Baseline HRCT pattern											0.5574
UIP-like	116	53	45.7	121	61	50.4	0.4669	1.10 (0.85, 1.44)	1.21 (0.73, 2.01)	4.72 (-7.89, 17.13)	
Other fibrotic patterns	53	24	45.3	49	21	42.9	0.8053	0.95 (0.61, 1.47)	0.91 (0.41, 1.98)	-2.43 (-20.88, 16.33)	
Underlying ILD diagnosis											0.1417
iNSIP	32	12	37.5	27	13	48.1	0.4096	1.28 (0.71, 2.33)	1.55 (0.55, 4.38)	10.65 (-13.85, 33.70)	
Unclassifiable IIP	46	28	60.9	32	13	40.6	0.0782	0.67 (0.41, 1.08)	0.44 (0.18, 1.10)	-20.24 (-40.00, 2.13)	
HP	38	13	34.2	43	24	55.8	0.0514	1.63 (0.97, 2.73)	2.43 (0.99, 5.98)	21.60 (-0.05, 40.53)	
Autoimmune ILD	29	14	48.3	43	20	46.5	0.8831	0.96 (0.59, 1.58)	0.93 (0.36, 2.39)	-1.76 (-24.01, 20.54)	
Other ILD	24	10	41.7	25	12	48.0	0.6559	1.15 (0.62, 2.15)	1.29 (0.42, 4.00)	6.33 (-20.18, 31.59)	
Region											0.9140
Europe	78	35	44.9	67	31	46.3	0.8663	1.03 (0.72, 1.47)	1.06 (0.55, 2.04)	1.40 (-14.47, 17.23)	
Asia	45	27	60.0	41	26	63.4	0.7450	1.06 (0.76, 1.47)	1.16 (0.48, 2.76)	3.41 (-16.64, 22.92)	
Canada and USA	30	9	30.0	37	12	32.4	0.8310	1.08 (0.53, 2.22)	1.12 (0.40, 3.17)	2.43 (-19.55, 23.34)	
Rest of the World	16	6	37.5	25	13	52.0	0.3638	1.39 (0.66, 2.90)	1.81 (0.50, 6.50)	14.50 (-15.69, 40.66)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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I.1.1.2.1.2 Adverse events by intensity over the whole trial

Table I.1.1.2.1.2: 1 Proportion of patients with any adverse events with CTCAE grade >=3 over the whole trial - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	71	42.0	170	81	47.6	0.2969	1.13 (0.89, 1.44)	1.26 (0.82, 1.93)	5.64 (-4.91, 16.00)	
Age											0.3078
<65 years	65	24	36.9	64	22	34.4	0.7626	0.93 (0.59, 1.48)	0.89 (0.44, 1.84)	-2.55 (-18.58, 13.69)	
>=65 years	104	47	45.2	106	59	55.7	0.1293	1.23 (0.94, 1.62)	1.52 (0.88, 2.62)	10.47 (-3.01, 23.42)	
Sex											0.3773
Male	114	49	43.0	108	57	52.8	0.1442	1.23 (0.93, 1.62)	1.48 (0.87, 2.52)	9.80 (-3.30, 22.43)	
Female	55	22	40.0	62	24	38.7	0.8866	0.97 (0.62, 1.52)	0.95 (0.45, 1.99)	-1.29 (-18.54, 15.91)	
Baseline FVC percent predicted											0.0385
<=70%	95	46	48.4	97	43	44.3	0.5698	0.92 (0.68, 1.24)	0.85 (0.48, 1.50)	-4.09 (-17.81, 9.84)	
>70%	74	25	33.8	73	38	52.1	0.0252	1.54 (1.05, 2.27)	2.13 (1.09, 4.14)	18.27 (2.28, 33.01)	
Baseline HRCT pattern											0.2448
UIP-like	116	49	42.2	121	63	52.1	0.1299	1.23 (0.94, 1.62)	1.49 (0.89, 2.48)	9.82 (-2.85, 22.06)	
Other fibrotic patterns	53	22	41.5	49	18	36.7	0.6217	0.88 (0.54, 1.44)	0.82 (0.37, 1.82)	-4.77 (-22.81, 13.83)	
Underlying ILD diagnosis											0.4756
iNSIP	32	13	40.6	27	12	44.4	0.7674	1.09 (0.60, 1.98)	1.17 (0.41, 3.30)	3.82 (-20.20, 27.50)	
Unclassifiable IIP	46	24	52.2	32	13	40.6	0.3150	0.78 (0.47, 1.29)	0.63 (0.25, 1.56)	-11.55 (-31.94, 10.59)	
HP	38	13	34.2	43	22	51.2	0.1243	1.50 (0.88, 2.54)	2.01 (0.82, 4.95)	16.95 (-4.50, 36.22)	
Autoimmune ILD	29	11	37.9	43	21	48.8	0.3610	1.29 (0.74, 2.25)	1.56 (0.60, 4.08)	10.91 (-12.09, 31.88)	
Other ILD	24	10	41.7	25	13	52.0	0.4687	1.25 (0.68, 2.29)	1.52 (0.49, 4.69)	10.33 (-16.55, 35.21)	
Region											0.9398
Europe	78	33	42.3	67	32	47.8	0.5103	1.13 (0.79, 1.62)	1.25 (0.65, 2.40)	5.45 (-10.52, 21.11)	
Asia	45	24	53.3	41	24	58.5	0.6275	1.10 (0.75, 1.60)	1.24 (0.53, 2.90)	5.20 (-15.26, 24.98)	
Canada and USA	30	6	20.0	37	11	29.7	0.3628	1.49 (0.62, 3.55)	1.69 (0.54, 5.29)	9.73 (-11.47, 28.91)	
Rest of the World	16	8	50.0	25	14	56.0	0.7070	1.12 (0.61, 2.04)	1.27 (0.36, 4.48)	6.00 (-23.03, 34.01)	

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.1.2.1.2: 2 Proportion of patients with any adverse events (excluding disease-related events) with CTCAE grade >=3 over the whole trial - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	67	39.6	170	77	45.3	0.2928	1.14 (0.89, 1.47)	1.26 (0.82, 1.94)	5.65 (-4.83, 15.96)	
Age											0.1345
<65 years	65	24	36.9	64	20	31.3	0.4968	0.85 (0.52, 1.37)	0.78 (0.37, 1.61)	-5.67 (-21.42, 10.51)	
>=65 years	104	43	41.3	106	57	53.8	0.0714	1.30 (0.97, 1.74)	1.65 (0.96, 2.85)	12.43 (-1.05, 25.29)	
Sex											0.3631
Male	114	45	39.5	108	53	49.1	0.1499	1.24 (0.92, 1.67)	1.48 (0.87, 2.52)	9.60 (-3.42, 22.19)	
Female	55	22	40.0	62	24	38.7	0.8866	0.97 (0.62, 1.52)	0.95 (0.45, 1.99)	-1.29 (-18.54, 15.91)	
Baseline FVC percent predicted											0.0635
<=70%	95	43	45.3	97	41	42.3	0.6757	0.93 (0.68, 1.29)	0.89 (0.50, 1.57)	-3.00 (-16.69, 10.85)	
>70%	74	24	32.4	73	36	49.3	0.0373	1.52 (1.02, 2.27)	2.03 (1.04, 3.96)	16.88 (1.01, 31.62)	
Baseline HRCT pattern											0.4737
UIP-like	116	47	40.5	121	59	48.8	0.2020	1.20 (0.90, 1.60)	1.40 (0.84, 2.34)	8.24 (-4.37, 20.48)	
Other fibrotic patterns	53	20	37.7	49	18	36.7	0.9168	0.97 (0.59, 1.61)	0.96 (0.43, 2.14)	-1.00 (-19.08, 17.31)	
Underlying ILD diagnosis											0.3333
iNSIP	32	13	40.6	27	11	40.7	0.9928	1.00 (0.54, 1.86)	1.00 (0.35, 2.85)	0.12 (-23.47, 24.02)	
Unclassifiable IIP	46	22	47.8	32	11	34.4	0.2369	0.72 (0.41, 1.27)	0.57 (0.23, 1.45)	-13.45 (-33.25, 8.63)	
HP	38	12	31.6	43	22	51.2	0.0747	1.62 (0.93, 2.81)	2.27 (0.92, 5.63)	19.58 (-1.86, 38.51)	
Autoimmune ILD	29	11	37.9	43	21	48.8	0.3610	1.29 (0.74, 2.25)	1.56 (0.60, 4.08)	10.91 (-12.09, 31.88)	
Other ILD	24	9	37.5	25	12	48.0	0.4578	1.28 (0.66, 2.47)	1.54 (0.49, 4.81)	10.50 (-16.23, 35.18)	
Region											0.9053
Europe	78	31	39.7	67	30	44.8	0.5405	1.13 (0.77, 1.65)	1.23 (0.63, 2.38)	5.03 (-10.80, 20.64)	
Asia	45	23	51.1	41	23	56.1	0.6433	1.10 (0.74, 1.63)	1.22 (0.52, 2.86)	4.99 (-15.53, 24.87)	
Canada and USA	30	5	16.7	37	10	27.0	0.3117	1.62 (0.62, 4.23)	1.85 (0.56, 6.17)	10.36 (-10.15, 28.84)	
Rest of the World	16	8	50.0	25	14	56.0	0.7070	1.12 (0.61, 2.04)	1.27 (0.36, 4.48)	6.00 (-23.03, 34.01)	

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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I.1.1.2.1.3 Adverse events leading to treatment discontinuation over the whole trial

Table I.1.1.2.1.3: 1 Proportion of patients with any adverse events leading to treatment discontinuation over the whole trial - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	22	13.0	170	26	15.3	0.5478	1.17 (0.69, 1.99)	1.21 (0.65, 2.23)	2.28 (-5.23, 9.78)	
Age											0.1807
<65 years	65	2	3.1	64	6	9.4	0.1381	3.05 (0.64, 14.54)	3.26 (0.63, 16.79)	6.30 (-2.69, 16.16)	
>=65 years	104	20	19.2	106	20	18.9	0.9466	0.98 (0.56, 1.71)	0.98 (0.49, 1.95)	-0.36 (-11.04, 10.28)	
Sex											0.0879
Male	114	19	16.7	108	16	14.8	0.7051	0.89 (0.48, 1.64)	0.87 (0.42, 1.79)	-1.85 (-11.47, 7.91)	
Female	55	3	5.5	62	10	16.1	0.0667	2.96 (0.86, 10.20)	3.33 (0.87, 12.81)	10.67 (-1.12, 22.32)	
Baseline FVC percent predicted											0.2533
<=70%	95	15	15.8	97	14	14.4	0.7930	0.91 (0.47, 1.79)	0.90 (0.41, 1.98)	-1.36 (-11.67, 8.91)	
>70%	74	7	9.5	73	12	16.4	0.2073	1.74 (0.72, 4.17)	1.88 (0.70, 5.09)	6.98 (-4.13, 18.19)	
Baseline HRCT pattern											0.8653
UIP-like	116	16	13.8	121	19	15.7	0.6788	1.14 (0.62, 2.10)	1.16 (0.57, 2.39)	1.91 (-7.29, 11.01)	
Other fibrotic patterns	53	6	11.3	49	7	14.3	0.6537	1.26 (0.46, 3.50)	1.31 (0.41, 4.19)	2.96 (-10.39, 16.74)	
Underlying ILD diagnosis											0.9795
iNSIP	32	5	15.6	27	5	18.5	0.7679	1.19 (0.38, 3.66)	1.23 (0.31, 4.79)	2.89 (-16.26, 23.07)	
Unclassifiable IIP	46	7	15.2	32	5	15.6	0.9609	1.03 (0.36, 2.95)	1.03 (0.30, 3.59)	0.41 (-15.27, 18.26)	
HP	38	3	7.9	43	5	11.6	0.5741	1.47 (0.38, 5.76)	1.54 (0.34, 6.90)	3.73 (-10.74, 17.59)	
Autoimmune ILD	29	4	13.8	43	6	14.0	0.9846	1.01 (0.31, 3.27)	1.01 (0.26, 3.96)	0.16 (-18.17, 15.84)	
Other ILD	24	3	12.5	25	5	20.0	0.4777	1.60 (0.43, 5.97)	1.75 (0.37, 8.30)	7.50 (-14.10, 28.30)	
Region											0.3801
Europe	78	10	12.8	67	12	17.9	0.3943	1.40 (0.64, 3.03)	1.48 (0.60, 3.69)	5.09 (-6.69, 17.34)	
Asia	45	6	13.3	41	10	24.4	0.1882	1.83 (0.73, 4.59)	2.10 (0.69, 6.40)	11.06 (-5.57, 27.60)	
Canada and USA	30	4	13.3	37	2	5.4	0.2584	0.41 (0.08, 2.06)	0.37 (0.06, 2.18)	-7.93 (-24.74, 6.76)	
Rest of the World	16	2	12.5	25	2	8.0	0.6357	0.64 (0.10, 4.10)	0.61 (0.08, 4.82)	-4.50 (-28.72, 14.71)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.1.2.1.3: 2 Proportion of patients with any adverse events leading to treatment discontinuation (excluding disease-related events) over the whole trial - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	16	9.5	170	22	12.9	0.3108	1.37 (0.74, 2.51)	1.42 (0.72, 2.81)	3.47 (-3.36, 10.34)	
Age											0.6004
<65 years	65	2	3.1	64	4	6.3	0.3922	2.03 (0.39, 10.70)	2.10 (0.37, 11.89)	3.17 (-5.20, 12.20)	
>=65 years	104	14	13.5	106	18	17.0	0.4780	1.26 (0.66, 2.40)	1.31 (0.62, 2.81)	3.52 (-6.36, 13.33)	
Sex											0.2107
Male	114	13	11.4	108	13	12.0	0.8834	1.06 (0.51, 2.17)	1.06 (0.47, 2.41)	0.63 (-8.00, 9.42)	
Female	55	3	5.5	62	9	14.5	0.1069	2.66 (0.76, 9.34)	2.94 (0.75, 11.49)	9.06 (-2.47, 20.47)	
Baseline FVC percent predicted											0.6463
<=70%	95	9	9.5	97	11	11.3	0.6721	1.20 (0.52, 2.76)	1.22 (0.48, 3.10)	1.87 (-7.14, 10.86)	
>70%	74	7	9.5	73	11	15.1	0.2996	1.59 (0.65, 3.88)	1.70 (0.62, 4.66)	5.61 (-5.30, 16.64)	
Baseline HRCT pattern											0.8255
UIP-like	116	11	9.5	121	15	12.4	0.4730	1.31 (0.63, 2.73)	1.35 (0.59, 3.08)	2.91 (-5.29, 11.07)	
Other fibrotic patterns	53	5	9.4	49	7	14.3	0.4473	1.51 (0.51, 4.46)	1.60 (0.47, 5.42)	4.85 (-8.14, 18.33)	
Underlying ILD diagnosis											
iNSIP	32	4	12.5	27	3	11.1					
Unclassifiable IIP	46	4	8.7	32	5	15.6					
HP	38	3	7.9	43	5	11.6					
Autoimmune ILD	29	3	10.3	43	5	11.6					
Other ILD	24	2	8.3	25	4	16.0					
Region											0.6163
Europe	78	8	10.3	67	10	14.9	0.3953	1.46 (0.61, 3.48)	1.54 (0.57, 4.14)	4.67 (-6.26, 16.21)	
Asia	45	4	8.9	41	8	19.5	0.1556	2.20 (0.71, 6.75)	2.48 (0.69, 8.98)	10.62 (-4.42, 26.09)	
Canada and USA	30	3	10.0	37	2	5.4	0.4767	0.54 (0.10, 3.03)	0.51 (0.08, 3.30)	-4.59 (-20.70, 9.34)	
Rest of the World	16	1	6.3	25	2	8.0	0.8337	1.28 (0.13, 12.99)	1.30 (0.11, 15.69)	1.75 (-21.07, 19.48)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.1.2.1.3: 3 Descriptive statistics of patients with any adverse events leading to treatment discontinuation over the whole trial by SOC and PT - 18mg - TS (NIN background)

Primary System Organ Class Preferred Term	Placebo N	 n	 %	Nera 18mg N	 n	 %
Overall	169	22	13.0	170	26	15.3
General disorders and administration site conditions		11	6.5		6	3.5
Condition aggravated		9	5.3		6	3.5
Disease progression		1	0.6		0	0.0
Fatigue		1	0.6		0	0.0
Gastrointestinal disorders		3	1.8		7	4.1
Diarrhoea		2	1.2		7	4.1
Nausea		0	0.0		2	1.2
Anal haemorrhage		0	0.0		1	0.6
Frequent bowel movements		1	0.6		0	0.0
Investigations		1	0.6		5	2.9
Weight decreased		1	0.6		2	1.2
Atypical mycobacterium test positive		0	0.0		1	0.6
False positive tuberculosis test		0	0.0		1	0.6
Red blood cell sedimentation rate increased		0	0.0		1	0.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		1	0.6		4	2.4
Keratoacanthoma		0	0.0		1	0.6
Localised melanoma		1	0.6		0	0.0
Small cell lung cancer		0	0.0		1	0.6
Small intestine carcinoma		0	0.0		1	0.6
Squamous cell carcinoma		0	0.0		1	0.6
Respiratory, thoracic and mediastinal disorders		4	2.4		1	0.6
Dyspnoea		2	1.2		0	0.0
Respiratory failure		2	1.2		0	0.0
Acute respiratory failure		0	0.0		1	0.6
Hypoxia		1	0.6		0	0.0
Interstitial lung disease		1	0.6		0	0.0
Pneumothorax		1	0.6		0	0.0
Infections and infestations		1	0.6		3	1.8
Bacteraemia		1	0.6		0	0.0
Bacterial infection		0	0.0		1	0.6
Lower respiratory tract infection		0	0.0		1	0.6
Pneumonia		0	0.0		1	0.6
Nervous system disorders		1	0.6		2	1.2

Study: 1305-0023. MedDRA version: 27.1
N is the number of patients, n the number of patients with at least one event.
Percentages are calculated using total number of patients per treatment as the denominator.

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Table I.1.1.2.1.3: 3 Descriptive statistics of patients with any adverse events leading to treatment discontinuation over the whole trial by SOC and PT - 18mg - TS (NIN background)

Primary System Organ Class Preferred Term	Placebo N	 n	 %	Nera 18mg N	 n	 %
Headache		0	0.0		2	1.2
Dizziness		1	0.6		0	0.0
Cardiac disorders		0	0.0		2	1.2
Palpitations		0	0.0		1	0.6
Ventricular extrasystoles		0	0.0		1	0.6
Injury, poisoning and procedural complications		1	0.6		0	0.0
Post procedural complication		1	0.6		0	0.0
Musculoskeletal and connective tissue disorders		1	0.6		0	0.0
Osteolysis		1	0.6		0	0.0
Reproductive system and breast disorders		1	0.6		0	0.0
Ejaculation failure		1	0.6		0	0.0
Erectile dysfunction		1	0.6		0	0.0
Skin and subcutaneous tissue disorders		1	0.6		0	0.0
Rash macular		1	0.6		0	0.0
Vascular disorders		0	0.0		1	0.6
Hypertension		0	0.0		1	0.6

Study: 1305-0023. MedDRA version: 27.1
N is the number of patients, n the number of patients with at least one event.
Percentages are calculated using total number of patients per treatment as the denominator.

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I.1.1.2.1.4 Adverse events on SOC level over the whole trial

Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Blood and lymphatic system disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	9	5.3	170	10	5.9	0.8236	1.10 (0.46, 2.65)	1.11 (0.44, 2.81)	0.56 (-4.66, 5.80)	
Age											
<65 years	65	2	3.1	64	0	0.0					
>=65 years	104	7	6.7	106	10	9.4					
Sex											
Male	114	4	3.5	108	4	3.7					
Female	55	5	9.1	62	6	9.7					
Baseline FVC percent predicted											
<=70%	95	5	5.3	97	4	4.1					
>70%	74	4	5.4	73	6	8.2					
Baseline HRCT pattern											
UIP-like	116	8	6.9	121	8	6.6					
Other fibrotic patterns	53	1	1.9	49	2	4.1					
Underlying ILD diagnosis											
iNSIP	32	0	0.0	27	0	0.0					
Unclassifiable IIP	46	2	4.3	32	2	6.3					
HP	38	1	2.6	43	1	2.3					
Autoimmune ILD	29	5	17.2	43	7	16.3					
Other ILD	24	1	4.2	25	0	0.0					
Region											
Europe	78	4	5.1	67	0	0.0					
Asia	45	3	6.7	41	5	12.2					
Canada and USA	30	1	3.3	37	2	5.4					
Rest of the World	16	1	6.3	25	3	12.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Cardiac disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	15	8.9	170	28	16.5	0.0356	1.86 (1.03, 3.35)	2.02 (1.04, 3.95)	7.59 (0.47, 14.77)	
Age											0.9397
<65 years	65	4	6.2	64	7	10.9	0.3307	1.78 (0.55, 5.78)	1.87 (0.52, 6.74)	4.78 (-5.47, 15.42)	
>=65 years	104	11	10.6	106	21	19.8	0.0626	1.87 (0.95, 3.69)	2.09 (0.95, 4.59)	9.23 (-0.58, 18.96)	
Sex											0.9081
Male	114	11	9.6	108	20	18.5	0.0567	1.92 (0.97, 3.82)	2.13 (0.97, 4.68)	8.87 (-0.34, 18.22)	
Female	55	4	7.3	62	8	12.9	0.3164	1.77 (0.57, 5.57)	1.89 (0.54, 6.66)	5.63 (-6.13, 17.06)	
Baseline FVC percent predicted											0.1224
<=70%	95	6	6.3	97	18	18.6	0.0103	2.94 (1.22, 7.08)	3.38 (1.28, 8.94)	12.24 (2.86, 21.75)	
>70%	74	9	12.2	73	10	13.7	0.7813	1.13 (0.49, 2.61)	1.15 (0.44, 3.01)	1.54 (-9.63, 12.76)	
Baseline HRCT pattern											0.2404
UIP-like	116	9	7.8	121	22	18.2	0.0174	2.34 (1.13, 4.88)	2.64 (1.16, 6.01)	10.42 (1.80, 19.04)	
Other fibrotic patterns	53	6	11.3	49	6	12.2	0.8849	1.08 (0.37, 3.13)	1.09 (0.33, 3.65)	0.92 (-12.08, 14.35)	
Underlying ILD diagnosis											0.2821
iNSIP	32	3	9.4	27	5	18.5	0.3068	1.98 (0.52, 7.52)	2.20 (0.47, 10.20)	9.14 (-8.94, 28.33)	
Unclassifiable IIP	46	5	10.9	32	2	6.3	0.4826	0.58 (0.12, 2.78)	0.55 (0.10, 3.01)	-4.62 (-17.60, 10.57)	
HP	38	2	5.3	43	5	11.6	0.3090	2.21 (0.45, 10.73)	2.37 (0.43, 12.99)	6.36 (-7.33, 19.77)	
Autoimmune ILD	29	1	3.4	43	12	27.9	0.0081	8.09 (1.11, 58.90)	>10 (1.32, 88.78)	24.46 (6.77, 39.51)	
Other ILD	24	4	16.7	25	4	16.0	0.9497	0.96 (0.27, 3.41)	0.95 (0.21, 4.33)	-0.67 (-22.12, 20.49)	
Region											0.4395
Europe	78	10	12.8	67	12	17.9	0.3943	1.40 (0.64, 3.03)	1.48 (0.60, 3.69)	5.09 (-6.69, 17.34)	
Asia	45	2	4.4	41	8	19.5	0.0295	4.39 (0.99, 19.49)	5.21 (1.04, 26.19)	15.07 (1.14, 29.92)	
Canada and USA	30	2	6.7	37	7	18.9	0.1436	2.84 (0.64, 12.67)	3.27 (0.63, 17.07)	12.25 (-5.18, 28.28)	
Rest of the World	16	1	6.3	25	1	4.0	0.7442	0.64 (0.04, 9.52)	0.63 (0.04, 10.76)	-2.25 (-24.57, 14.12)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Eye disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	2	1.2	170	12	7.1	0.0066	5.96 (1.36, 26.25)	6.34 (1.40, 28.78)	5.88 (1.63, 10.82)	
Age											0.6133
<65 years	65	0	0.0	64	4	6.3	0.0656	9.14 (0.50, >99)	NC (NC, NC)	6.25 (-0.50, 15.00)	
>=65 years	104	2	1.9	106	8	7.5	0.0557	3.92 (0.85, 18.05)	4.16 (0.86, 20.09)	5.62 (-0.44, 12.41)	
Sex											0.8728
Male	114	2	1.8	108	9	8.3	0.0240	4.75 (1.05, 21.49)	5.09 (1.07, 24.13)	6.58 (0.69, 13.45)	
Female	55	0	0.0	62	3	4.8	0.1589	6.22 (0.33, >99)	NC (NC, NC)	4.84 (-2.42, 13.29)	
Baseline FVC percent predicted											
<=70%	95	1	1.1	97	8	8.2					
>70%	74	1	1.4	73	4	5.5					
Baseline HRCT pattern											0.5269
UIP-like	116	1	0.9	121	9	7.4	0.0118	8.63 (1.11, 67.04)	9.24 (1.15, 74.14)	6.58 (1.38, 12.71)	
Other fibrotic patterns	53	1	1.9	49	3	6.1	0.2709	3.24 (0.35, 30.16)	3.39 (0.34, 33.75)	4.24 (-4.77, 14.75)	
Underlying ILD diagnosis											
iNSIP	32	0	0.0	27	2	7.4					
Unclassifiable IIP	46	1	2.2	32	2	6.3					
HP	38	1	2.6	43	3	7.0					
Autoimmune ILD	29	0	0.0	43	3	7.0					
Other ILD	24	0	0.0	25	2	8.0					
Region											
Europe	78	1	1.3	67	3	4.5					
Asia	45	0	0.0	41	3	7.3					
Canada and USA	30	1	3.3	37	4	10.8					
Rest of the World	16	0	0.0	25	2	8.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Gastrointestinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	103	60.9	170	108	63.5	0.6238	1.04 (0.88, 1.23)	1.12 (0.72, 1.73)	2.58 (-7.67, 12.76)	
Age											
<65 years	65	36	55.4	64	34	53.1					
>=65 years	104	67	64.4	106	74	69.8					
Sex											
Male	114	63	55.3	108	67	62.0					
Female	55	40	72.7	62	41	66.1					
Baseline FVC percent predicted											
<=70%	95	56	58.9	97	59	60.8					
>70%	74	47	63.5	73	49	67.1					
Baseline HRCT pattern											
UIP-like	116	72	62.1	121	76	62.8					
Other fibrotic patterns	53	31	58.5	49	32	65.3					
Underlying ILD diagnosis											
iNSIP	32	19	59.4	27	17	63.0					
Unclassifiable IIP	46	28	60.9	32	21	65.6					
HP	38	21	55.3	43	26	60.5					
Autoimmune ILD	29	19	65.5	43	27	62.8					
Other ILD	24	16	66.7	25	17	68.0					
Region											
Europe	78	50	64.1	67	42	62.7					
Asia	45	22	48.9	41	26	63.4					
Canada and USA	30	19	63.3	37	23	62.2					
Rest of the World	16	12	75.0	25	17	68.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: General disorders and administration site conditions

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	71	42.0	170	69	40.6	0.7901	0.97 (0.75, 1.25)	0.94 (0.61, 1.45)	-1.42 (-11.78, 8.97)	
Age											
<65 years	65	22	33.8	64	22	34.4					
>=65 years	104	49	47.1	106	47	44.3					
Sex											
Male	114	47	41.2	108	48	44.4					
Female	55	24	43.6	62	21	33.9					
Baseline FVC percent predicted											
<=70%	95	46	48.4	97	42	43.3					
>70%	74	25	33.8	73	27	37.0					
Baseline HRCT pattern											
UIP-like	116	48	41.4	121	49	40.5					
Other fibrotic patterns	53	23	43.4	49	20	40.8					
Underlying ILD diagnosis											
iNSIP	32	11	34.4	27	14	51.9					
Unclassifiable IIP	46	22	47.8	32	14	43.8					
HP	38	14	36.8	43	16	37.2					
Autoimmune ILD	29	10	34.5	43	15	34.9					
Other ILD	24	14	58.3	25	10	40.0					
Region											
Europe	78	40	51.3	67	26	38.8					
Asia	45	11	24.4	41	18	43.9					
Canada and USA	30	15	50.0	37	18	48.6					
Rest of the World	16	5	31.3	25	7	28.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Hepatobiliary disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	11	6.5	170	9	5.3	0.6351	0.81 (0.35, 1.91)	0.80 (0.32, 1.99)	-1.21 (-6.59, 4.07)	
Age											
<65 years	65	4	6.2	64	3	4.7					
>=65 years	104	7	6.7	106	6	5.7					
Sex											
Male	114	3	2.6	108	5	4.6					
Female	55	8	14.5	62	4	6.5					
Baseline FVC percent predicted											
<=70%	95	5	5.3	97	6	6.2					
>70%	74	6	8.1	73	3	4.1					
Baseline HRCT pattern											
UIP-like	116	9	7.8	121	6	5.0					
Other fibrotic patterns	53	2	3.8	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	2	7.4					
Unclassifiable IIP	46	4	8.7	32	2	6.3					
HP	38	0	0.0	43	2	4.7					
Autoimmune ILD	29	5	17.2	43	0	0.0					
Other ILD	24	1	4.2	25	3	12.0					
Region											
Europe	78	4	5.1	67	3	4.5					
Asia	45	6	13.3	41	3	7.3					
Canada and USA	30	1	3.3	37	2	5.4					
Rest of the World	16	0	0.0	25	1	4.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	124	73.4	170	121	71.2	0.6515	0.97 (0.85, 1.11)	0.90 (0.56, 1.44)	-2.20 (-11.64, 7.31)	
Age											
<65 years	65	51	78.5	64	46	71.9					
>=65 years	104	73	70.2	106	75	70.8					
Sex											
Male	114	79	69.3	108	71	65.7					
Female	55	45	81.8	62	50	80.6					
Baseline FVC percent predicted											
<=70%	95	70	73.7	97	73	75.3					
>70%	74	54	73.0	73	48	65.8					
Baseline HRCT pattern											
UIP-like	116	88	75.9	121	90	74.4					
Other fibrotic patterns	53	36	67.9	49	31	63.3					
Underlying ILD diagnosis											
iNSIP	32	23	71.9	27	16	59.3					
Unclassifiable IIP	46	33	71.7	32	25	78.1					
HP	38	26	68.4	43	30	69.8					
Autoimmune ILD	29	22	75.9	43	33	76.7					
Other ILD	24	20	83.3	25	17	68.0					
Region											
Europe	78	62	79.5	67	50	74.6					
Asia	45	32	71.1	41	29	70.7					
Canada and USA	30	21	70.0	37	28	75.7					
Rest of the World	16	9	56.3	25	14	56.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Injury, poisoning and procedural complications

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	27	16.0	170	21	12.4	0.3387	0.77 (0.46, 1.31)	0.74 (0.40, 1.37)	-3.62 (-11.13, 3.87)	
Age											
<65 years	65	11	16.9	64	3	4.7					
>=65 years	104	16	15.4	106	18	17.0					
Sex											
Male	114	13	11.4	108	15	13.9					
Female	55	14	25.5	62	6	9.7					
Baseline FVC percent predicted											
<=70%	95	15	15.8	97	11	11.3					
>70%	74	12	16.2	73	10	13.7					
Baseline HRCT pattern											
UIP-like	116	16	13.8	121	15	12.4					
Other fibrotic patterns	53	11	20.8	49	6	12.2					
Underlying ILD diagnosis											
iNSIP	32	4	12.5	27	1	3.7					
Unclassifiable IIP	46	7	15.2	32	6	18.8					
HP	38	8	21.1	43	3	7.0					
Autoimmune ILD	29	4	13.8	43	6	14.0					
Other ILD	24	4	16.7	25	5	20.0					
Region											
Europe	78	15	19.2	67	10	14.9					
Asia	45	5	11.1	41	3	7.3					
Canada and USA	30	6	20.0	37	4	10.8					
Rest of the World	16	1	6.3	25	4	16.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Investigations

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	43	25.4	170	52	30.6	0.2917	1.20 (0.85, 1.69)	1.29 (0.80, 2.08)	5.14 (-4.41, 14.57)	
Age											
<65 years	65	13	20.0	64	12	18.8					
>=65 years	104	30	28.8	106	40	37.7					
Sex											
Male	114	25	21.9	108	34	31.5					
Female	55	18	32.7	62	18	29.0					
Baseline FVC percent predicted											
<=70%	95	23	24.2	97	31	32.0					
>70%	74	20	27.0	73	21	28.8					
Baseline HRCT pattern											
UIP-like	116	31	26.7	121	37	30.6					
Other fibrotic patterns	53	12	22.6	49	15	30.6					
Underlying ILD diagnosis											
iNSIP	32	6	18.8	27	6	22.2					
Unclassifiable IIP	46	15	32.6	32	12	37.5					
HP	38	6	15.8	43	13	30.2					
Autoimmune ILD	29	9	31.0	43	14	32.6					
Other ILD	24	7	29.2	25	7	28.0					
Region											
Europe	78	19	24.4	67	22	32.8					
Asia	45	17	37.8	41	18	43.9					
Canada and USA	30	5	16.7	37	7	18.9					
Rest of the World	16	2	12.5	25	5	20.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Metabolism and nutrition disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	31	18.3	170	33	19.4	0.8015	1.06 (0.68, 1.65)	1.07 (0.62, 1.85)	1.07 (-7.29, 9.41)	
Age											
<65 years	65	10	15.4	64	8	12.5					
>=65 years	104	21	20.2	106	25	23.6					
Sex											
Male	114	18	15.8	108	20	18.5					
Female	55	13	23.6	62	13	21.0					
Baseline FVC percent predicted											
<=70%	95	19	20.0	97	15	15.5					
>70%	74	12	16.2	73	18	24.7					
Baseline HRCT pattern											
UIP-like	116	21	18.1	121	28	23.1					
Other fibrotic patterns	53	10	18.9	49	5	10.2					
Underlying ILD diagnosis											
iNSIP	32	5	15.6	27	5	18.5					
Unclassifiable IIP	46	9	19.6	32	8	25.0					
HP	38	7	18.4	43	5	11.6					
Autoimmune ILD	29	4	13.8	43	14	32.6					
Other ILD	24	6	25.0	25	1	4.0					
Region											
Europe	78	19	24.4	67	10	14.9					
Asia	45	6	13.3	41	13	31.7					
Canada and USA	30	1	3.3	37	6	16.2					
Rest of the World	16	5	31.3	25	4	16.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Musculoskeletal and connective tissue disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	44	26.0	170	43	25.3	0.8758	0.97 (0.68, 1.40)	0.96 (0.59, 1.57)	-0.74 (-10.00, 8.52)	
Age											
<65 years	65	17	26.2	64	16	25.0					
>=65 years	104	27	26.0	106	27	25.5					
Sex											
Male	114	26	22.8	108	24	22.2					
Female	55	18	32.7	62	19	30.6					
Baseline FVC percent predicted											
<=70%	95	22	23.2	97	28	28.9					
>70%	74	22	29.7	73	15	20.5					
Baseline HRCT pattern											
UIP-like	116	29	25.0	121	30	24.8					
Other fibrotic patterns	53	15	28.3	49	13	26.5					
Underlying ILD diagnosis											
iNSIP	32	3	9.4	27	5	18.5					
Unclassifiable IIP	46	10	21.7	32	13	40.6					
HP	38	15	39.5	43	7	16.3					
Autoimmune ILD	29	11	37.9	43	12	27.9					
Other ILD	24	5	20.8	25	6	24.0					
Region											
Europe	78	21	26.9	67	22	32.8					
Asia	45	17	37.8	41	7	17.1					
Canada and USA	30	5	16.7	37	10	27.0					
Rest of the World	16	1	6.3	25	4	16.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	5	3.0	170	12	7.1	0.0837	2.39 (0.86, 6.63)	2.49 (0.86, 7.23)	4.10 (-0.71, 9.26)	
Age											
<65 years	65	3	4.6	64	5	7.8					
>=65 years	104	2	1.9	106	7	6.6					
Sex											
Male	114	3	2.6	108	9	8.3					
Female	55	2	3.6	62	3	4.8					
Baseline FVC percent predicted											
<=70%	95	3	3.2	97	5	5.2					
>70%	74	2	2.7	73	7	9.6					
Baseline HRCT pattern											
UIP-like	116	5	4.3	121	8	6.6					
Other fibrotic patterns	53	0	0.0	49	4	8.2					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	1	3.7					
Unclassifiable IIP	46	1	2.2	32	2	6.3					
HP	38	1	2.6	43	5	11.6					
Autoimmune ILD	29	2	6.9	43	2	4.7					
Other ILD	24	0	0.0	25	2	8.0					
Region											
Europe	78	4	5.1	67	2	3.0					
Asia	45	1	2.2	41	4	9.8					
Canada and USA	30	0	0.0	37	4	10.8					
Rest of the World	16	0	0.0	25	2	8.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Nervous system disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	25	14.8	170	37	21.8	0.0969	1.47 (0.93, 2.33)	1.60 (0.92, 2.80)	6.97 (-1.29, 15.16)	
Age											
<65 years	65	8	12.3	64	12	18.8					
>=65 years	104	17	16.3	106	25	23.6					
Sex											
Male	114	15	13.2	108	23	21.3					
Female	55	10	18.2	62	14	22.6					
Baseline FVC percent predicted											
<=70%	95	16	16.8	97	21	21.6					
>70%	74	9	12.2	73	16	21.9					
Baseline HRCT pattern											
UIP-like	116	17	14.7	121	25	20.7					
Other fibrotic patterns	53	8	15.1	49	12	24.5					
Underlying ILD diagnosis											
iNSIP	32	7	21.9	27	4	14.8					
Unclassifiable IIP	46	9	19.6	32	6	18.8					
HP	38	5	13.2	43	9	20.9					
Autoimmune ILD	29	1	3.4	43	11	25.6					
Other ILD	24	3	12.5	25	7	28.0					
Region											
Europe	78	16	20.5	67	15	22.4					
Asia	45	2	4.4	41	5	12.2					
Canada and USA	30	4	13.3	37	10	27.0					
Rest of the World	16	3	18.8	25	7	28.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Psychiatric disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	42	24.9	170	45	26.5	0.7330	1.07 (0.74, 1.53)	1.09 (0.67, 1.77)	1.62 (-7.66, 10.85)	
Age											
<65 years	65	15	23.1	64	12	18.8					
>=65 years	104	27	26.0	106	33	31.1					
Sex											
Male	114	27	23.7	108	29	26.9					
Female	55	15	27.3	62	16	25.8					
Baseline FVC percent predicted											
<=70%	95	27	28.4	97	33	34.0					
>70%	74	15	20.3	73	12	16.4					
Baseline HRCT pattern											
UIP-like	116	28	24.1	121	35	28.9					
Other fibrotic patterns	53	14	26.4	49	10	20.4					
Underlying ILD diagnosis											
iNSIP	32	9	28.1	27	6	22.2					
Unclassifiable IIP	46	11	23.9	32	10	31.3					
HP	38	7	18.4	43	10	23.3					
Autoimmune ILD	29	6	20.7	43	9	20.9					
Other ILD	24	9	37.5	25	10	40.0					
Region											
Europe	78	21	26.9	67	19	28.4					
Asia	45	12	26.7	41	13	31.7					
Canada and USA	30	4	13.3	37	5	13.5					
Rest of the World	16	5	31.3	25	8	32.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Renal and urinary disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	13	7.7	170	15	8.8	0.7052	1.15 (0.56, 2.34)	1.16 (0.53, 2.52)	1.13 (-4.94, 7.23)	
Age											
<65 years	65	7	10.8	64	7	10.9					
>=65 years	104	6	5.8	106	8	7.5					
Sex											
Male	114	9	7.9	108	10	9.3					
Female	55	4	7.3	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	9	9.5	97	9	9.3					
>70%	74	4	5.4	73	6	8.2					
Baseline HRCT pattern											
UIP-like	116	12	10.3	121	11	9.1					
Other fibrotic patterns	53	1	1.9	49	4	8.2					
Underlying ILD diagnosis											
iNSIP	32	2	6.3	27	2	7.4					
Unclassifiable IIP	46	6	13.0	32	2	6.3					
HP	38	3	7.9	43	5	11.6					
Autoimmune ILD	29	1	3.4	43	2	4.7					
Other ILD	24	1	4.2	25	4	16.0					
Region											
Europe	78	7	9.0	67	7	10.4					
Asia	45	2	4.4	41	3	7.3					
Canada and USA	30	3	10.0	37	4	10.8					
Rest of the World	16	1	6.3	25	1	4.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo						
								Risk		Odds		Risk		Interaction
Category	N	n	%	N	n	%	p-value*	ratio (95% CI)		ratio (95% CI)		diff.	(95% CI)	p-value**
Overall	169	82	48.5	170	75	44.1	0.4163	0.91 (0.72,	1.14)	0.84 (0.55,	1.28)	-4.40	(-14.82, 6.15)	
Age														
<65 years	65	35	53.8	64	28	43.8								
>=65 years	104	47	45.2	106	47	44.3								
Sex														
Male	114	57	50.0	108	54	50.0								
Female	55	25	45.5	62	21	33.9								
Baseline FVC percent predicted														
<=70%	95	55	57.9	97	43	44.3								
>70%	74	27	36.5	73	32	43.8								
Baseline HRCT pattern														
UIP-like	116	53	45.7	121	60	49.6								
Other fibrotic patterns	53	29	54.7	49	15	30.6								
Underlying ILD diagnosis														
iNSIP	32	13	40.6	27	11	40.7								
Unclassifiable IIP	46	25	54.3	32	14	43.8								
HP	38	20	52.6	43	18	41.9								
Autoimmune ILD	29	13	44.8	43	16	37.2								
Other ILD	24	11	45.8	25	16	64.0								
Region														
Europe	78	40	51.3	67	26	38.8								
Asia	45	22	48.9	41	21	51.2								
Canada and USA	30	16	53.3	37	20	54.1								
Rest of the World	16	4	25.0	25	8	32.0								

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Skin and subcutaneous tissue disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	35	20.7	170	27	15.9	0.2503	0.77 (0.49, 1.21)	0.72 (0.42, 1.26)	-4.83 (-13.05, 3.44)	
Age											
<65 years	65	13	20.0	64	8	12.5					
>=65 years	104	22	21.2	106	19	17.9					
Sex											
Male	114	20	17.5	108	16	14.8					
Female	55	15	27.3	62	11	17.7					
Baseline FVC percent predicted											
<=70%	95	13	13.7	97	16	16.5					
>70%	74	22	29.7	73	11	15.1					
Baseline HRCT pattern											
UIP-like	116	25	21.6	121	20	16.5					
Other fibrotic patterns	53	10	18.9	49	7	14.3					
Underlying ILD diagnosis											
iNSIP	32	5	15.6	27	3	11.1					
Unclassifiable IIP	46	7	15.2	32	5	15.6					
HP	38	7	18.4	43	6	14.0					
Autoimmune ILD	29	9	31.0	43	8	18.6					
Other ILD	24	7	29.2	25	5	20.0					
Region											
Europe	78	22	28.2	67	11	16.4					
Asia	45	7	15.6	41	8	19.5					
Canada and USA	30	3	10.0	37	4	10.8					
Rest of the World	16	3	18.8	25	4	16.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Vascular disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	9	5.3	170	21	12.4	0.0227	2.32 (1.09, 4.92)	2.51 (1.11, 5.64)	7.03 (0.93, 13.34)	
Age											0.8932
<65 years	65	2	3.1	64	5	7.8	0.2352	2.54 (0.51, 12.61)	2.67 (0.50, 14.29)	4.74 (-3.95, 14.21)	
>=65 years	104	7	6.7	106	16	15.1	0.0523	2.24 (0.96, 5.23)	2.46 (0.97, 6.26)	8.36 (-0.22, 17.09)	
Sex											0.0552
Male	114	3	2.6	108	14	13.0	0.0038	4.93 (1.46, 16.67)	5.51 (1.54, 19.76)	10.33 (3.33, 18.15)	
Female	55	6	10.9	62	7	11.3	0.9478	1.03 (0.37, 2.89)	1.04 (0.33, 3.30)	0.38 (-11.94, 12.15)	
Baseline FVC percent predicted											0.5373
<=70%	95	4	4.2	97	12	12.4	0.0408	2.94 (0.98, 8.79)	3.21 (1.00, 10.34)	8.16 (0.16, 16.58)	
>70%	74	5	6.8	73	9	12.3	0.2499	1.82 (0.64, 5.18)	1.94 (0.62, 6.10)	5.57 (-4.34, 15.79)	
Baseline HRCT pattern											0.4472
UIP-like	116	7	6.0	121	14	11.6	0.1338	1.92 (0.80, 4.58)	2.04 (0.79, 5.25)	5.54 (-1.92, 13.11)	
Other fibrotic patterns	53	2	3.8	49	7	14.3	0.0615	3.79 (0.83, 17.36)	4.25 (0.84, 21.55)	10.51 (-0.99, 23.19)	
Underlying ILD diagnosis											0.5199
iNSIP	32	3	9.4	27	6	22.2	0.1715	2.37 (0.65, 8.59)	2.76 (0.62, 12.32)	12.85 (-6.00, 32.37)	
Unclassifiable IIP	46	0	0.0	32	3	9.4	0.0539	9.97 (0.53, >99)	NC (NC, NC)	9.38 (-0.48, 24.22)	
HP	38	0	0.0	43	2	4.7	0.2838	4.43 (0.22, 89.52)	NC (NC, NC)	4.65 (-5.13, 15.46)	
Autoimmune ILD	29	3	10.3	43	8	18.6	0.3393	1.80 (0.52, 6.22)	1.98 (0.48, 8.20)	8.26 (-10.07, 23.82)	
Other ILD	24	3	12.5	25	2	8.0	0.6029	0.64 (0.12, 3.50)	0.61 (0.09, 4.01)	-4.50 (-23.89, 14.32)	
Region											0.5720
Europe	78	6	7.7	67	10	14.9	0.1658	1.94 (0.74, 5.06)	2.11 (0.72, 6.14)	7.23 (-3.22, 18.43)	
Asia	45	1	2.2	41	7	17.1	0.0179	7.68 (0.99, 59.81)	9.06 (1.06, 77.19)	14.85 (2.19, 29.16)	
Canada and USA	30	2	6.7	37	4	10.8	0.5547	1.62 (0.32, 8.26)	1.70 (0.29, 9.97)	4.14 (-11.90, 18.85)	
Rest of the World	16	0	0.0	25	0	0.0	0.8285	0.65 (0.01, 31.41)	NC (NC, NC)	0.00 (NC, NC)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Cardiac disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	11	6.5	170	11	6.5	0.9886	0.99 (0.44, 2.23)	0.99 (0.42, 2.36)	-0.04 (-5.58, 5.49)	
Age											
<65 years	65	2	3.1	64	3	4.7					
>=65 years	104	9	8.7	106	8	7.5					
Sex											
Male	114	8	7.0	108	6	5.6					
Female	55	3	5.5	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	4	4.2	97	4	4.1					
>70%	74	7	9.5	73	7	9.6					
Baseline HRCT pattern											
UIP-like	116	7	6.0	121	9	7.4					
Other fibrotic patterns	53	4	7.5	49	2	4.1					
Underlying ILD diagnosis											
iNSIP	32	3	9.4	27	1	3.7					
Unclassifiable IIP	46	3	6.5	32	1	3.1					
HP	38	1	2.6	43	2	4.7					
Autoimmune ILD	29	1	3.4	43	5	11.6					
Other ILD	24	3	12.5	25	2	8.0					
Region											
Europe	78	7	9.0	67	3	4.5					
Asia	45	1	2.2	41	4	9.8					
Canada and USA	30	2	6.7	37	4	10.8					
Rest of the World	16	1	6.3	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: General disorders and administration site conditions

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	31	18.3	170	21	12.4	0.1259	0.67 (0.40, 1.12)	0.63 (0.34, 1.14)	-5.99 (-13.70, 1.73)	
Age											
<65 years	65	8	12.3	64	6	9.4					
>=65 years	104	23	22.1	106	15	14.2					
Sex											
Male	114	25	21.9	108	19	17.6					
Female	55	6	10.9	62	2	3.2					
Baseline FVC percent predicted											
<=70%	95	22	23.2	97	12	12.4					
>70%	74	9	12.2	73	9	12.3					
Baseline HRCT pattern											
UIP-like	116	19	16.4	121	18	14.9					
Other fibrotic patterns	53	12	22.6	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	2	6.3	27	6	22.2					
Unclassifiable IIP	46	13	28.3	32	6	18.8					
HP	38	4	10.5	43	5	11.6					
Autoimmune ILD	29	6	20.7	43	2	4.7					
Other ILD	24	6	25.0	25	2	8.0					
Region											
Europe	78	15	19.2	67	9	13.4					
Asia	45	10	22.2	41	6	14.6					
Canada and USA	30	2	6.7	37	3	8.1					
Rest of the World	16	4	25.0	25	3	12.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	26	15.4	170	32	18.8	0.4005	1.22 (0.76, 1.96)	1.28 (0.72, 2.25)	3.44 (-4.63, 11.47)	
Age											
<65 years	65	9	13.8	64	7	10.9					
>=65 years	104	17	16.3	106	25	23.6					
Sex											
Male	114	18	15.8	108	22	20.4					
Female	55	8	14.5	62	10	16.1					
Baseline FVC percent predicted											
<=70%	95	14	14.7	97	18	18.6					
>70%	74	12	16.2	73	14	19.2					
Baseline HRCT pattern											
UIP-like	116	20	17.2	121	27	22.3					
Other fibrotic patterns	53	6	11.3	49	5	10.2					
Underlying ILD diagnosis											
iNSIP	32	6	18.8	27	7	25.9					
Unclassifiable IIP	46	6	13.0	32	4	12.5					
HP	38	2	5.3	43	10	23.3					
Autoimmune ILD	29	7	24.1	43	6	14.0					
Other ILD	24	5	20.8	25	5	20.0					
Region											
Europe	78	11	14.1	67	14	20.9					
Asia	45	10	22.2	41	8	19.5					
Canada and USA	30	3	10.0	37	4	10.8					
Rest of the World	16	2	12.5	25	6	24.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff.	(95% CI)	Interaction p-value**
Overall	169	2	1.2	170	11	6.5	0.0113	5.47 (1.23, 24.30)	5.78 (1.26, 26.47)	5.29	(1.15, 10.11)	
Age												
<65 years	65	1	1.5	64	5	7.8						
>=65 years	104	1	1.0	106	6	5.7						
Sex												0.9692
Male	114	2	1.8	108	9	8.3	0.0240	4.75 (1.05, 21.49)	5.09 (1.07, 24.13)	6.58	(0.69, 13.45)	
Female	55	0	0.0	62	2	3.2	0.2854	4.44 (0.22, 90.61)	NC (NC, NC)	3.23	(-3.71, 11.02)	
Baseline FVC percent predicted												
<=70%	95	2	2.1	97	5	5.2						
>70%	74	0	0.0	73	6	8.2						
Baseline HRCT pattern												
UIP-like	116	2	1.7	121	7	5.8						
Other fibrotic patterns	53	0	0.0	49	4	8.2						
Underlying ILD diagnosis												
iNSIP	32	1	3.1	27	1	3.7						
Unclassifiable IIP	46	0	0.0	32	2	6.3						
HP	38	1	2.6	43	5	11.6						
Autoimmune ILD	29	0	0.0	43	1	2.3						
Other ILD	24	0	0.0	25	2	8.0						
Region												
Europe	78	2	2.6	67	2	3.0						
Asia	45	0	0.0	41	4	9.8						
Canada and USA	30	0	0.0	37	3	8.1						
Rest of the World	16	0	0.0	25	2	8.0						

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	35	20.7	170	28	16.5	0.3157	0.80 (0.51, 1.25)	0.75 (0.44, 1.31)	-4.24 (-12.52, 4.08)	
Age											
<65 years	65	12	18.5	64	9	14.1					
>=65 years	104	23	22.1	106	19	17.9					
Sex											
Male	114	27	23.7	108	20	18.5					
Female	55	8	14.5	62	8	12.9					
Baseline FVC percent predicted											
<=70%	95	24	25.3	97	16	16.5					
>70%	74	11	14.9	73	12	16.4					
Baseline HRCT pattern											
UIP-like	116	24	20.7	121	20	16.5					
Other fibrotic patterns	53	11	20.8	49	8	16.3					
Underlying ILD diagnosis											
iNSIP	32	5	15.6	27	6	22.2					
Unclassifiable IIP	46	15	32.6	32	5	15.6					
HP	38	6	15.8	43	5	11.6					
Autoimmune ILD	29	6	20.7	43	8	18.6					
Other ILD	24	3	12.5	25	4	16.0					
Region											
Europe	78	13	16.7	67	7	10.4					
Asia	45	14	31.1	41	12	29.3					
Canada and USA	30	6	20.0	37	5	13.5					
Rest of the World	16	2	12.5	25	4	16.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Cardiac disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	10	5.9	170	12	7.1	0.6696	1.19 (0.53, 2.69)	1.21 (0.51, 2.88)	1.14 (-4.36, 6.70)	
Age											
<65 years	65	1	1.5	64	3	4.7					
>=65 years	104	9	8.7	106	9	8.5					
Sex											
Male	114	7	6.1	108	7	6.5					
Female	55	3	5.5	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	4	4.2	97	5	5.2					
>70%	74	6	8.1	73	7	9.6					
Baseline HRCT pattern											
UIP-like	116	7	6.0	121	9	7.4					
Other fibrotic patterns	53	3	5.7	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	3	9.4	27	1	3.7					
Unclassifiable IIP	46	2	4.3	32	1	3.1					
HP	38	1	2.6	43	2	4.7					
Autoimmune ILD	29	1	3.4	43	6	14.0					
Other ILD	24	3	12.5	25	2	8.0					
Region											
Europe	78	8	10.3	67	5	7.5					
Asia	45	1	2.2	41	3	7.3					
Canada and USA	30	1	3.3	37	4	10.8					
Rest of the World	16	0	0.0	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: General disorders and administration site conditions

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo						
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)		Odds ratio (95% CI)		Risk diff.	(95% CI)	Interaction p-value**
Overall	169	30	17.8	170	21	12.4	0.1645	0.70 (0.42,	1.17)	0.65 (0.36,	1.19)	-5.40	(-13.06, 2.27)	
Age														
<65 years	65	7	10.8	64	6	9.4								
>=65 years	104	23	22.1	106	15	14.2								
Sex														
Male	114	25	21.9	108	18	16.7								
Female	55	5	9.1	62	3	4.8								
Baseline FVC percent predicted														
<=70%	95	21	22.1	97	13	13.4								
>70%	74	9	12.2	73	8	11.0								
Baseline HRCT pattern														
UIP-like	116	19	16.4	121	18	14.9								
Other fibrotic patterns	53	11	20.8	49	3	6.1								
Underlying ILD diagnosis														
iNSIP	32	2	6.3	27	6	22.2								
Unclassifiable IIP	46	13	28.3	32	6	18.8								
HP	38	4	10.5	43	4	9.3								
Autoimmune ILD	29	5	17.2	43	3	7.0								
Other ILD	24	6	25.0	25	2	8.0								
Region														
Europe	78	15	19.2	67	9	13.4								
Asia	45	9	20.0	41	7	17.1								
Canada and USA	30	2	6.7	37	2	5.4								
Rest of the World	16	4	25.0	25	3	12.0								

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	24	14.2	170	33	19.4	0.1996	1.37 (0.85, 2.21)	1.46 (0.82, 2.59)	5.21 (-2.80, 13.18)	
Age											
<65 years	65	9	13.8	64	7	10.9					
>=65 years	104	15	14.4	106	26	24.5					
Sex											
Male	114	16	14.0	108	23	21.3					
Female	55	8	14.5	62	10	16.1					
Baseline FVC percent predicted											
<=70%	95	13	13.7	97	19	19.6					
>70%	74	11	14.9	73	14	19.2					
Baseline HRCT pattern											
UIP-like	116	20	17.2	121	28	23.1					
Other fibrotic patterns	53	4	7.5	49	5	10.2					
Underlying ILD diagnosis											
iNSIP	32	5	15.6	27	7	25.9					
Unclassifiable IIP	46	5	10.9	32	4	12.5					
HP	38	2	5.3	43	11	25.6					
Autoimmune ILD	29	7	24.1	43	6	14.0					
Other ILD	24	5	20.8	25	5	20.0					
Region											
Europe	78	9	11.5	67	15	22.4					
Asia	45	10	22.2	41	8	19.5					
Canada and USA	30	2	6.7	37	4	10.8					
Rest of the World	16	3	18.8	25	6	24.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)		Odds ratio (95% CI)		Risk diff. (95% CI)		Interaction p-value**
Overall	169	25	14.8	170	18	10.6	0.2448	0.72 (0.41,	1.26)	0.68 (0.36,	1.30)	-4.20 (-11.41,	2.97)	
Age														
<65 years	65	8	12.3	64	5	7.8								
>=65 years	104	17	16.3	106	13	12.3								
Sex														
Male	114	18	15.8	108	14	13.0								
Female	55	7	12.7	62	4	6.5								
Baseline FVC percent predicted														
<=70%	95	17	17.9	97	11	11.3								
>70%	74	8	10.8	73	7	9.6								
Baseline HRCT pattern														
UIP-like	116	18	15.5	121	13	10.7								
Other fibrotic patterns	53	7	13.2	49	5	10.2								
Underlying ILD diagnosis														
iNSIP	32	5	15.6	27	3	11.1								
Unclassifiable IIP	46	9	19.6	32	2	6.3								
HP	38	5	13.2	43	6	14.0								
Autoimmune ILD	29	5	17.2	43	5	11.6								
Other ILD	24	1	4.2	25	2	8.0								
Region														
Europe	78	10	12.8	67	4	6.0								
Asia	45	9	20.0	41	7	17.1								
Canada and USA	30	5	16.7	37	4	10.8								
Rest of the World	16	1	6.3	25	3	12.0								

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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I.1.1.2.1.5 Adverse events on PT level over the whole trial

Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Gastrointestinal disorders
PT: Constipation

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	11	6.5	170	11	6.5	0.9886	0.99 (0.44, 2.23)	0.99 (0.42, 2.36)	-0.04 (-5.58, 5.49)	
Age											
<65 years	65	0	0.0	64	3	4.7					
>=65 years	104	11	10.6	106	8	7.5					
Sex											
Male	114	7	6.1	108	6	5.6					
Female	55	4	7.3	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	5	5.3	97	5	5.2					
>70%	74	6	8.1	73	6	8.2					
Baseline HRCT pattern											
UIP-like	116	10	8.6	121	10	8.3					
Other fibrotic patterns	53	1	1.9	49	1	2.0					
Underlying ILD diagnosis											
iNSIP	32	0	0.0	27	1	3.7					
Unclassifiable IIP	46	7	15.2	32	3	9.4					
HP	38	0	0.0	43	1	2.3					
Autoimmune ILD	29	3	10.3	43	4	9.3					
Other ILD	24	1	4.2	25	2	8.0					
Region											
Europe	78	6	7.7	67	4	6.0					
Asia	45	3	6.7	41	6	14.6					
Canada and USA	30	0	0.0	37	1	2.7					
Rest of the World	16	2	12.5	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo						
								Risk		Odds		Risk		Interaction
Category	N	n	%	N	n	%	p-value*	ratio (95% CI)		ratio (95% CI)		diff. (95% CI)		p-value**
Overall	169	64	37.9	170	86	50.6	0.0184	1.34 (1.05, 1.70)		1.68 (1.09, 2.59)		12.72 (2.15, 22.90)		
Age														0.3343
<65 years	65	22	33.8	64	24	37.5	0.6649	1.11 (0.70, 1.76)		1.17 (0.57, 2.41)		3.65 (-12.60, 19.67)		
>=65 years	104	42	40.4	106	62	58.5	0.0087	1.45 (1.09, 1.92)		2.08 (1.20, 3.61)		18.11 (4.58, 30.73)		
Sex														0.2961
Male	114	41	36.0	108	57	52.8	0.0117	1.47 (1.08, 1.99)		1.99 (1.16, 3.41)		16.81 (3.74, 29.12)		
Female	55	23	41.8	62	29	46.8	0.5903	1.12 (0.74, 1.68)		1.22 (0.59, 2.54)		4.96 (-12.75, 22.15)		
Baseline FVC percent predicted														0.4002
<=70%	95	40	42.1	97	50	51.5	0.1900	1.22 (0.90, 1.66)		1.46 (0.83, 2.59)		9.44 (-4.60, 22.97)		
>70%	74	24	32.4	73	36	49.3	0.0373	1.52 (1.02, 2.27)		2.03 (1.04, 3.96)		16.88 (1.01, 31.62)		
Baseline HRCT pattern														0.4555
UIP-like	116	45	38.8	121	59	48.8	0.1222	1.26 (0.94, 1.68)		1.50 (0.90, 2.52)		9.97 (-2.64, 22.12)		
Other fibrotic patterns	53	19	35.8	49	27	55.1	0.0509	1.54 (0.99, 2.39)		2.20 (0.99, 4.86)		19.25 (-0.01, 36.67)		
Underlying ILD diagnosis														0.8408
iNSIP	32	10	31.3	27	15	55.6	0.0598	1.78 (0.96, 3.29)		2.75 (0.95, 7.98)		24.31 (-0.85, 45.78)		
Unclassifiable IIP	46	19	41.3	32	16	50.0	0.4475	1.21 (0.74, 1.97)		1.42 (0.57, 3.52)		8.70 (-13.08, 29.61)		
HP	38	14	36.8	43	23	53.5	0.1334	1.45 (0.88, 2.40)		1.97 (0.81, 4.80)		16.65 (-4.90, 36.07)		
Autoimmune ILD	29	10	34.5	43	19	44.2	0.4103	1.28 (0.70, 2.34)		1.50 (0.57, 3.98)		9.70 (-13.09, 30.39)		
Other ILD	24	11	45.8	25	13	52.0	0.6660	1.13 (0.64, 2.02)		1.28 (0.42, 3.93)		6.17 (-20.42, 31.56)		
Region														0.8284
Europe	78	32	41.0	67	35	52.2	0.1769	1.27 (0.90, 1.81)		1.57 (0.81, 3.04)		11.21 (-4.94, 26.62)		
Asia	45	15	33.3	41	21	51.2	0.0931	1.54 (0.92, 2.56)		2.10 (0.88, 5.02)		17.89 (-2.85, 36.71)		
Canada and USA	30	13	43.3	37	19	51.4	0.5135	1.19 (0.71, 1.98)		1.38 (0.52, 3.63)		8.02 (-15.31, 30.06)		
Rest of the World	16	4	25.0	25	11	44.0	0.2179	1.76 (0.68, 4.58)		2.36 (0.59, 9.37)		19.00 (-11.01, 43.04)		

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk ratio p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	21	12.4	170	30	17.6	0.1788	1.42 (0.85, 2.38)	1.51 (0.83, 2.76)	5.22 (-2.45, 12.87)	
Age											
<65 years	65	11	16.9	64	8	12.5					
>=65 years	104	10	9.6	106	22	20.8					
Sex											
Male	114	10	8.8	108	18	16.7					
Female	55	11	20.0	62	12	19.4					
Baseline FVC percent predicted											
<=70%	95	9	9.5	97	14	14.4					
>70%	74	12	16.2	73	16	21.9					
Baseline HRCT pattern											
UIP-like	116	17	14.7	121	22	18.2					
Other fibrotic patterns	53	4	7.5	49	8	16.3					
Underlying ILD diagnosis											
iNSIP	32	6	18.8	27	3	11.1					
Unclassifiable IIP	46	2	4.3	32	5	15.6					
HP	38	3	7.9	43	8	18.6					
Autoimmune ILD	29	5	17.2	43	10	23.3					
Other ILD	24	5	20.8	25	4	16.0					
Region											
Europe	78	14	17.9	67	14	20.9					
Asia	45	3	6.7	41	3	7.3					
Canada and USA	30	1	3.3	37	9	24.3					
Rest of the World	16	3	18.8	25	4	16.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Gastrointestinal disorders
PT: Vomiting

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	21	12.4	170	18	10.6	0.5959	0.85 (0.47, 1.54)	0.83 (0.43, 1.63)	-1.84 (-8.78, 5.08)	
Age											
<65 years	65	8	12.3	64	5	7.8					
>=65 years	104	13	12.5	106	13	12.3					
Sex											
Male	114	9	7.9	108	8	7.4					
Female	55	12	21.8	62	10	16.1					
Baseline FVC percent predicted											
<=70%	95	14	14.7	97	9	9.3					
>70%	74	7	9.5	73	9	12.3					
Baseline HRCT pattern											
UIP-like	116	10	8.6	121	13	10.7					
Other fibrotic patterns	53	11	20.8	49	5	10.2					
Underlying ILD diagnosis											
iNSIP	32	5	15.6	27	2	7.4					
Unclassifiable IIP	46	4	8.7	32	6	18.8					
HP	38	5	13.2	43	5	11.6					
Autoimmune ILD	29	5	17.2	43	0	0.0					
Other ILD	24	2	8.3	25	5	20.0					
Region											
Europe	78	11	14.1	67	10	14.9					
Asia	45	1	2.2	41	4	9.8					
Canada and USA	30	5	16.7	37	3	8.1					
Rest of the World	16	4	25.0	25	1	4.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)		Odds ratio (95% CI)		Risk diff. (95% CI)	Interaction p-value**
Overall	169	31	18.3	170	24	14.1	0.2914	0.77 (0.47,	1.25)	0.73 (0.41,	1.31)	-4.23 (-12.11, 3.68)	
Age													
<65 years	65	8	12.3	64	7	10.9							
>=65 years	104	23	22.1	106	17	16.0							
Sex													
Male	114	25	21.9	108	18	16.7							
Female	55	6	10.9	62	6	9.7							
Baseline FVC percent predicted													
<=70%	95	23	24.2	97	15	15.5							
>70%	74	8	10.8	73	9	12.3							
Baseline HRCT pattern													
UIP-like	116	20	17.2	121	19	15.7							
Other fibrotic patterns	53	11	20.8	49	5	10.2							
Underlying ILD diagnosis													
iNSIP	32	2	6.3	27	7	25.9							
Unclassifiable IIP	46	11	23.9	32	4	12.5							
HP	38	6	15.8	43	4	9.3							
Autoimmune ILD	29	6	20.7	43	5	11.6							
Other ILD	24	6	25.0	25	4	16.0							
Region													
Europe	78	13	16.7	67	7	10.4							
Asia	45	10	22.2	41	8	19.5							
Canada and USA	30	5	16.7	37	6	16.2							
Rest of the World	16	3	18.8	25	3	12.0							

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: General disorders and administration site conditions
PT: Fatigue

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk ratio p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	16	9.5	170	15	8.8	0.8371	0.93 (0.48, 1.82)	0.93 (0.44, 1.94)	-0.64 (-6.99, 5.67)	
Age											
<65 years	65	6	9.2	64	3	4.7					
>=65 years	104	10	9.6	106	12	11.3					
Sex											
Male	114	10	8.8	108	10	9.3					
Female	55	6	10.9	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	11	11.6	97	10	10.3					
>70%	74	5	6.8	73	5	6.8					
Baseline HRCT pattern											
UIP-like	116	12	10.3	121	11	9.1					
Other fibrotic patterns	53	4	7.5	49	4	8.2					
Underlying ILD diagnosis											
iNSIP	32	3	9.4	27	4	14.8					
Unclassifiable IIP	46	7	15.2	32	2	6.3					
HP	38	2	5.3	43	3	7.0					
Autoimmune ILD	29	1	3.4	43	2	4.7					
Other ILD	24	3	12.5	25	4	16.0					
Region											
Europe	78	8	10.3	67	5	7.5					
Asia	45	0	0.0	41	2	4.9					
Canada and USA	30	7	23.3	37	7	18.9					
Rest of the World	16	1	6.3	25	1	4.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Bronchitis

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	14	8.3	170	11	6.5	0.5230	0.78 (0.37, 1.67)	0.77 (0.34, 1.74)	-1.81 (-7.68, 3.96)	
Age											
<65 years	65	4	6.2	64	3	4.7					
>=65 years	104	10	9.6	106	8	7.5					
Sex											
Male	114	9	7.9	108	7	6.5					
Female	55	5	9.1	62	4	6.5					
Baseline FVC percent predicted											
<=70%	95	10	10.5	97	8	8.2					
>70%	74	4	5.4	73	3	4.1					
Baseline HRCT pattern											
UIP-like	116	11	9.5	121	9	7.4					
Other fibrotic patterns	53	3	5.7	49	2	4.1					
Underlying ILD diagnosis											
iNSIP	32	2	6.3	27	1	3.7					
Unclassifiable IIP	46	2	4.3	32	2	6.3					
HP	38	3	7.9	43	2	4.7					
Autoimmune ILD	29	2	6.9	43	5	11.6					
Other ILD	24	5	20.8	25	1	4.0					
Region											
Europe	78	9	11.5	67	6	9.0					
Asia	45	4	8.9	41	4	9.8					
Canada and USA	30	1	3.3	37	1	2.7					
Rest of the World	16	0	0.0	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: COVID-19

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	33	19.5	170	24	14.1	0.1830	0.72 (0.45, 1.17)	0.68 (0.38, 1.20)	-5.41 (-13.39, 2.60)	
Age											
<65 years	65	12	18.5	64	11	17.2					
>=65 years	104	21	20.2	106	13	12.3					
Sex											
Male	114	22	19.3	108	14	13.0					
Female	55	11	20.0	62	10	16.1					
Baseline FVC percent predicted											
<=70%	95	18	18.9	97	13	13.4					
>70%	74	15	20.3	73	11	15.1					
Baseline HRCT pattern											
UIP-like	116	26	22.4	121	20	16.5					
Other fibrotic patterns	53	7	13.2	49	4	8.2					
Underlying ILD diagnosis											
iNSIP	32	7	21.9	27	5	18.5					
Unclassifiable IIP	46	11	23.9	32	5	15.6					
HP	38	7	18.4	43	5	11.6					
Autoimmune ILD	29	6	20.7	43	5	11.6					
Other ILD	24	2	8.3	25	4	16.0					
Region											
Europe	78	14	17.9	67	8	11.9					
Asia	45	8	17.8	41	10	24.4					
Canada and USA	30	9	30.0	37	5	13.5					
Rest of the World	16	2	12.5	25	1	4.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Influenza

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	16	9.5	170	14	8.2	0.6896	0.87 (0.44, 1.73)	0.86 (0.40, 1.82)	-1.23 (-7.51, 5.00)	
Age											
<65 years	65	8	12.3	64	8	12.5					
>=65 years	104	8	7.7	106	6	5.7					
Sex											
Male	114	12	10.5	108	7	6.5					
Female	55	4	7.3	62	7	11.3					
Baseline FVC percent predicted											
<=70%	95	9	9.5	97	9	9.3					
>70%	74	7	9.5	73	5	6.8					
Baseline HRCT pattern											
UIP-like	116	12	10.3	121	8	6.6					
Other fibrotic patterns	53	4	7.5	49	6	12.2					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	5	18.5					
Unclassifiable IIP	46	5	10.9	32	1	3.1					
HP	38	4	10.5	43	2	4.7					
Autoimmune ILD	29	3	10.3	43	4	9.3					
Other ILD	24	3	12.5	25	2	8.0					
Region											
Europe	78	10	12.8	67	8	11.9					
Asia	45	6	13.3	41	4	9.8					
Canada and USA	30	0	0.0	37	2	5.4					
Rest of the World	16	0	0.0	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Lower respiratory tract infection

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	6	3.6	170	10	5.9	0.3114	1.66 (0.62, 4.46)	1.70 (0.60, 4.78)	2.33 (-2.45, 7.32)	
Age											
<65 years	65	4	6.2	64	4	6.3					
>=65 years	104	2	1.9	106	6	5.7					
Sex											
Male	114	5	4.4	108	7	6.5					
Female	55	1	1.8	62	3	4.8					
Baseline FVC percent predicted											
<=70%	95	6	6.3	97	5	5.2					
>70%	74	0	0.0	73	5	6.8					
Baseline HRCT pattern											
UIP-like	116	4	3.4	121	7	5.8					
Other fibrotic patterns	53	2	3.8	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	0	0.0	27	1	3.7					
Unclassifiable IIP	46	2	4.3	32	2	6.3					
HP	38	0	0.0	43	2	4.7					
Autoimmune ILD	29	0	0.0	43	3	7.0					
Other ILD	24	4	16.7	25	2	8.0					
Region											
Europe	78	6	7.7	67	7	10.4					
Asia	45	0	0.0	41	0	0.0					
Canada and USA	30	0	0.0	37	0	0.0					
Rest of the World	16	0	0.0	25	3	12.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Nasopharyngitis

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	26	15.4	170	23	13.5	0.6272	0.88 (0.52, 1.48)	0.86 (0.47, 1.58)	-1.86 (-9.43, 5.71)	
Age											
<65 years	65	13	20.0	64	9	14.1					
>=65 years	104	13	12.5	106	14	13.2					
Sex											
Male	114	16	14.0	108	12	11.1					
Female	55	10	18.2	62	11	17.7					
Baseline FVC percent predicted											
<=70%	95	15	15.8	97	11	11.3					
>70%	74	11	14.9	73	12	16.4					
Baseline HRCT pattern											
UIP-like	116	17	14.7	121	20	16.5					
Other fibrotic patterns	53	9	17.0	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	5	15.6	27	3	11.1					
Unclassifiable IIP	46	6	13.0	32	5	15.6					
HP	38	6	15.8	43	5	11.6					
Autoimmune ILD	29	4	13.8	43	7	16.3					
Other ILD	24	5	20.8	25	3	12.0					
Region											
Europe	78	18	23.1	67	8	11.9					
Asia	45	5	11.1	41	8	19.5					
Canada and USA	30	1	3.3	37	5	13.5					
Rest of the World	16	2	12.5	25	2	8.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	14	8.3	170	21	12.4	0.2183	1.49 (0.78, 2.83)	1.56 (0.77, 3.18)	4.07 (-2.52, 10.73)	
Age											
<65 years	65	5	7.7	64	6	9.4					
>=65 years	104	9	8.7	106	15	14.2					
Sex											
Male	114	8	7.0	108	13	12.0					
Female	55	6	10.9	62	8	12.9					
Baseline FVC percent predicted											
<=70%	95	7	7.4	97	13	13.4					
>70%	74	7	9.5	73	8	11.0					
Baseline HRCT pattern											
UIP-like	116	10	8.6	121	13	10.7					
Other fibrotic patterns	53	4	7.5	49	8	16.3					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	2	7.4					
Unclassifiable IIP	46	3	6.5	32	4	12.5					
HP	38	3	7.9	43	7	16.3					
Autoimmune ILD	29	6	20.7	43	4	9.3					
Other ILD	24	1	4.2	25	4	16.0					
Region											
Europe	78	4	5.1	67	7	10.4					
Asia	45	8	17.8	41	6	14.6					
Canada and USA	30	1	3.3	37	5	13.5					
Rest of the World	16	1	6.3	25	3	12.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Respiratory tract infection

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	10	5.9	170	14	8.2	0.4054	1.39 (0.64, 3.05)	1.43 (0.62, 3.31)	2.32 (-3.35, 8.09)	
Age											
<65 years	65	6	9.2	64	7	10.9					
>=65 years	104	4	3.8	106	7	6.6					
Sex											
Male	114	4	3.5	108	8	7.4					
Female	55	6	10.9	62	6	9.7					
Baseline FVC percent predicted											
<=70%	95	5	5.3	97	7	7.2					
>70%	74	5	6.8	73	7	9.6					
Baseline HRCT pattern											
UIP-like	116	6	5.2	121	13	10.7					
Other fibrotic patterns	53	4	7.5	49	1	2.0					
Underlying ILD diagnosis											
iNSIP	32	2	6.3	27	1	3.7					
Unclassifiable IIP	46	0	0.0	32	2	6.3					
HP	38	4	10.5	43	3	7.0					
Autoimmune ILD	29	3	10.3	43	6	14.0					
Other ILD	24	1	4.2	25	2	8.0					
Region											
Europe	78	7	9.0	67	11	16.4					
Asia	45	1	2.2	41	0	0.0					
Canada and USA	30	2	6.7	37	1	2.7					
Rest of the World	16	0	0.0	25	2	8.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Upper respiratory tract infection

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	20	11.8	170	19	11.2	0.8495	0.94 (0.52, 1.70)	0.94 (0.48, 1.83)	-0.66 (-7.60, 6.26)	
Age											
<65 years	65	13	20.0	64	9	14.1					
>=65 years	104	7	6.7	106	10	9.4					
Sex											
Male	114	14	12.3	108	12	11.1					
Female	55	6	10.9	62	7	11.3					
Baseline FVC percent predicted											
<=70%	95	13	13.7	97	16	16.5					
>70%	74	7	9.5	73	3	4.1					
Baseline HRCT pattern											
UIP-like	116	12	10.3	121	13	10.7					
Other fibrotic patterns	53	8	15.1	49	6	12.2					
Underlying ILD diagnosis											
iNSIP	32	7	21.9	27	1	3.7					
Unclassifiable IIP	46	5	10.9	32	6	18.8					
HP	38	4	10.5	43	3	7.0					
Autoimmune ILD	29	3	10.3	43	6	14.0					
Other ILD	24	1	4.2	25	3	12.0					
Region											
Europe	78	6	7.7	67	5	7.5					
Asia	45	9	20.0	41	5	12.2					
Canada and USA	30	4	13.3	37	9	24.3					
Rest of the World	16	1	6.3	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Investigations
PT: Weight decreased

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	18	10.7	170	25	14.7	0.2620	1.38 (0.78, 2.43)	1.45 (0.76, 2.76)	4.05 (-3.12, 11.25)	
Age											
<65 years	65	7	10.8	64	4	6.3					
>=65 years	104	11	10.6	106	21	19.8					
Sex											
Male	114	12	10.5	108	16	14.8					
Female	55	6	10.9	62	9	14.5					
Baseline FVC percent predicted											
<=70%	95	12	12.6	97	16	16.5					
>70%	74	6	8.1	73	9	12.3					
Baseline HRCT pattern											
UIP-like	116	14	12.1	121	20	16.5					
Other fibrotic patterns	53	4	7.5	49	5	10.2					
Underlying ILD diagnosis											
iNSIP	32	3	9.4	27	1	3.7					
Unclassifiable IIP	46	8	17.4	32	4	12.5					
HP	38	2	5.3	43	6	14.0					
Autoimmune ILD	29	2	6.9	43	7	16.3					
Other ILD	24	3	12.5	25	7	28.0					
Region											
Europe	78	7	9.0	67	10	14.9					
Asia	45	9	20.0	41	12	29.3					
Canada and USA	30	1	3.3	37	1	2.7					
Rest of the World	16	1	6.3	25	2	8.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	16	9.5	170	22	12.9	0.3108	1.37 (0.74, 2.51)	1.42 (0.72, 2.81)	3.47 (-3.36, 10.34)	
Age											
<65 years	65	3	4.6	64	3	4.7					
>=65 years	104	13	12.5	106	19	17.9					
Sex											
Male	114	9	7.9	108	13	12.0					
Female	55	7	12.7	62	9	14.5					
Baseline FVC percent predicted											
<=70%	95	10	10.5	97	9	9.3					
>70%	74	6	8.1	73	13	17.8					
Baseline HRCT pattern											
UIP-like	116	9	7.8	121	20	16.5					
Other fibrotic patterns	53	7	13.2	49	2	4.1					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	2	7.4					
Unclassifiable IIP	46	5	10.9	32	6	18.8					
HP	38	3	7.9	43	4	9.3					
Autoimmune ILD	29	2	6.9	43	9	20.9					
Other ILD	24	5	20.8	25	1	4.0					
Region											
Europe	78	9	11.5	67	5	7.5					
Asia	45	3	6.7	41	9	22.0					
Canada and USA	30	0	0.0	37	4	10.8					
Rest of the World	16	4	25.0	25	4	16.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	7	4.1	170	15	8.8	0.0802	2.13 (0.89, 5.09)	2.24 (0.89, 5.64)	4.68 (-0.69, 10.32)	
Age											
<65 years	65	2	3.1	64	4	6.3					
>=65 years	104	5	4.8	106	11	10.4					
Sex											
Male	114	3	2.6	108	9	8.3					
Female	55	4	7.3	62	6	9.7					
Baseline FVC percent predicted											
<=70%	95	4	4.2	97	6	6.2					
>70%	74	3	4.1	73	9	12.3					
Baseline HRCT pattern											
UIP-like	116	4	3.4	121	11	9.1					
Other fibrotic patterns	53	3	5.7	49	4	8.2					
Underlying ILD diagnosis											
iNSIP	32	0	0.0	27	1	3.7					
Unclassifiable IIP	46	1	2.2	32	4	12.5					
HP	38	2	5.3	43	2	4.7					
Autoimmune ILD	29	2	6.9	43	6	14.0					
Other ILD	24	2	8.3	25	2	8.0					
Region											
Europe	78	4	5.1	67	8	11.9					
Asia	45	1	2.2	41	1	2.4					
Canada and USA	30	1	3.3	37	6	16.2					
Rest of the World	16	1	6.3	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Musculoskeletal and connective tissue disorders
PT: Back pain

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	5	3.0	170	10	5.9	0.1906	1.99 (0.69, 5.69)	2.05 (0.69, 6.13)	2.92 (-1.70, 7.83)	
Age											
<65 years	65	4	6.2	64	1	1.6					
>=65 years	104	1	1.0	106	9	8.5					
Sex											
Male	114	4	3.5	108	5	4.6					
Female	55	1	1.8	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	3	3.2	97	6	6.2					
>70%	74	2	2.7	73	4	5.5					
Baseline HRCT pattern											
UIP-like	116	4	3.4	121	9	7.4					
Other fibrotic patterns	53	1	1.9	49	1	2.0					
Underlying ILD diagnosis											
iNSIP	32	0	0.0	27	2	7.4					
Unclassifiable IIP	46	0	0.0	32	3	9.4					
HP	38	2	5.3	43	1	2.3					
Autoimmune ILD	29	0	0.0	43	2	4.7					
Other ILD	24	3	12.5	25	2	8.0					
Region											
Europe	78	3	3.8	67	6	9.0					
Asia	45	2	4.4	41	2	4.9					
Canada and USA	30	0	0.0	37	1	2.7					
Rest of the World	16	0	0.0	25	1	4.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Nervous system disorders
PT: Headache

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	9	5.3	170	14	8.2	0.2868	1.55 (0.69, 3.48)	1.60 (0.67, 3.79)	2.91 (-2.64, 8.60)	
Age											
<65 years	65	4	6.2	64	6	9.4					
>=65 years	104	5	4.8	106	8	7.5					
Sex											
Male	114	4	3.5	108	6	5.6					
Female	55	5	9.1	62	8	12.9					
Baseline FVC percent predicted											
<=70%	95	7	7.4	97	8	8.2					
>70%	74	2	2.7	73	6	8.2					
Baseline HRCT pattern											
UIP-like	116	5	4.3	121	8	6.6					
Other fibrotic patterns	53	4	7.5	49	6	12.2					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	2	7.4					
Unclassifiable IIP	46	2	4.3	32	4	12.5					
HP	38	3	7.9	43	3	7.0					
Autoimmune ILD	29	0	0.0	43	3	7.0					
Other ILD	24	3	12.5	25	2	8.0					
Region											
Europe	78	8	10.3	67	10	14.9					
Asia	45	0	0.0	41	0	0.0					
Canada and USA	30	1	3.3	37	4	10.8					
Rest of the World	16	0	0.0	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Psychiatric disorders
PT: Anxiety

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	19	11.2	170	23	13.5	0.5228	1.20 (0.68, 2.13)	1.24 (0.65, 2.36)	2.29 (-4.84, 9.42)	
Age											
<65 years	65	9	13.8	64	6	9.4					
>=65 years	104	10	9.6	106	17	16.0					
Sex											
Male	114	12	10.5	108	16	14.8					
Female	55	7	12.7	62	7	11.3					
Baseline FVC percent predicted											
<=70%	95	12	12.6	97	18	18.6					
>70%	74	7	9.5	73	5	6.8					
Baseline HRCT pattern											
UIP-like	116	14	12.1	121	16	13.2					
Other fibrotic patterns	53	5	9.4	49	7	14.3					
Underlying ILD diagnosis											
iNSIP	32	6	18.8	27	3	11.1					
Unclassifiable IIP	46	4	8.7	32	7	21.9					
HP	38	1	2.6	43	5	11.6					
Autoimmune ILD	29	3	10.3	43	4	9.3					
Other ILD	24	5	20.8	25	4	16.0					
Region											
Europe	78	9	11.5	67	8	11.9					
Asia	45	5	11.1	41	7	17.1					
Canada and USA	30	1	3.3	37	4	10.8					
Rest of the World	16	4	25.0	25	4	16.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Psychiatric disorders
PT: Depression

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	24	14.2	170	23	13.5	0.8580	0.95 (0.56, 1.62)	0.95 (0.51, 1.75)	-0.67 (-8.13, 6.77)	
Age											
<65 years	65	10	15.4	64	6	9.4					
>=65 years	104	14	13.5	106	17	16.0					
Sex											
Male	114	19	16.7	108	17	15.7					
Female	55	5	9.1	62	6	9.7					
Baseline FVC percent predicted											
<=70%	95	19	20.0	97	18	18.6					
>70%	74	5	6.8	73	5	6.8					
Baseline HRCT pattern											
UIP-like	116	17	14.7	121	18	14.9					
Other fibrotic patterns	53	7	13.2	49	5	10.2					
Underlying ILD diagnosis											
iNSIP	32	7	21.9	27	4	14.8					
Unclassifiable IIP	46	6	13.0	32	4	12.5					
HP	38	1	2.6	43	5	11.6					
Autoimmune ILD	29	3	10.3	43	5	11.6					
Other ILD	24	7	29.2	25	5	20.0					
Region											
Europe	78	14	17.9	67	9	13.4					
Asia	45	6	13.3	41	8	19.5					
Canada and USA	30	1	3.3	37	2	5.4					
Rest of the World	16	3	18.8	25	4	16.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk ratio p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	28	16.6	170	25	14.7	0.6369	0.89 (0.54, 1.46)	0.87 (0.48, 1.56)	-1.86 (-9.66, 5.93)	
Age											
<65 years	65	12	18.5	64	10	15.6					
>=65 years	104	16	15.4	106	15	14.2					
Sex											
Male	114	20	17.5	108	18	16.7					
Female	55	8	14.5	62	7	11.3					
Baseline FVC percent predicted											
<=70%	95	21	22.1	97	13	13.4					
>70%	74	7	9.5	73	12	16.4					
Baseline HRCT pattern											
UIP-like	116	19	16.4	121	20	16.5					
Other fibrotic patterns	53	9	17.0	49	5	10.2					
Underlying ILD diagnosis											
iNSIP	32	4	12.5	27	2	7.4					
Unclassifiable IIP	46	7	15.2	32	4	12.5					
HP	38	10	26.3	43	7	16.3					
Autoimmune ILD	29	2	6.9	43	4	9.3					
Other ILD	24	5	20.8	25	8	32.0					
Region											
Europe	78	21	26.9	67	9	13.4					
Asia	45	3	6.7	41	2	4.9					
Canada and USA	30	2	6.7	37	11	29.7					
Rest of the World	16	2	12.5	25	3	12.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	28	16.6	170	20	11.8	0.2047	0.71 (0.42, 1.21)	0.67 (0.36, 1.25)	-4.80 (-12.31, 2.69)	
Age											
<65 years	65	7	10.8	64	7	10.9					
>=65 years	104	21	20.2	106	13	12.3					
Sex											
Male	114	17	14.9	108	16	14.8					
Female	55	11	20.0	62	4	6.5					
Baseline FVC percent predicted											
<=70%	95	19	20.0	97	14	14.4					
>70%	74	9	12.2	73	6	8.2					
Baseline HRCT pattern											
UIP-like	116	16	13.8	121	17	14.0					
Other fibrotic patterns	53	12	22.6	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	3	9.4	27	3	11.1					
Unclassifiable IIP	46	8	17.4	32	4	12.5					
HP	38	10	26.3	43	7	16.3					
Autoimmune ILD	29	3	10.3	43	3	7.0					
Other ILD	24	4	16.7	25	3	12.0					
Region											
Europe	78	15	19.2	67	9	13.4					
Asia	45	2	4.4	41	0	0.0					
Canada and USA	30	9	30.0	37	6	16.2					
Rest of the World	16	2	12.5	25	5	20.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Vascular disorders
PT: Hypertension

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk ratio p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	4	2.4	170	11	6.5	0.0662	2.73 (0.89, 8.42)	2.85 (0.89, 9.15)	4.10 (-0.44, 9.06)	
Age											
<65 years	65	0	0.0	64	3	4.7					
>=65 years	104	4	3.8	106	8	7.5					
Sex											
Male	114	1	0.9	108	5	4.6					
Female	55	3	5.5	62	6	9.7					
Baseline FVC percent predicted											
<=70%	95	2	2.1	97	5	5.2					
>70%	74	2	2.7	73	6	8.2					
Baseline HRCT pattern											
UIP-like	116	3	2.6	121	8	6.6					
Other fibrotic patterns	53	1	1.9	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	2	7.4					
Unclassifiable IIP	46	0	0.0	32	3	9.4					
HP	38	0	0.0	43	0	0.0					
Autoimmune ILD	29	1	3.4	43	5	11.6					
Other ILD	24	2	8.3	25	1	4.0					
Region											
Europe	78	3	3.8	67	5	7.5					
Asia	45	0	0.0	41	5	12.2					
Canada and USA	30	1	3.3	37	1	2.7					
Rest of the World	16	0	0.0	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 2 Proportion of patients with frequent serious AEs by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup / Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk ratio p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	26	15.4	170	14	8.2	0.0413	0.54 (0.29, 0.99)	0.49 (0.25, 0.98)	-7.15 (-14.16, -0.23)	
Age											0.6539
<65 years	65	6	9.2	64	4	6.3	0.5267	0.68 (0.20, 2.29)	0.66 (0.18, 2.44)	-2.98 (-13.19, 7.06)	
>=65 years	104	20	19.2	106	10	9.4	0.0425	0.49 (0.24, 1.00)	0.44 (0.19, 0.99)	-9.80 (-19.39, -0.25)	
Sex											0.3784
Male	114	20	17.5	108	12	11.1	0.1726	0.63 (0.33, 1.23)	0.59 (0.27, 1.27)	-6.43 (-15.69, 2.96)	
Female	55	6	10.9	62	2	3.2	0.1003	0.30 (0.06, 1.41)	0.27 (0.05, 1.41)	-7.68 (-18.85, 2.04)	
Baseline FVC percent predicted											0.5109
<=70%	95	19	20.0	97	9	9.3	0.0353	0.46 (0.22, 0.97)	0.41 (0.17, 0.96)	-10.72 (-20.83, -0.65)	
>70%	74	7	9.5	73	5	6.8	0.5633	0.72 (0.24, 2.18)	0.70 (0.21, 2.33)	-2.61 (-12.23, 6.89)	
Baseline HRCT pattern											0.0695
UIP-like	116	16	13.8	121	13	10.7	0.4739	0.78 (0.39, 1.55)	0.75 (0.34, 1.64)	-3.05 (-11.67, 5.44)	
Other fibrotic patterns	53	10	18.9	49	1	2.0	0.0062	0.11 (0.01, 0.81)	0.09 (0.01, 0.73)	-16.83 (-29.43, -4.85)	
Underlying ILD diagnosis											0.1667
iNSIP	32	1	3.1	27	4	14.8	0.1082	4.74 (0.56, 39.92)	5.39 (0.56, 51.50)	11.69 (-3.75, 29.54)	
Unclassifiable IIP	46	10	21.7	32	4	12.5	0.2956	0.58 (0.20, 1.67)	0.51 (0.15, 1.81)	-9.24 (-24.99, 8.99)	
HP	38	4	10.5	43	3	7.0	0.5705	0.66 (0.16, 2.77)	0.64 (0.13, 3.05)	-3.55 (-17.90, 9.71)	
Autoimmune ILD	29	6	20.7	43	1	2.3	0.0099	0.11 (0.01, 0.89)	0.09 (0.01, 0.81)	-18.36 (-36.17, -3.79)	
Other ILD	24	5	20.8	25	2	8.0	0.1994	0.38 (0.08, 1.79)	0.33 (0.06, 1.90)	-12.83 (-33.30, 7.71)	
Region											0.5298
Europe	78	12	15.4	67	4	6.0	0.0712	0.39 (0.13, 1.15)	0.35 (0.11, 1.14)	-9.41 (-19.68, 1.12)	
Asia	45	10	22.2	41	5	12.2	0.2210	0.55 (0.20, 1.47)	0.49 (0.15, 1.57)	-10.03 (-25.66, 6.46)	
Canada and USA	30	1	3.3	37	3	8.1	0.4121	2.43 (0.27, 22.20)	2.56 (0.25, 25.95)	4.77 (-9.58, 18.25)	
Rest of the World	16	3	18.8	25	2	8.0	0.3048	0.43 (0.08, 2.28)	0.38 (0.06, 2.56)	-10.75 (-35.69, 10.12)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 2 Proportion of patients with frequent serious AEs by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	9	5.3	170	12	7.1	0.5080	1.33 (0.57, 3.06)	1.35 (0.55, 3.29)	1.73 (-3.65, 7.21)	
Age											
<65 years	65	4	6.2	64	3	4.7					
>=65 years	104	5	4.8	106	9	8.5					
Sex											
Male	114	5	4.4	108	8	7.4					
Female	55	4	7.3	62	4	6.5					
Baseline FVC percent predicted											
<=70%	95	5	5.3	97	8	8.2					
>70%	74	4	5.4	73	4	5.5					
Baseline HRCT pattern											
UIP-like	116	7	6.0	121	8	6.6					
Other fibrotic patterns	53	2	3.8	49	4	8.2					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	2	7.4					
Unclassifiable IIP	46	1	2.2	32	2	6.3					
HP	38	1	2.6	43	4	9.3					
Autoimmune ILD	29	5	17.2	43	3	7.0					
Other ILD	24	1	4.2	25	1	4.0					
Region											
Europe	78	3	3.8	67	4	6.0					
Asia	45	6	13.3	41	4	9.8					
Canada and USA	30	0	0.0	37	1	2.7					
Rest of the World	16	0	0.0	25	3	12.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 2 Proportion of patients with frequent serious AEs by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pneumothorax

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	9	5.3	170	3	1.8	0.0761	0.33 (0.09, 1.20)	0.32 (0.08, 1.20)	-3.56 (-8.19, 0.57)	
Age											
<65 years	65	3	4.6	64	2	3.1					
>=65 years	104	6	5.8	106	1	0.9					
Sex											
Male	114	8	7.0	108	3	2.8					
Female	55	1	1.8	62	0	0.0					
Baseline FVC percent predicted											
<=70%	95	6	6.3	97	3	3.1					
>70%	74	3	4.1	73	0	0.0					
Baseline HRCT pattern											
UIP-like	116	6	5.2	121	3	2.5					
Other fibrotic patterns	53	3	5.7	49	0	0.0					
Underlying ILD diagnosis											
iNSIP	32	4	12.5	27	0	0.0					
Unclassifiable IIP	46	2	4.3	32	1	3.1					
HP	38	0	0.0	43	0	0.0					
Autoimmune ILD	29	2	6.9	43	1	2.3					
Other ILD	24	1	4.2	25	1	4.0					
Region											
Europe	78	4	5.1	67	1	1.5					
Asia	45	4	8.9	41	2	4.9					
Canada and USA	30	1	3.3	37	0	0.0					
Rest of the World	16	0	0.0	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 2 Proportion of patients with frequent serious AEs by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pulmonary hypertension

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	Risk p-value*	ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	9	5.3	170	9	5.3	0.9897	0.99 (0.40, 2.44)	0.99 (0.38, 2.57)	-0.03 (-5.16, 5.08)	
Age											
<65 years	65	2	3.1	64	3	4.7					
>=65 years	104	7	6.7	106	6	5.7					
Sex											
Male	114	6	5.3	108	5	4.6					
Female	55	3	5.5	62	4	6.5					
Baseline FVC percent predicted											
<=70%	95	7	7.4	97	5	5.2					
>70%	74	2	2.7	73	4	5.5					
Baseline HRCT pattern											
UIP-like	116	6	5.2	121	6	5.0					
Other fibrotic patterns	53	3	5.7	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	1	3.7					
Unclassifiable IIP	46	4	8.7	32	3	9.4					
HP	38	2	5.3	43	1	2.3					
Autoimmune ILD	29	2	6.9	43	4	9.3					
Other ILD	24	0	0.0	25	0	0.0					
Region											
Europe	78	4	5.1	67	2	3.0					
Asia	45	3	6.7	41	5	12.2					
Canada and USA	30	1	3.3	37	0	0.0					
Rest of the World	16	1	6.3	25	2	8.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)		Odds ratio (95% CI)		Risk diff. (95% CI)	Interaction p-value**
Overall	169	25	14.8	170	14	8.2	0.0585	0.56 (0.30,	1.03)	0.52 (0.26,	1.03)	-6.56 (-13.51, 0.30)	
Age													
<65 years	65	5	7.7	64	4	6.3							
>=65 years	104	20	19.2	106	10	9.4							
Sex													
Male	114	20	17.5	108	11	10.2							
Female	55	5	9.1	62	3	4.8							
Baseline FVC percent predicted													
<=70%	95	18	18.9	97	10	10.3							
>70%	74	7	9.5	73	4	5.5							
Baseline HRCT pattern													
UIP-like	116	16	13.8	121	13	10.7							
Other fibrotic patterns	53	9	17.0	49	1	2.0							
Underlying ILD diagnosis													
iNSIP	32	1	3.1	27	4	14.8							
Unclassifiable IIP	46	10	21.7	32	4	12.5							
HP	38	4	10.5	43	2	4.7							
Autoimmune ILD	29	5	17.2	43	2	4.7							
Other ILD	24	5	20.8	25	2	8.0							
Region													
Europe	78	12	15.4	67	4	6.0							
Asia	45	9	20.0	41	6	14.6							
Canada and USA	30	1	3.3	37	2	5.4							
Rest of the World	16	3	18.8	25	2	8.0							

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.1.2.1.5: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	10	5.9	170	12	7.1	0.6696	1.19 (0.53, 2.69)	1.21 (0.51, 2.88)	1.14 (-4.36, 6.70)	
Age											
<65 years	65	4	6.2	64	3	4.7					
>=65 years	104	6	5.8	106	9	8.5					
Sex											
Male	114	6	5.3	108	8	7.4					
Female	55	4	7.3	62	4	6.5					
Baseline FVC percent predicted											
<=70%	95	5	5.3	97	8	8.2					
>70%	74	5	6.8	73	4	5.5					
Baseline HRCT pattern											
UIP-like	116	8	6.9	121	8	6.6					
Other fibrotic patterns	53	2	3.8	49	4	8.2					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	2	7.4					
Unclassifiable IIP	46	1	2.2	32	2	6.3					
HP	38	2	5.3	43	4	9.3					
Autoimmune ILD	29	5	17.2	43	3	7.0					
Other ILD	24	1	4.2	25	1	4.0					
Region											
Europe	78	3	3.8	67	4	6.0					
Asia	45	6	13.3	41	4	9.8					
Canada and USA	30	0	0.0	37	1	2.7					
Rest of the World	16	1	6.3	25	3	12.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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I.1.1.2.1.6 C-SSRS

Table I.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (NIN background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Number of patients (N, %)		169	100.0	170	100.0
Baseline	No Ideation	168	99.4	170	100.0
	Type 1-3	1	0.6	0	0.0
	Wish to be Dead	1	0.6	0	0.0
	Non-Specific Suicidal Thought	0	0.0	0	0.0
	Suicidal Ideation-No Intent	0	0.0	0	0.0
	Type 4-5	0	0.0	0	0.0
	Ideation with Intent, No Plan	0	0.0	0	0.0
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	169	100.0	169	99.4
	Type 6-9	0	0.0	0	0.0
	Preparatory Acts/Behavior	0	0.0	0	0.0
	Aborted Attempt	0	0.0	0	0.0
	Interrupted Attempt	0	0.0	0	0.0
	Actual Attempt	0	0.0	0	0.0
	Type 10	0	0.0	0	0.0
	Suicide	0	0.0	0	0.0
Week 2	No Ideation	166	98.2	166	97.6
	Type 1-3	0	0.0	0	0.0
	Wish to be Dead	0	0.0	0	0.0
	Non-Specific Suicidal Thought	0	0.0	0	0.0
	Suicidal Ideation-No Intent	0	0.0	0	0.0
	Type 4-5	0	0.0	0	0.0
	Ideation with Intent, No Plan	0	0.0	0	0.0
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	166	98.2	166	97.6
	Type 6-9	0	0.0	0	0.0
	Preparatory Acts/Behavior	0	0.0	0	0.0
	Aborted Attempt	0	0.0	0	0.0
	Interrupted Attempt	0	0.0	0	0.0
	Actual Attempt	0	0.0	0	0.0
	Type 10	0	0.0	0	0.0
	Suicide	0	0.0	0	0.0

Study: 1305-0023
A subject may appear in more than one category.

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Table I.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (NIN background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Week 6	No Ideation	163	96.4	165	97.1
	Type 1-3	1	0.6	0	0.0
	Wish to be Dead	1	0.6	0	0.0
	Non-Specific Suicidal Thought	1	0.6	0	0.0
	Suicidal Ideation-No Intent	1	0.6	0	0.0
	Type 4-5	0	0.0	0	0.0
	Ideation with Intent, No Plan	0	0.0	0	0.0
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	164	97.0	165	97.1
	Type 6-9	0	0.0	0	0.0
	Preparatory Acts/Behavior	0	0.0	0	0.0
	Aborted Attempt	0	0.0	0	0.0
	Interrupted Attempt	0	0.0	0	0.0
	Actual Attempt	0	0.0	0	0.0
	Type 10	0	0.0	0	0.0
	Suicide	0	0.0	0	0.0
Week 12	No Ideation	161	95.3	161	94.7
	Type 1-3	0	0.0	0	0.0
	Wish to be Dead	0	0.0	0	0.0
	Non-Specific Suicidal Thought	0	0.0	0	0.0
	Suicidal Ideation-No Intent	0	0.0	0	0.0
	Type 4-5	0	0.0	0	0.0
	Ideation with Intent, No Plan	0	0.0	0	0.0
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	161	95.3	161	94.7
	Type 6-9	0	0.0	0	0.0
	Preparatory Acts/Behavior	0	0.0	0	0.0
	Aborted Attempt	0	0.0	0	0.0
	Interrupted Attempt	0	0.0	0	0.0
	Actual Attempt	0	0.0	0	0.0
	Type 10	0	0.0	0	0.0
	Suicide	0	0.0	0	0.0

Study: 1305-0023
A subject may appear in more than one category.

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Table I.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (NIN background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Week 18	No Ideation	159	94.1	157	92.4
	Type 1-3	0	0.0	1	0.6
	Wish to be Dead	0	0.0	1	0.6
	Non-Specific Suicidal Thought	0	0.0	0	0.0
	Suicidal Ideation-No Intent	0	0.0	0	0.0
	Type 4-5	0	0.0	0	0.0
	Ideation with Intent, No Plan	0	0.0	0	0.0
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	159	94.1	158	92.9
	Type 6-9	0	0.0	0	0.0
	Preparatory Acts/Behavior	0	0.0	0	0.0
	Aborted Attempt	0	0.0	0	0.0
	Interrupted Attempt	0	0.0	0	0.0
	Actual Attempt	0	0.0	0	0.0
	Type 10	0	0.0	0	0.0
	Suicide	0	0.0	0	0.0
Week 26	No Ideation	156	92.3	155	91.2
	Type 1-3	1	0.6	0	0.0
	Wish to be Dead	0	0.0	0	0.0
	Non-Specific Suicidal Thought	1	0.6	0	0.0
	Suicidal Ideation-No Intent	0	0.0	0	0.0
	Type 4-5	0	0.0	0	0.0
	Ideation with Intent, No Plan	0	0.0	0	0.0
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	157	92.9	155	91.2
	Type 6-9	0	0.0	0	0.0
	Preparatory Acts/Behavior	0	0.0	0	0.0
	Aborted Attempt	0	0.0	0	0.0
	Interrupted Attempt	0	0.0	0	0.0
	Actual Attempt	0	0.0	0	0.0
	Type 10	0	0.0	0	0.0
	Suicide	0	0.0	0	0.0

Study: 1305-0023
A subject may appear in more than one category.

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Table I.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (NIN background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Week 36	No Ideation	150	88.8	147	86.5
	Type 1-3	1	0.6	0	0.0
	Wish to be Dead	0	0.0	0	0.0
	Non-Specific Suicidal Thought	1	0.6	0	0.0
	Suicidal Ideation-No Intent	0	0.0	0	0.0
	Type 4-5	0	0.0	0	0.0
	Ideation with Intent, No Plan	0	0.0	0	0.0
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	151	89.3	147	86.5
	Type 6-9	0	0.0	0	0.0
	Preparatory Acts/Behavior	0	0.0	0	0.0
	Aborted Attempt	0	0.0	0	0.0
	Interrupted Attempt	0	0.0	0	0.0
	Actual Attempt	0	0.0	0	0.0
	Type 10	0	0.0	0	0.0
	Suicide	0	0.0	0	0.0
Week 44	No Ideation	146	86.4	140	82.4
	Type 1-3	1	0.6	0	0.0
	Wish to be Dead	1	0.6	0	0.0
	Non-Specific Suicidal Thought	0	0.0	0	0.0
	Suicidal Ideation-No Intent	0	0.0	0	0.0
	Type 4-5	0	0.0	0	0.0
	Ideation with Intent, No Plan	0	0.0	0	0.0
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	147	87.0	140	82.4
	Type 6-9	0	0.0	0	0.0
	Preparatory Acts/Behavior	0	0.0	0	0.0
	Aborted Attempt	0	0.0	0	0.0
	Interrupted Attempt	0	0.0	0	0.0
	Actual Attempt	0	0.0	0	0.0
	Type 10	0	0.0	0	0.0
	Suicide	0	0.0	0	0.0

Study: 1305-0023
A subject may appear in more than one category.

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Table I.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (NIN background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Week 52	No Ideation	148	87.6	139	81.8
	Type 1-3	1	0.6	0	0.0
	Wish to be Dead	1	0.6	0	0.0
	Non-Specific Suicidal Thought	0	0.0	0	0.0
	Suicidal Ideation-No Intent	0	0.0	0	0.0
	Type 4-5	0	0.0	0	0.0
	Ideation with Intent, No Plan	0	0.0	0	0.0
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	149	88.2	139	81.8
	Type 6-9	0	0.0	0	0.0
	Preparatory Acts/Behavior	0	0.0	0	0.0
	Aborted Attempt	0	0.0	0	0.0
	Interrupted Attempt	0	0.0	0	0.0
	Actual Attempt	0	0.0	0	0.0
	Type 10	0	0.0	0	0.0
	Suicide	0	0.0	0	0.0
Week 64	No Ideation	129	76.3	123	72.4
	Type 1-3	1	0.6	0	0.0
	Wish to be Dead	1	0.6	0	0.0
	Non-Specific Suicidal Thought	0	0.0	0	0.0
	Suicidal Ideation-No Intent	0	0.0	0	0.0
	Type 4-5	0	0.0	0	0.0
	Ideation with Intent, No Plan	0	0.0	0	0.0
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	130	76.9	123	72.4
	Type 6-9	0	0.0	0	0.0
	Preparatory Acts/Behavior	0	0.0	0	0.0
	Aborted Attempt	0	0.0	0	0.0
	Interrupted Attempt	0	0.0	0	0.0
	Actual Attempt	0	0.0	0	0.0
	Type 10	0	0.0	0	0.0
	Suicide	0	0.0	0	0.0

Study: 1305-0023
A subject may appear in more than one category.

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Table I.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (NIN background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Week 76	No Ideation	89	52.7	85	50.0
	Type 1-3	0	0.0	0	0.0
	Wish to be Dead	0	0.0	0	0.0
	Non-Specific Suicidal Thought	0	0.0	0	0.0
	Suicidal Ideation-No Intent	0	0.0	0	0.0
	Type 4-5	0	0.0	0	0.0
	Ideation with Intent, No Plan	0	0.0	0	0.0
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	89	52.7	85	50.0
	Type 6-9	0	0.0	0	0.0
	Preparatory Acts/Behavior	0	0.0	0	0.0
	Aborted Attempt	0	0.0	0	0.0
	Interrupted Attempt	0	0.0	0	0.0
	Actual Attempt	0	0.0	0	0.0
	Type 10	0	0.0	0	0.0
	Suicide	0	0.0	0	0.0
Week 88	No Ideation	38	22.5	33	19.4
	Type 1-3	0	0.0	0	0.0
	Wish to be Dead	0	0.0	0	0.0
	Non-Specific Suicidal Thought	0	0.0	0	0.0
	Suicidal Ideation-No Intent	0	0.0	0	0.0
	Type 4-5	0	0.0	0	0.0
	Ideation with Intent, No Plan	0	0.0	0	0.0
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	38	22.5	33	19.4
	Type 6-9	0	0.0	0	0.0
	Preparatory Acts/Behavior	0	0.0	0	0.0
	Aborted Attempt	0	0.0	0	0.0
	Interrupted Attempt	0	0.0	0	0.0
	Actual Attempt	0	0.0	0	0.0
	Type 10	0	0.0	0	0.0
	Suicide	0	0.0	0	0.0

Study: 1305-0023
A subject may appear in more than one category.

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Table I.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (NIN background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Week 100	No Ideation	11	6.5	9	5.3
	Type 1-3	0	0.0	0	0.0
	Wish to be Dead	0	0.0	0	0.0
	Non-Specific Suicidal Thought	0	0.0	0	0.0
	Suicidal Ideation-No Intent	0	0.0	0	0.0
	Type 4-5	0	0.0	0	0.0
	Ideation with Intent, No Plan	0	0.0	0	0.0
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	11	6.5	9	5.3
	Type 6-9	0	0.0	0	0.0
	Preparatory Acts/Behavior	0	0.0	0	0.0
	Aborted Attempt	0	0.0	0	0.0
	Interrupted Attempt	0	0.0	0	0.0
	Actual Attempt	0	0.0	0	0.0
	Type 10	0	0.0	0	0.0
	Suicide	0	0.0	0	0.0
Week 112	No Ideation	4	2.4	0	0.0
	Type 1-3	0	0.0	0	0.0
	Wish to be Dead	0	0.0	0	0.0
	Non-Specific Suicidal Thought	0	0.0	0	0.0
	Suicidal Ideation-No Intent	0	0.0	0	0.0
	Type 4-5	0	0.0	0	0.0
	Ideation with Intent, No Plan	0	0.0	0	0.0
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	4	2.4	0	0.0
	Type 6-9	0	0.0	0	0.0
	Preparatory Acts/Behavior	0	0.0	0	0.0
	Aborted Attempt	0	0.0	0	0.0
	Interrupted Attempt	0	0.0	0	0.0
	Actual Attempt	0	0.0	0	0.0
	Type 10	0	0.0	0	0.0
	Suicide	0	0.0	0	0.0

Study: 1305-0023
A subject may appear in more than one category.

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Table I.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (NIN background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Worst Ideation/Behavior over the whole trial	No Ideation	162	95.9	168	98.8
	Type 1-3	6	3.6	1	0.6
	Wish to be Dead	3	1.8	1	0.6
	Non-Specific Suicidal Thought	2	1.2	0	0.0
	Suicidal Ideation-No Intent	1	0.6	0	0.0
	Type 4-5	0	0.0	0	0.0
	Ideation with Intent, No Plan	0	0.0	0	0.0
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	168	99.4	169	99.4
	Type 6-9	0	0.0	0	0.0
	Preparatory Acts/Behavior	0	0.0	0	0.0
	Aborted Attempt	0	0.0	0	0.0
	Interrupted Attempt	0	0.0	0	0.0
	Actual Attempt	0	0.0	0	0.0
	Type 10	0	0.0	0	0.0
	Suicide	0	0.0	0	0.0

Study: 1305-0023
A subject may appear in more than one category.

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Table I.1.1.2.1.6: 2 Shift table of Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (NIN background)

			Baseline					
			No Ideation		Type 1-3		Type 4-5	
Visit	Treatment	Suicidal ideation type	n	%	n	%	n	%
Week 2	Placebo	No Ideation	165	97.6	1	0.6	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	166	97.6	0	0.0	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
Week 6	Placebo	No Ideation	163	96.4	0	0.0	0	0.0
		Type 1-3	0	0.0	1	0.6	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	165	97.1	0	0.0	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
Week 12	Placebo	No Ideation	160	94.7	1	0.6	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	161	94.7	0	0.0	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
Week 18	Placebo	No Ideation	158	93.5	1	0.6	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	157	92.4	0	0.0	0	0.0
		Type 1-3	1	0.6	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0

Study: 1305-0023
Patients without a baseline C-SSRS assessment are excluded from analysis.

anav4\tlf\t-cssrs-shift-ppf.sas 23JUN2026

Table I.1.1.2.1.6: 2 Shift table of Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (NIN background)

			Baseline					
			No Ideation		Type 1-3		Type 4-5	
Visit	Treatment	Suicidal ideation type	n	%	n	%	n	%
Week 26	Placebo	No Ideation	155	91.7	1	0.6	0	0.0
		Type 1-3	1	0.6	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	155	91.2	0	0.0	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
Week 36	Placebo	No Ideation	149	88.2	1	0.6	0	0.0
		Type 1-3	1	0.6	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	147	86.5	0	0.0	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
Week 44	Placebo	No Ideation	145	85.8	1	0.6	0	0.0
		Type 1-3	1	0.6	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	140	82.4	0	0.0	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
Week 52	Placebo	No Ideation	147	87.0	1	0.6	0	0.0
		Type 1-3	1	0.6	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	139	81.8	0	0.0	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0

Study: 1305-0023
Patients without a baseline C-SSRS assessment are excluded from analysis.

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Table I.1.1.2.1.6: 2 Shift table of Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (NIN background)

			Baseline					
			No Ideation		Type 1-3		Type 4-5	
Visit	Treatment	Suicidal ideation type	n	%	n	%	n	%
Week 64	Placebo	No Ideation	128	75.7	1	0.6	0	0.0
		Type 1-3	1	0.6	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	123	72.4	0	0.0	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
Week 76	Placebo	No Ideation	88	52.1	1	0.6	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	85	50.0	0	0.0	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
Week 88	Placebo	No Ideation	38	22.5	0	0.0	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	33	19.4	0	0.0	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
Week 100	Placebo	No Ideation	11	6.5	0	0.0	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	9	5.3	0	0.0	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0

Study: 1305-0023
Patients without a baseline C-SSRS assessment are excluded from analysis.

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Table I.1.1.2.1.6: 2 Shift table of Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (NIN background)

			Baseline					
			No Ideation		Type 1-3		Type 4-5	
Visit	Treatment	Suicidal ideation type	n	%	n	%	n	%
Week 112	Placebo	No Ideation	4	2.4	0	0.0	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	0	0.0	0	0.0	0	0.0
		Type 1-3	0	0.0	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
Worst value over the whole trial	Placebo	No Ideation	162	95.9	0	0.0	0	0.0
		Type 1-3	5	3.0	1	0.6	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	168	98.8	0	0.0	0	0.0
		Type 1-3	1	0.6	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0

Study: 1305-0023
Patients without a baseline C-SSRS assessment are excluded from analysis.

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I.1.1.2.1.7 HADS

Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Overall																	
Baseline																	
Placebo	169	169	3.6	0.2	164 (100.0%)												
Nera 18mg	170	170	3.7	0.2	164 (100.0%)												
Week 12																	
Placebo		159	3.7	0.3	159 (97.0%)	0.1	0.2	-0.3	0.5								
Nera 18mg		160	3.5	0.2	160 (97.6%)	-0.2	0.2	-0.5	0.2	-0.3	0.3	-0.8	0.2	0.3067			
Week 26																	
Placebo		155	3.7	0.3	155 (94.5%)	0.1	0.2	-0.3	0.5								
Nera 18mg		148	3.6	0.3	148 (90.2%)	0.1	0.2	-0.3	0.5	-0.0	0.3	-0.6	0.5	0.9053			
Week 36																	
Placebo		150	3.7	0.3	150 (91.5%)	0.1	0.2	-0.3	0.5								
Nera 18mg		143	3.6	0.3	143 (87.2%)	-0.1	0.2	-0.5	0.3	-0.2	0.3	-0.8	0.4	0.4615			
Week 44																	
Placebo		147	3.5	0.3	147 (89.6%)	-0.0	0.2	-0.5	0.4								
Nera 18mg		140	4.0	0.3	140 (85.4%)	0.3	0.2	-0.1	0.8	0.4	0.3	-0.3	1.0	0.2669			
Week 52																	
Placebo		148	3.5	0.3	148 (90.2%)	-0.0	0.2	-0.4	0.4								
Nera 18mg		138	3.9	0.3	138 (84.1%)	0.3	0.2	-0.2	0.7	0.3	0.3	-0.3	0.9	0.3554			
Week 64																	
Placebo		107	3.4	0.3	107 (65.2%)	0.1	0.2	-0.4	0.5								
Nera 18mg		105	3.7	0.3	105 (64.0%)	0.1	0.2	-0.4	0.5	0.0	0.3	-0.6	0.7	0.9054			
Week 76																	
Placebo		46	3.3	0.5	46 (28.0%)												
Nera 18mg		45	4.0	0.6	45 (27.4%)												
Week 88																	
Placebo		17	3.6	0.6	17 (10.4%)												
Nera 18mg		16	4.3	1.1	16 (9.8%)												
Week 100																	
Placebo		3	3.7	1.9	3 (1.8%)												
Nera 18mg		2	4.0	3.0	2 (1.2%)												
Age																	
Test for homogeneity (H0)^																	
Week 12														0.9597			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Anxiety total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 26														0.8296			
Week 36														0.5804			
Week 44														0.4298			
Week 52														0.1828			
Week 64														0.4947			
<65 years																	
Baseline																	
Placebo	65	65	3.6	0.4	64 (100.0%)												
Nera 18mg	64	64	3.6	0.4	62 (100.0%)												
Week 12																	
Placebo		62	3.6	0.4	62 (96.9%)	0.1	0.3	-0.5	0.6								
Nera 18mg		61	3.3	0.4	61 (98.4%)	-0.2	0.3	-0.8	0.3	-0.3	0.4	-1.1	0.5	0.4973			
Week 26																	
Placebo		62	3.3	0.4	62 (96.9%)	-0.3	0.3	-0.9	0.4								
Nera 18mg		58	3.1	0.4	58 (93.5%)	-0.4	0.3	-1.1	0.3	-0.1	0.5	-1.0	0.8	0.7888			
Week 36																	
Placebo		61	3.6	0.4	61 (95.3%)	-0.1	0.3	-0.7	0.5								
Nera 18mg		54	3.0	0.4	54 (87.1%)	-0.5	0.3	-1.2	0.1	-0.4	0.5	-1.4	0.5	0.3595			
Week 44																	
Placebo		61	3.2	0.4	61 (95.3%)	-0.4	0.3	-1.1	0.3								
Nera 18mg		52	3.2	0.4	52 (83.9%)	-0.4	0.4	-1.1	0.3	0.0	0.5	-1.0	1.0	0.9701			
Week 52																	
Placebo		62	3.5	0.4	62 (96.9%)	-0.2	0.3	-0.9	0.4								
Nera 18mg		52	3.1	0.4	52 (83.9%)	-0.5	0.4	-1.1	0.2	-0.2	0.5	-1.2	0.7	0.6229			
Week 64																	
Placebo		47	3.3	0.4	47 (73.4%)	-0.1	0.4	-0.8	0.6								
Nera 18mg		42	3.3	0.5	42 (67.7%)	-0.4	0.4	-1.1	0.4	-0.2	0.5	-1.3	0.8	0.6263			
Week 76																	
Placebo		19	3.5	0.8	19 (29.7%)												
Nera 18mg		11	2.3	1.3	11 (17.7%)												
Week 88																	
Placebo		5	3.2	1.2	5 (7.8%)												
Nera 18mg		4	7.0	2.7	4 (6.5%)												
Week 100																	
Placebo		2	2.5	2.5	2 (3.1%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Anxiety total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

anav4\tlf\t-mmrm-ppf.sas 23JUN2026

Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	104	104	3.7	0.3	100 (100.0%)												
Nera 18mg	106	106	3.8	0.3	102 (100.0%)												
Week 12																	
Placebo		97	3.8	0.3	97 (97.0%)	0.1	0.2	-0.3	0.6								
Nera 18mg		99	3.6	0.3	99 (97.1%)	-0.1	0.2	-0.6	0.3	-0.3	0.3	-0.9	0.4	0.4386			
Week 26																	
Placebo		93	4.0	0.4	93 (93.0%)	0.3	0.3	-0.2	0.9								
Nera 18mg		90	3.9	0.3	90 (88.2%)	0.3	0.3	-0.2	0.9	0.0	0.4	-0.7	0.7	0.9917			
Week 36																	
Placebo		89	3.7	0.3	89 (89.0%)	0.3	0.3	-0.2	0.8								
Nera 18mg		89	3.9	0.3	89 (87.3%)	0.2	0.3	-0.3	0.7	-0.1	0.4	-0.8	0.6	0.7949			
Week 44																	
Placebo		86	3.6	0.3	86 (86.0%)	0.2	0.3	-0.3	0.8								
Nera 18mg		88	4.6	0.4	88 (86.3%)	0.7	0.3	0.2	1.3	0.5	0.4	-0.3	1.3	0.1910			
Week 52																	
Placebo		86	3.5	0.3	86 (86.0%)	0.1	0.3	-0.4	0.6								
Nera 18mg		86	4.3	0.3	86 (84.3%)	0.7	0.3	0.2	1.2	0.6	0.4	-0.2	1.4	0.1300			
Week 64																	
Placebo		60	3.6	0.4	60 (60.0%)	0.2	0.3	-0.4	0.8								
Nera 18mg		63	4.1	0.4	63 (61.8%)	0.4	0.3	-0.2	0.9	0.2	0.4	-0.6	1.0	0.6285			
Week 76																	
Placebo		27	3.2	0.5	27 (27.0%)												
Nera 18mg		34	4.5	0.6	34 (33.3%)												
Week 88																	
Placebo		12	3.8	0.7	12 (12.0%)												
Nera 18mg		12	3.3	1.1	12 (11.8%)												
Week 100																	
Placebo		1	6.0	NC	1 (1.0%)												
Nera 18mg		2	4.0	3.0	2 (2.0%)												
Sex																	
Test for homogeneity (H0)^																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 12														0.7728			
Week 26														0.7294			
Week 36														0.2980			
Week 44														0.9074			
Week 52														0.8359			
Week 64														0.1311			
Male																	
Baseline																	
Placebo	114	114	3.3	0.3	111 (100.0%)												
Nera 18mg	108	108	3.6	0.3	103 (100.0%)												
Week 12																	
Placebo		107	3.5	0.3	107 (96.4%)	0.2	0.2	-0.3	0.6								
Nera 18mg		100	3.4	0.3	100 (97.1%)	-0.1	0.2	-0.6	0.3	-0.3	0.3	-0.9	0.3	0.3317			
Week 26																	
Placebo		103	3.7	0.3	103 (92.8%)	0.3	0.3	-0.2	0.7								
Nera 18mg		92	3.6	0.3	92 (89.3%)	0.2	0.3	-0.4	0.7	-0.1	0.4	-0.8	0.6	0.8031			
Week 36																	
Placebo		99	3.4	0.3	99 (89.2%)	0.2	0.3	-0.3	0.7								
Nera 18mg		86	3.7	0.3	86 (83.5%)	0.2	0.3	-0.3	0.7	0.0	0.4	-0.7	0.8	0.9069			
Week 44																	
Placebo		97	3.4	0.3	97 (87.4%)	0.2	0.3	-0.4	0.7								
Nera 18mg		83	4.0	0.3	83 (80.6%)	0.5	0.3	-0.1	1.1	0.4	0.4	-0.4	1.1	0.3769			
Week 52																	
Placebo		97	3.5	0.3	97 (87.4%)	0.3	0.3	-0.2	0.8								
Nera 18mg		83	4.1	0.4	83 (80.6%)	0.6	0.3	0.1	1.2	0.4	0.4	-0.4	1.1	0.3155			
Week 64																	
Placebo		67	3.0	0.3	67 (60.4%)	-0.0	0.3	-0.6	0.5								
Nera 18mg		62	4.1	0.4	62 (60.2%)	0.4	0.3	-0.2	1.0	0.5	0.4	-0.3	1.3	0.2652			
Week 76																	
Placebo		30	3.3	0.5	30 (27.0%)												
Nera 18mg		26	4.3	0.9	26 (25.2%)												
Week 88																	
Placebo		12	3.8	0.7	12 (10.8%)												
Nera 18mg		9	4.8	1.9	9 (8.7%)												
Week 100																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Anxiety total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		1	6.0	NC	1 (0.9%)												
Nera 18mg		1	1.0	NC	1 (1.0%)												
Female																	
Baseline																	
Placebo	55	55	4.3	0.4	53 (100.0%)												
Nera 18mg	62	62	4.0	0.4	61 (100.0%)												
Week 12																	
Placebo		52	4.1	0.5	52 (98.1%)	-0.1	0.3	-0.7	0.6								
Nera 18mg		60	3.7	0.4	60 (98.4%)	-0.2	0.3	-0.8	0.4	-0.2	0.4	-1.0	0.7	0.7254			
Week 26																	
Placebo		52	3.9	0.5	52 (98.1%)	-0.2	0.4	-0.9	0.5								
Nera 18mg		56	3.7	0.4	56 (91.8%)	-0.1	0.3	-0.8	0.6	0.1	0.5	-0.8	1.1	0.8055			
Week 36																	
Placebo		51	4.2	0.5	51 (96.2%)	0.0	0.4	-0.7	0.8								
Nera 18mg		57	3.3	0.4	57 (93.4%)	-0.6	0.3	-1.2	0.1	-0.6	0.5	-1.6	0.4	0.2243			
Week 44																	
Placebo		50	3.6	0.5	50 (94.3%)	-0.4	0.4	-1.2	0.4								
Nera 18mg		57	4.0	0.5	57 (93.4%)	0.0	0.4	-0.7	0.7	0.4	0.5	-0.6	1.5	0.4154			
Week 52																	
Placebo		51	3.5	0.4	51 (96.2%)	-0.6	0.4	-1.3	0.1								
Nera 18mg		55	3.4	0.4	55 (90.2%)	-0.3	0.3	-1.0	0.4	0.3	0.5	-0.7	1.2	0.6182			
Week 64																	
Placebo		40	4.2	0.5	40 (75.5%)	0.2	0.4	-0.6	0.9								
Nera 18mg		43	3.3	0.4	43 (70.5%)	-0.4	0.4	-1.1	0.3	-0.6	0.5	-1.6	0.5	0.2922			
Week 76																	
Placebo		16	3.5	0.9	16 (30.2%)												
Nera 18mg		19	3.5	0.7	19 (31.1%)												
Week 88																	
Placebo		5	3.4	1.2	5 (9.4%)												
Nera 18mg		7	3.6	0.7	7 (11.5%)												
Week 100																	
Placebo		2	2.5	2.5	2 (3.8%)												
Nera 18mg		1	7.0	NC	1 (1.6%)												
Baseline FVC percent predicted																	

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Test for homogeneity (H0)^																	
Week 12														0.0118			
Week 26														0.3901			
Week 36														0.6950			
Week 44														0.0878			
Week 52														0.1112			
Week 64														0.3767			
<=70%																	
Baseline																	
Placebo	95	95	3.6	0.3	91 (100.0%)												
Nera 18mg	97	97	3.9	0.3	95 (100.0%)												
Week 12																	
Placebo		87	3.4	0.4	87 (95.6%)	-0.1	0.2	-0.5	0.4								
Nera 18mg		92	4.1	0.3	92 (96.8%)	0.2	0.2	-0.2	0.7	0.3	0.3	-0.4	1.0	0.3829			
Week 26																	
Placebo		85	3.7	0.4	85 (93.4%)	-0.0	0.3	-0.6	0.5								
Nera 18mg		85	3.9	0.3	85 (89.5%)	0.2	0.3	-0.4	0.7	0.2	0.4	-0.6	1.0	0.6370			
Week 36																	
Placebo		82	3.7	0.4	82 (90.1%)	0.2	0.3	-0.4	0.7								
Nera 18mg		83	3.9	0.4	83 (87.4%)	0.1	0.3	-0.5	0.6	-0.1	0.4	-0.9	0.7	0.7567			
Week 44																	
Placebo		81	3.4	0.3	81 (89.0%)	-0.1	0.3	-0.7	0.5								
Nera 18mg		80	4.5	0.4	80 (84.2%)	0.7	0.3	0.2	1.3	0.8	0.4	-0.0	1.6	0.0535			
Week 52																	
Placebo		80	3.6	0.4	80 (87.9%)	0.1	0.3	-0.4	0.7								
Nera 18mg		79	4.5	0.4	79 (83.2%)	0.8	0.3	0.2	1.4	0.7	0.4	-0.1	1.5	0.0944			
Week 64																	
Placebo		56	3.3	0.4	56 (61.5%)	0.1	0.3	-0.5	0.7								
Nera 18mg		60	4.1	0.4	60 (63.2%)	0.4	0.3	-0.2	1.0	0.3	0.4	-0.6	1.1	0.5327			
Week 76																	
Placebo		26	3.3	0.7	26 (28.6%)												
Nera 18mg		25	4.4	0.8	25 (26.3%)												
Week 88																	
Placebo		10	3.7	0.8	10 (11.0%)												
Nera 18mg		9	4.3	1.5	9 (9.5%)												

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 100																	
Placebo		2	2.5	2.5	2 (2.2%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	74	74	3.7	0.3	73 (100.0%)												
Nera 18mg	73	73	3.4	0.3	69 (100.0%)												
Week 12																	
Placebo		72	4.0	0.4	72 (98.6%)	0.3	0.3	-0.2	0.8								
Nera 18mg		68	2.7	0.3	68 (98.6%)	-0.7	0.3	-1.3	-0.2	-1.0	0.4	-1.8	-0.2	0.0095	-0.44	-0.77	-0.10
Week 26																	
Placebo		70	3.8	0.4	70 (95.9%)	0.2	0.3	-0.4	0.8								
Nera 18mg		63	3.3	0.4	63 (91.3%)	-0.1	0.3	-0.7	0.5	-0.3	0.4	-1.2	0.5	0.4652			
Week 36																	
Placebo		68	3.6	0.4	68 (93.2%)	0.1	0.3	-0.5	0.7								
Nera 18mg		60	3.2	0.4	60 (87.0%)	-0.3	0.3	-0.9	0.4	-0.4	0.5	-1.2	0.5	0.4272			
Week 44																	
Placebo		66	3.5	0.4	66 (90.4%)	0.0	0.3	-0.6	0.7								
Nera 18mg		60	3.4	0.4	60 (87.0%)	-0.2	0.3	-0.9	0.4	-0.3	0.5	-1.2	0.7	0.5669			
Week 52																	
Placebo		68	3.3	0.4	68 (93.2%)	-0.2	0.3	-0.8	0.4								
Nera 18mg		59	3.0	0.4	59 (85.5%)	-0.5	0.3	-1.1	0.2	-0.3	0.5	-1.2	0.6	0.5184			
Week 64																	
Placebo		51	3.5	0.4	51 (69.9%)	-0.0	0.3	-0.7	0.6								
Nera 18mg		45	3.2	0.5	45 (65.2%)	-0.3	0.4	-1.0	0.4	-0.3	0.5	-1.3	0.7	0.5293			
Week 76																	
Placebo		20	3.5	0.6	20 (27.4%)												
Nera 18mg		20	3.4	0.8	20 (29.0%)												
Week 88																	
Placebo		7	3.6	0.8	7 (9.6%)												
Nera 18mg		7	4.1	1.7	7 (10.1%)												
Week 100																	
Placebo		1	6.0	NC	1 (1.4%)												
Nera 18mg		2	4.0	3.0	2 (2.9%)												

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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Baseline HRCT pattern																	
Test for homogeneity (H0)^																	
Week 12														0.7519			
Week 26														0.1597			
Week 36														0.3350			
Week 44														0.6324			
Week 52														0.4132			
Week 64														0.4773			
UIP-like																	
Baseline																	
Placebo	116	116	3.5	0.3	113 (100.0%)												
Nera 18mg	121	121	3.9	0.3	118 (100.0%)												
Week 12																	
Placebo		110	3.5	0.3	110 (97.3%)	0.1	0.2	-0.4	0.5								
Nera 18mg		117	3.5	0.3	117 (99.2%)	-0.3	0.2	-0.7	0.2	-0.3	0.3	-0.9	0.3	0.2998			
Week 26																	
Placebo		106	3.6	0.3	106 (93.8%)	0.1	0.2	-0.4	0.6								
Nera 18mg		106	3.5	0.3	106 (89.8%)	-0.2	0.2	-0.7	0.3	-0.3	0.3	-1.0	0.4	0.3838			
Week 36																	
Placebo		102	3.4	0.3	102 (90.3%)	0.0	0.3	-0.5	0.5								
Nera 18mg		102	3.4	0.3	102 (86.4%)	-0.4	0.3	-0.9	0.1	-0.4	0.4	-1.1	0.3	0.2547			
Week 44																	
Placebo		99	3.4	0.3	99 (87.6%)	0.1	0.3	-0.4	0.7								
Nera 18mg		100	4.2	0.4	100 (84.7%)	0.4	0.3	-0.1	0.9	0.3	0.4	-0.5	1.0	0.5047			
Week 52																	
Placebo		100	3.2	0.3	100 (88.5%)	-0.1	0.3	-0.6	0.4								
Nera 18mg		99	3.7	0.3	99 (83.9%)	0.0	0.3	-0.5	0.5	0.1	0.4	-0.6	0.8	0.7469			
Week 64																	
Placebo		75	3.1	0.3	75 (66.4%)	-0.1	0.3	-0.7	0.4								
Nera 18mg		76	3.4	0.3	76 (64.4%)	-0.2	0.3	-0.8	0.3	-0.1	0.4	-0.9	0.6	0.7724			
Week 76																	
Placebo		30	2.5	0.4	30 (26.5%)												
Nera 18mg		32	3.8	0.6	32 (27.1%)												
Week 88																	
Placebo		14	3.4	0.7	14 (12.4%)												

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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		15	4.3	1.1	15 (12.7%)												
Week 100																	
Placebo		2	3.0	3.0	2 (1.8%)												
Nera 18mg		2	4.0	3.0	2 (1.7%)												
Other fibrotic patterns																	
Baseline																	
Placebo	53	53	4.1	0.4	51 (100.0%)												
Nera 18mg	49	49	3.2	0.4	46 (100.0%)												
Week 12																	
Placebo		49	4.1	0.5	49 (96.1%)	0.2	0.3	-0.4	0.9								
Nera 18mg		43	3.4	0.5	43 (93.5%)	0.1	0.3	-0.6	0.8	-0.1	0.5	-1.1	0.8	0.7738			
Week 26																	
Placebo		49	4.1	0.5	49 (96.1%)	0.1	0.4	-0.6	0.8								
Nera 18mg		42	4.0	0.5	42 (91.3%)	0.7	0.4	-0.1	1.5	0.6	0.5	-0.5	1.7	0.2652			
Week 36																	
Placebo		48	4.3	0.5	48 (94.1%)	0.4	0.4	-0.3	1.1								
Nera 18mg		41	3.9	0.5	41 (89.1%)	0.6	0.4	-0.2	1.4	0.2	0.5	-0.8	1.3	0.6828			
Week 44																	
Placebo		48	3.6	0.4	48 (94.1%)	-0.4	0.4	-1.2	0.4								
Nera 18mg		40	3.7	0.5	40 (87.0%)	0.2	0.4	-0.6	1.0	0.6	0.6	-0.6	1.7	0.3119			
Week 52																	
Placebo		48	4.1	0.5	48 (94.1%)	0.2	0.4	-0.6	0.9								
Nera 18mg		39	4.4	0.5	39 (84.8%)	0.8	0.4	0.0	1.6	0.7	0.6	-0.4	1.8	0.2340			
Week 64																	
Placebo		32	4.2	0.6	32 (62.7%)	0.5	0.4	-0.3	1.3								
Nera 18mg		29	4.6	0.7	29 (63.0%)	0.9	0.4	0.0	1.7	0.4	0.6	-0.8	1.6	0.5088			
Week 76																	
Placebo		16	4.9	1.0	16 (31.4%)												
Nera 18mg		13	4.5	1.3	13 (28.3%)												
Week 88																	
Placebo		3	5.0	0.6	3 (5.9%)												
Nera 18mg		1	3.0	NC	1 (2.2%)												
Week 100																	
Placebo		1	5.0	NC	1 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Anxiety total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Underlying ILD diagnosis																	
Test for homogeneity (H0)^																	
Week 12														0.4853			
Week 26														0.9558			
Week 36														0.3037			
Week 44														0.3050			
Week 52														0.5671			
Week 64														0.2493			
iNSIP																	
Baseline																	
Placebo	32	32	4.4	0.6	31 (100.0%)												
Nera 18mg	27	27	3.9	0.6	25 (100.0%)												
Week 12																	
Placebo		29	4.0	0.7	29 (93.5%)	-0.0	0.4	-0.9	0.8								
Nera 18mg		23	4.0	0.7	23 (92.0%)	0.0	0.5	-0.9	1.0	0.1	0.6	-1.2	1.3	0.9198			
Week 26																	
Placebo		29	4.1	0.8	29 (93.5%)	0.2	0.5	-0.8	1.1								
Nera 18mg		23	4.3	0.7	23 (92.0%)	0.1	0.5	-0.9	1.2	-0.0	0.7	-1.5	1.4	0.9527			
Week 36																	
Placebo		28	3.3	0.6	28 (90.3%)	-0.3	0.5	-1.2	0.6								
Nera 18mg		20	4.3	0.7	20 (80.0%)	0.1	0.5	-1.0	1.1	0.4	0.7	-1.0	1.8	0.5990			
Week 44																	
Placebo		28	3.4	0.6	28 (90.3%)	-0.3	0.5	-1.3	0.7								
Nera 18mg		19	5.3	1.1	19 (76.0%)	0.8	0.6	-0.4	2.0	1.1	0.8	-0.4	2.7	0.1626			
Week 52																	
Placebo		27	3.8	0.7	27 (87.1%)	0.3	0.5	-0.7	1.3								
Nera 18mg		17	4.4	0.8	17 (68.0%)	0.2	0.6	-1.0	1.3	-0.1	0.8	-1.7	1.4	0.8828			
Week 64																	
Placebo		19	3.7	0.8	19 (61.3%)	-0.1	0.5	-1.2	1.0								
Nera 18mg		13	5.3	1.0	13 (52.0%)	0.8	0.6	-0.4	2.1	0.9	0.8	-0.7	2.6	0.2647			
Week 76																	
Placebo		10	4.1	1.2	10 (32.3%)												
Nera 18mg		6	8.2	1.8	6 (24.0%)												
Week 88																	
Placebo		5	2.8	0.8	5 (16.1%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Anxiety total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		2	4.5	1.5	2 (8.0%)												
Week 100																	
Placebo		1	6.0	NC	1 (3.2%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Unclassifiable IIP																	
Baseline																	
Placebo	46	46	2.9	0.4	44 (100.0%)												
Nera 18mg	32	32	4.2	0.6	32 (100.0%)												
Week 12																	
Placebo		44	3.2	0.5	44 (100.0%)	0.1	0.3	-0.6	0.7								
Nera 18mg		32	3.3	0.5	32 (100.0%)	-0.7	0.4	-1.5	0.1	-0.8	0.5	-1.8	0.3	0.1601			
Week 26																	
Placebo		40	3.6	0.6	40 (90.9%)	0.3	0.4	-0.5	1.1								
Nera 18mg		28	3.9	0.6	28 (87.5%)	0.0	0.5	-0.9	1.0	-0.3	0.6	-1.5	1.0	0.6533			
Week 36																	
Placebo		38	3.4	0.5	38 (86.4%)	0.3	0.4	-0.5	1.1								
Nera 18mg		27	2.9	0.5	27 (84.4%)	-1.0	0.5	-1.9	-0.1	-1.3	0.6	-2.5	-0.1	0.0396	-0.52	-1.01	-0.02
Week 44																	
Placebo		37	3.4	0.5	37 (84.1%)	0.3	0.4	-0.5	1.2								
Nera 18mg		27	3.7	0.6	27 (84.4%)	-0.3	0.5	-1.3	0.7	-0.6	0.7	-2.0	0.7	0.3491			
Week 52																	
Placebo		38	3.3	0.5	38 (86.4%)	0.2	0.4	-0.6	1.1								
Nera 18mg		28	3.3	0.5	28 (87.5%)	-0.5	0.5	-1.5	0.5	-0.7	0.7	-2.0	0.6	0.2731			
Week 64																	
Placebo		30	2.9	0.6	30 (68.2%)	0.2	0.4	-0.7	1.1								
Nera 18mg		20	3.4	0.7	20 (62.5%)	-0.5	0.5	-1.6	0.5	-0.7	0.7	-2.1	0.6	0.2992			
Week 76																	
Placebo		13	2.7	0.8	13 (29.5%)												
Nera 18mg		14	2.6	0.7	14 (43.8%)												
Week 88																	
Placebo		3	4.7	1.8	3 (6.8%)												
Nera 18mg		5	5.6	1.9	5 (15.6%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	7.0	NC	1 (3.1%)												
HP																	

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Baseline																	
Placebo	38	38	2.9	0.3	38 (100.0%)												
Nera 18mg	43	43	3.8	0.4	40 (100.0%)												
Week 12																	
Placebo		37	2.9	0.4	37 (97.4%)	-0.1	0.4	-0.9	0.6								
Nera 18mg		38	3.7	0.4	38 (95.0%)	-0.0	0.4	-0.8	0.7	0.1	0.5	-0.9	1.2	0.8444			
Week 26																	
Placebo		38	3.1	0.5	38 (100.0%)	-0.1	0.4	-0.9	0.8								
Nera 18mg		36	3.7	0.5	36 (90.0%)	0.1	0.4	-0.7	1.0	0.2	0.6	-1.0	1.4	0.7520			
Week 36																	
Placebo		37	2.9	0.4	37 (97.4%)	-0.5	0.4	-1.3	0.4								
Nera 18mg		36	3.9	0.5	36 (90.0%)	0.2	0.4	-0.6	1.0	0.7	0.6	-0.5	1.8	0.2608			
Week 44																	
Placebo		37	2.7	0.4	37 (97.4%)	-0.5	0.4	-1.4	0.3								
Nera 18mg		35	4.1	0.5	35 (87.5%)	0.4	0.5	-0.5	1.3	1.0	0.6	-0.3	2.2	0.1325			
Week 52																	
Placebo		37	3.0	0.4	37 (97.4%)	-0.4	0.4	-1.2	0.5								
Nera 18mg		35	4.6	0.5	35 (87.5%)	0.8	0.4	-0.1	1.7	1.2	0.6	-0.1	2.4	0.0630			
Week 64																	
Placebo		24	3.4	0.6	24 (63.2%)	0.2	0.5	-0.8	1.1								
Nera 18mg		27	4.1	0.7	27 (67.5%)	0.4	0.5	-0.5	1.3	0.3	0.7	-1.1	1.6	0.7032			
Week 76																	
Placebo		10	2.4	0.7	10 (26.3%)												
Nera 18mg		8	4.8	1.3	8 (20.0%)												
Week 88																	
Placebo		1	6.0	NC	1 (2.6%)												
Nera 18mg		2	0.0	0.0	2 (5.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	1.0	NC	1 (2.5%)												
Autoimmune ILD																	
Baseline																	
Placebo	29	29	4.4	0.6	28 (100.0%)												
Nera 18mg	43	43	3.3	0.4	43 (100.0%)												
Week 12																	
Placebo		27	4.1	0.7	27 (96.4%)	-0.1	0.4	-1.0	0.7								

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		43	3.3	0.5	43 (100.0%)	-0.0	0.4	-0.7	0.7	0.1	0.6	-1.0	1.2	0.8465			
Week 26																	
Placebo		27	3.7	0.6	27 (96.4%)	-0.5	0.5	-1.5	0.5								
Nera 18mg		39	2.9	0.5	39 (90.7%)	-0.2	0.4	-1.0	0.6	0.3	0.6	-1.0	1.5	0.6719			
Week 36																	
Placebo		26	4.1	0.7	26 (92.9%)	-0.1	0.5	-1.0	0.9								
Nera 18mg		38	3.0	0.5	38 (88.4%)	-0.3	0.4	-1.1	0.5	-0.3	0.6	-1.5	1.0	0.6661			
Week 44																	
Placebo		24	3.7	0.6	24 (85.7%)	-0.3	0.5	-1.4	0.7								
Nera 18mg		37	3.3	0.5	37 (86.0%)	-0.1	0.4	-1.0	0.7	0.2	0.7	-1.1	1.6	0.7432			
Week 52																	
Placebo		25	3.8	0.6	25 (89.3%)	-0.3	0.5	-1.3	0.8								
Nera 18mg		36	3.1	0.5	36 (83.7%)	-0.0	0.4	-0.9	0.8	0.2	0.7	-1.1	1.6	0.7208			
Week 64																	
Placebo		17	3.8	0.7	17 (60.7%)	-0.5	0.6	-1.6	0.6								
Nera 18mg		28	2.9	0.4	28 (65.1%)	-0.2	0.5	-1.1	0.7	0.3	0.7	-1.1	1.8	0.6548			
Week 76																	
Placebo		7	3.3	1.1	7 (25.0%)												
Nera 18mg		8	1.4	0.7	8 (18.6%)												
Week 88																	
Placebo		4	2.8	1.4	4 (14.3%)												
Nera 18mg		3	3.3	1.8	3 (7.0%)												
Week 100																	
Placebo		2	2.5	2.5	2 (7.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other ILD																	
Baseline																	
Placebo	24	24	4.1	0.6	23 (100.0%)												
Nera 18mg	25	25	3.6	0.5	24 (100.0%)												
Week 12																	
Placebo		22	5.1	0.8	22 (95.7%)	1.0	0.5	0.0	2.0								
Nera 18mg		24	3.3	0.7	24 (100.0%)	-0.1	0.5	-1.1	0.8	-1.2	0.7	-2.5	0.2	0.0899			
Week 26																	
Placebo		21	4.7	0.8	21 (91.3%)	0.6	0.6	-0.5	1.7								
Nera 18mg		22	3.7	0.5	22 (91.7%)	0.4	0.5	-0.6	1.5	-0.2	0.8	-1.7	1.4	0.8249			
Week 36																	

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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo		21	5.6	0.8	21 (91.3%)	1.7	0.5	0.6	2.8								
Nera 18mg		22	4.2	0.7	22 (91.7%)	0.8	0.5	-0.2	1.9	-0.8	0.8	-2.3	0.7	0.2692			
Week 44																	
Placebo		21	4.7	0.8	21 (91.3%)	0.9	0.6	-0.2	2.1								
Nera 18mg		22	4.6	0.7	22 (91.7%)	1.2	0.6	0.1	2.4	0.3	0.8	-1.3	1.9	0.7112			
Week 52																	
Placebo		21	3.9	0.8	21 (91.3%)	0.1	0.6	-1.1	1.2								
Nera 18mg		22	4.2	0.7	22 (91.7%)	0.9	0.6	-0.2	2.0	0.8	0.8	-0.7	2.4	0.3027			
Week 64																	
Placebo		17	3.9	0.8	17 (73.9%)	0.6	0.6	-0.6	1.7								
Nera 18mg		17	3.8	0.8	17 (70.8%)	0.2	0.6	-0.9	1.4	-0.3	0.8	-2.0	1.3	0.6818			
Week 76																	
Placebo		6	5.2	1.6	6 (26.1%)												
Nera 18mg		9	5.0	1.5	9 (37.5%)												
Week 88																	
Placebo		4	4.3	1.1	4 (17.4%)												
Nera 18mg		4	5.3	3.3	4 (16.7%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Region																	
Test for homogeneity (H0)^																	
Week 12														0.4117			
Week 26														0.2190			
Week 36														0.5994			
Week 44														0.4996			
Week 52														0.0886			
Week 64														0.9596			
Europe																	
Baseline																	
Placebo	78	78	3.7	0.3	77 (100.0%)												
Nera 18mg	67	67	3.7	0.3	64 (100.0%)												
Week 12																	

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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Anxiety total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		76	3.8	0.4	76 (98.7%)	0.3	0.3	-0.3	0.8								
Nera 18mg		61	3.7	0.4	61 (95.3%)	0.1	0.3	-0.4	0.7	-0.1	0.4	-0.9	0.6	0.7441			
Week 26																	
Placebo		73	3.9	0.4	73 (94.8%)	0.3	0.3	-0.3	0.9								
Nera 18mg		56	4.0	0.4	56 (87.5%)	0.6	0.3	-0.1	1.3	0.3	0.4	-0.6	1.2	0.5072			
Week 36																	
Placebo		68	3.7	0.4	68 (88.3%)	0.3	0.3	-0.3	0.9								
Nera 18mg		54	3.7	0.4	54 (84.4%)	0.3	0.3	-0.4	0.9	-0.0	0.5	-1.0	0.9	0.9326			
Week 44																	
Placebo		68	3.3	0.4	68 (88.3%)	-0.1	0.3	-0.7	0.6								
Nera 18mg		54	4.0	0.4	54 (84.4%)	0.4	0.4	-0.3	1.1	0.5	0.5	-0.5	1.5	0.3196			
Week 52																	
Placebo		69	3.2	0.4	69 (89.6%)	-0.2	0.3	-0.8	0.5								
Nera 18mg		53	4.1	0.4	53 (82.8%)	0.6	0.4	-0.1	1.3	0.8	0.5	-0.2	1.7	0.1040			
Week 64																	
Placebo		50	3.4	0.4	50 (64.9%)	0.2	0.3	-0.5	0.8								
Nera 18mg		42	3.8	0.5	42 (65.6%)	0.2	0.4	-0.5	0.9	0.0	0.5	-1.0	1.0	0.9904			
Week 76																	
Placebo		19	3.7	0.7	19 (24.7%)												
Nera 18mg		15	5.3	1.1	15 (23.4%)												
Week 88																	
Placebo		5	3.6	1.1	5 (6.5%)												
Nera 18mg		3	1.3	1.3	3 (4.7%)												
Week 100																	
Placebo		1	5.0	NC	1 (1.3%)												
Nera 18mg		1	7.0	NC	1 (1.6%)												
Asia																	
Baseline																	
Placebo	45	45	3.5	0.5	43 (100.0%)												
Nera 18mg	41	41	2.8	0.4	39 (100.0%)												
Week 12																	
Placebo		41	2.8	0.5	41 (95.3%)	-0.6	0.4	-1.3	0.1								
Nera 18mg		39	2.3	0.4	39 (100.0%)	-0.7	0.4	-1.5	-0.0	-0.1	0.5	-1.1	0.9	0.7907			
Week 26																	
Placebo		42	2.7	0.5	42 (97.7%)	-0.7	0.4	-1.5	0.1								
Nera 18mg		34	2.4	0.5	34 (87.2%)	-0.6	0.4	-1.5	0.2	0.1	0.6	-1.1	1.2	0.8809			

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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 36																	
Placebo		41	3.2	0.6	41 (95.3%)	-0.2	0.4	-1.0	0.6								
Nera 18mg		33	2.6	0.5	33 (84.6%)	-0.5	0.4	-1.4	0.3	-0.3	0.6	-1.5	0.8	0.5722			
Week 44																	
Placebo		38	2.9	0.5	38 (88.4%)	-0.4	0.4	-1.3	0.4								
Nera 18mg		31	3.8	0.8	31 (79.5%)	0.4	0.5	-0.6	1.3	0.8	0.6	-0.4	2.1	0.2026			
Week 52																	
Placebo		39	3.2	0.5	39 (90.7%)	-0.2	0.4	-1.0	0.6								
Nera 18mg		32	3.3	0.6	32 (82.1%)	0.5	0.5	-0.4	1.4	0.7	0.6	-0.5	1.9	0.2527			
Week 64																	
Placebo		28	2.9	0.5	28 (65.1%)	-0.3	0.4	-1.2	0.5								
Nera 18mg		26	2.3	0.6	26 (66.7%)	-0.3	0.5	-1.3	0.6	-0.0	0.6	-1.3	1.3	0.9989			
Week 76																	
Placebo		16	2.1	0.6	16 (37.2%)												
Nera 18mg		12	3.1	1.2	12 (30.8%)												
Week 88																	
Placebo		7	4.3	1.1	7 (16.3%)												
Nera 18mg		8	5.8	1.9	8 (20.5%)												
Week 100																	
Placebo		1	0.0	NC	1 (2.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	
Baseline																	
Placebo	30	30	3.5	0.5	30 (100.0%)												
Nera 18mg	37	37	4.7	0.5	37 (100.0%)												
Week 12																	
Placebo		28	4.0	0.5	28 (93.3%)	0.3	0.4	-0.6	1.1								
Nera 18mg		37	4.6	0.5	37 (100.0%)	0.2	0.4	-0.6	0.9	-0.1	0.6	-1.2	1.0	0.8345			
Week 26																	
Placebo		26	4.3	0.6	26 (86.7%)	0.5	0.5	-0.5	1.5								
Nera 18mg		34	4.7	0.6	34 (91.9%)	0.4	0.4	-0.5	1.2	-0.2	0.7	-1.4	1.1	0.8114			
Week 36																	
Placebo		27	3.9	0.5	27 (90.0%)	0.1	0.5	-0.9	1.1								
Nera 18mg		34	4.2	0.5	34 (91.9%)	-0.2	0.4	-1.0	0.7	-0.2	0.7	-1.5	1.1	0.7239			
Week 44																	
Placebo		27	3.9	0.4	27 (90.0%)	0.2	0.5	-0.8	1.3								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Anxiety total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg		33	4.4	0.6	33 (89.2%)	0.2	0.5	-0.8	1.1	-0.1	0.7	-1.4	1.3	0.9401			
Week 52																	
Placebo		26	3.8	0.5	26 (86.7%)	0.1	0.5	-0.9	1.1								
Nera 18mg		33	4.3	0.5	33 (89.2%)	0.0	0.5	-0.9	0.9	-0.1	0.7	-1.4	1.3	0.9057			
Week 64																	
Placebo		19	3.6	0.7	19 (63.3%)	-0.1	0.5	-1.1	1.0								
Nera 18mg		25	4.6	0.6	25 (67.6%)	0.1	0.5	-0.8	1.1	0.2	0.7	-1.2	1.6	0.7737			
Week 76																	
Placebo		9	4.7	1.2	9 (30.0%)												
Nera 18mg		13	3.5	0.8	13 (35.1%)												
Week 88																	
Placebo		5	2.8	0.6	5 (16.7%)												
Nera 18mg		4	3.0	1.2	4 (10.8%)												
Week 100																	
Placebo		1	6.0	NC	1 (3.3%)												
Nera 18mg		1	1.0	NC	1 (2.7%)												
Rest of the World																	
Baseline																	
Placebo	16	16	4.3	0.6	14 (100.0%)												
Nera 18mg	25	25	3.9	0.7	24 (100.0%)												
Week 12																	
Placebo		14	5.0	0.7	14 (100.0%)	0.9	0.6	-0.3	2.1								
Nera 18mg		23	3.3	0.6	23 (95.8%)	-0.5	0.5	-1.5	0.4	-1.4	0.8	-3.0	0.1	0.0629			
Week 26																	
Placebo		14	4.6	1.1	14 (100.0%)	0.6	0.7	-0.8	1.9								
Nera 18mg		24	3.0	0.6	24 (100.0%)	-0.7	0.5	-1.7	0.3	-1.3	0.9	-3.0	0.4	0.1377			
Week 36																	
Placebo		14	4.4	1.1	14 (100.0%)	0.4	0.7	-1.0	1.7								
Nera 18mg		22	3.7	0.7	22 (91.7%)	-0.2	0.5	-1.2	0.9	-0.5	0.9	-2.3	1.2	0.5495			
Week 44																	
Placebo		14	4.9	1.1	14 (100.0%)	0.9	0.7	-0.6	2.3								
Nera 18mg		22	4.0	0.6	22 (91.7%)	0.2	0.6	-0.9	1.4	-0.6	0.9	-2.5	1.2	0.4895			
Week 52																	
Placebo		14	5.0	1.2	14 (100.0%)	1.0	0.7	-0.4	2.3								
Nera 18mg		20	3.4	0.7	20 (83.3%)	-0.6	0.6	-1.7	0.5	-1.6	0.9	-3.4	0.2	0.0811			
Week 64																	

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Table I.1.1.2.1.7: 1 Adjusted mean (SE) of absolute change from baseline in HADS for Anxiety total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		10	4.8	1.5	10 (71.4%)	0.8	0.8	-0.6	2.3								
Nera 18mg		12	4.9	1.1	12 (50.0%)	0.8	0.6	-0.5	2.0	-0.1	1.0	-2.0	1.9	0.9311			
Week 76																	
Placebo		2	3.5	2.5	2 (14.3%)												
Nera 18mg		5	3.6	1.7	5 (20.8%)												
Week 88																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	6.0	NC	1 (4.2%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Anxiety total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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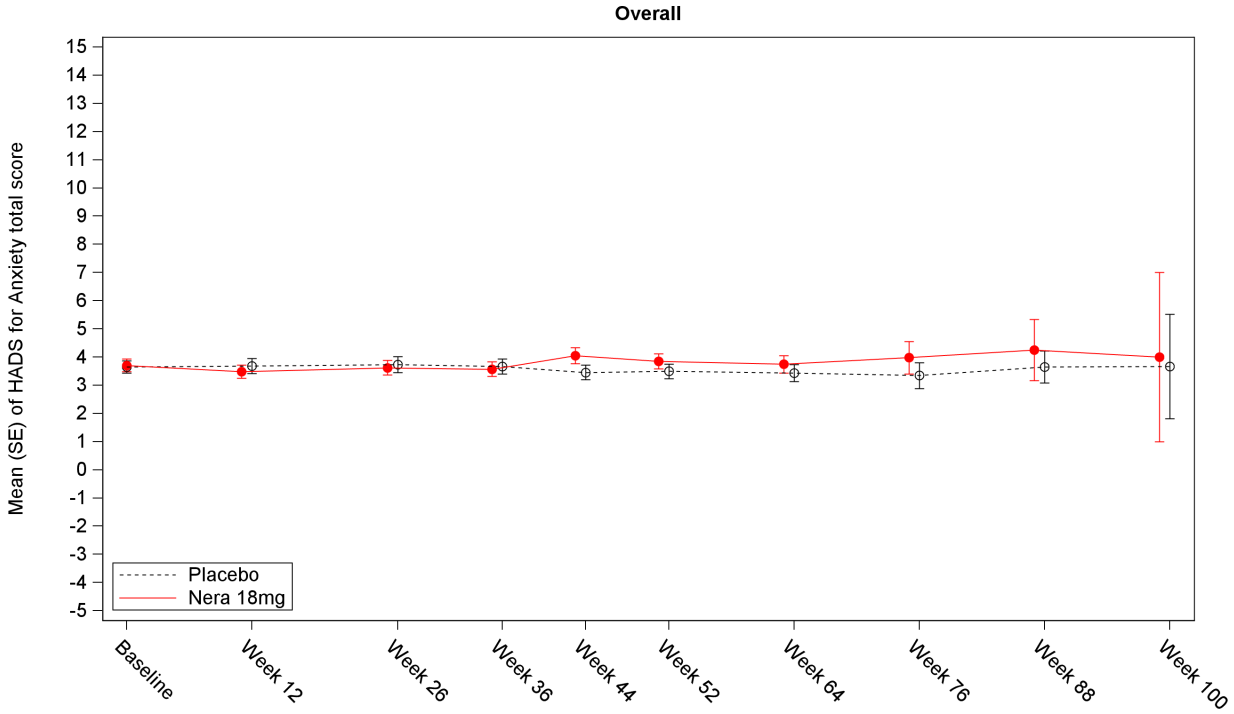

Number of patients

Placebo	169	159	155	150	147	148	107	46	17	3
Nera 18mg	170	160	148	143	140	138	105	45	16	2

Study: 1305-0023. Number of patients refers to the number of patients with observed data at visit.

Figure I.1.1.2.1.7: 1 Mean (SE) of HADS for Anxiety total score over the whole trial - 18mg - TS (NIN background)

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BI Trial No.: x1305p3.hta

Figure I.1.1.2.1.7: 1

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Overall																	
Baseline																	
Placebo	169	169	3.6	0.2	164 (100.0%)												
Nera 18mg	170	170	3.5	0.2	164 (100.0%)												
Week 12																	
Placebo		159	3.8	0.2	159 (97.0%)	0.2	0.2	-0.2	0.6								
Nera 18mg		160	3.9	0.2	160 (97.6%)	0.4	0.2	0.1	0.8	0.2	0.3	-0.3	0.7	0.4358			
Week 26																	
Placebo		155	4.2	0.3	155 (94.5%)	0.6	0.2	0.2	1.0								
Nera 18mg		148	3.9	0.3	148 (90.2%)	0.5	0.2	0.1	0.9	-0.1	0.3	-0.7	0.5	0.7794			
Week 36																	
Placebo		150	3.8	0.3	150 (91.5%)	0.3	0.2	-0.1	0.7								
Nera 18mg		143	4.0	0.3	143 (87.2%)	0.5	0.2	0.1	0.9	0.2	0.3	-0.3	0.8	0.3922			
Week 44																	
Placebo		147	3.8	0.3	147 (89.6%)	0.4	0.2	-0.1	0.8								
Nera 18mg		140	4.1	0.3	140 (85.4%)	0.7	0.2	0.3	1.1	0.4	0.3	-0.2	1.0	0.2302			
Week 52																	
Placebo		148	4.0	0.3	148 (90.2%)	0.6	0.2	0.2	1.1								
Nera 18mg		138	4.3	0.3	138 (84.1%)	1.0	0.2	0.5	1.4	0.3	0.3	-0.3	1.0	0.2933			
Week 64																	
Placebo		107	4.0	0.3	107 (65.2%)	0.6	0.2	0.1	1.0								
Nera 18mg		105	4.1	0.3	105 (64.0%)	1.0	0.2	0.5	1.4	0.4	0.3	-0.2	1.0	0.1809			
Week 76																	
Placebo		46	3.6	0.5	46 (28.0%)												
Nera 18mg		45	4.8	0.6	45 (27.4%)												
Week 88																	
Placebo		17	3.8	0.7	17 (10.4%)												
Nera 18mg		16	6.6	0.9	16 (9.8%)												
Week 100																	
Placebo		3	3.3	1.3	3 (1.8%)												
Nera 18mg		2	6.0	3.0	2 (1.2%)												
Age																	
Test for homogeneity (H0)^																	
Week 12														0.9586			

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 26														0.9425			
Week 36														0.3253			
Week 44														0.1697			
Week 52														0.2242			
Week 64														0.5001			
<65 years																	
Baseline																	
Placebo	65	65	3.4	0.3	64 (100.0%)												
Nera 18mg	64	64	2.7	0.3	62 (100.0%)												
Week 12																	
Placebo		62	3.7	0.4	62 (96.9%)	0.2	0.3	-0.4	0.8								
Nera 18mg		61	3.3	0.4	61 (98.4%)	0.4	0.3	-0.2	1.0	0.2	0.4	-0.6	1.0	0.6601			
Week 26																	
Placebo		62	3.7	0.4	62 (96.9%)	0.2	0.3	-0.4	0.9								
Nera 18mg		58	3.1	0.4	58 (93.5%)	0.1	0.3	-0.5	0.8	-0.1	0.5	-1.0	0.8	0.7973			
Week 36																	
Placebo		61	3.8	0.5	61 (95.3%)	0.3	0.3	-0.3	0.9								
Nera 18mg		54	3.1	0.4	54 (87.1%)	0.2	0.3	-0.5	0.8	-0.1	0.4	-1.0	0.8	0.8047			
Week 44																	
Placebo		61	3.9	0.5	61 (95.3%)	0.4	0.3	-0.2	1.1								
Nera 18mg		52	3.1	0.5	52 (83.9%)	0.3	0.4	-0.4	1.0	-0.2	0.5	-1.1	0.8	0.7372			
Week 52																	
Placebo		62	4.0	0.5	62 (96.9%)	0.5	0.4	-0.2	1.2								
Nera 18mg		52	3.1	0.5	52 (83.9%)	0.3	0.4	-0.4	1.1	-0.2	0.5	-1.2	0.9	0.7472			
Week 64																	
Placebo		47	3.7	0.5	47 (73.4%)	0.5	0.3	-0.2	1.2								
Nera 18mg		42	3.4	0.6	42 (67.7%)	0.7	0.4	-0.1	1.4	0.1	0.5	-0.8	1.1	0.7655			
Week 76																	
Placebo		19	3.7	0.8	19 (29.7%)												
Nera 18mg		11	1.5	0.7	11 (17.7%)												
Week 88																	
Placebo		5	4.4	1.3	5 (7.8%)												
Nera 18mg		4	6.8	2.5	4 (6.5%)												
Week 100																	
Placebo		2	4.0	2.0	2 (3.1%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Depression total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	104	104	3.8	0.3	100 (100.0%)												
Nera 18mg	106	106	3.9	0.3	102 (100.0%)												
Week 12																	
Placebo		97	3.9	0.3	97 (97.0%)	0.2	0.2	-0.3	0.7								
Nera 18mg		99	4.3	0.3	99 (97.1%)	0.4	0.2	-0.1	0.9	0.2	0.3	-0.4	0.9	0.5226			
Week 26																	
Placebo		93	4.5	0.4	93 (93.0%)	0.9	0.3	0.3	1.4								
Nera 18mg		90	4.5	0.3	90 (88.2%)	0.8	0.3	0.3	1.3	-0.1	0.4	-0.8	0.7	0.8378			
Week 36																	
Placebo		89	3.8	0.3	89 (89.0%)	0.3	0.2	-0.2	0.8								
Nera 18mg		89	4.5	0.3	89 (87.3%)	0.8	0.2	0.3	1.2	0.4	0.4	-0.2	1.1	0.2050			
Week 44																	
Placebo		86	3.8	0.3	86 (86.0%)	0.3	0.3	-0.3	0.8								
Nera 18mg		88	4.7	0.4	88 (86.3%)	1.0	0.3	0.4	1.5	0.7	0.4	-0.1	1.5	0.0751			
Week 52																	
Placebo		86	4.1	0.3	86 (86.0%)	0.7	0.3	0.1	1.3								
Nera 18mg		86	5.0	0.4	86 (84.3%)	1.3	0.3	0.7	1.9	0.7	0.4	-0.2	1.5	0.1234			
Week 64																	
Placebo		60	4.1	0.4	60 (60.0%)	0.6	0.3	0.0	1.2								
Nera 18mg		63	4.6	0.4	63 (61.8%)	1.2	0.3	0.6	1.8	0.6	0.4	-0.2	1.4	0.1556			
Week 76																	
Placebo		27	3.5	0.6	27 (27.0%)												
Nera 18mg		34	5.8	0.7	34 (33.3%)												
Week 88																	
Placebo		12	3.5	0.8	12 (12.0%)												
Nera 18mg		12	6.6	1.0	12 (11.8%)												
Week 100																	
Placebo		1	2.0	NC	1 (1.0%)												
Nera 18mg		2	6.0	3.0	2 (2.0%)												
Sex																	
Test for homogeneity (H0)^																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Depression total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 12														0.2065			
Week 26														0.7194			
Week 36														0.0598			
Week 44														0.9789			
Week 52														0.7020			
Week 64														0.1127			
Male																	
Baseline																	
Placebo	114	114	3.5	0.2	111 (100.0%)												
Nera 18mg	108	108	3.4	0.3	103 (100.0%)												
Week 12																	
Placebo		107	3.7	0.3	107 (96.4%)	0.2	0.2	-0.3	0.6								
Nera 18mg		100	4.1	0.3	100 (97.1%)	0.6	0.2	0.2	1.1	0.5	0.3	-0.2	1.1	0.1572			
Week 26																	
Placebo		103	4.1	0.4	103 (92.8%)	0.7	0.3	0.2	1.2								
Nera 18mg		92	4.0	0.3	92 (89.3%)	0.7	0.3	0.2	1.2	0.0	0.4	-0.7	0.7	0.9805			
Week 36																	
Placebo		99	3.6	0.3	99 (89.2%)	0.2	0.2	-0.2	0.7								
Nera 18mg		86	4.3	0.3	86 (83.5%)	0.9	0.2	0.4	1.4	0.6	0.3	-0.0	1.3	0.0611			
Week 44																	
Placebo		97	3.9	0.3	97 (87.4%)	0.5	0.3	0.0	1.0								
Nera 18mg		83	4.2	0.4	83 (80.6%)	0.9	0.3	0.4	1.5	0.4	0.4	-0.4	1.1	0.3195			
Week 52																	
Placebo		97	4.0	0.4	97 (87.4%)	0.8	0.3	0.2	1.3								
Nera 18mg		83	4.5	0.4	83 (80.6%)	1.2	0.3	0.6	1.8	0.5	0.4	-0.4	1.3	0.2610			
Week 64																	
Placebo		67	3.6	0.4	67 (60.4%)	0.5	0.3	-0.1	1.0								
Nera 18mg		62	4.5	0.5	62 (60.2%)	1.3	0.3	0.7	1.9	0.8	0.4	0.0	1.6	0.0376	0.37	0.02	0.71
Week 76																	
Placebo		30	3.8	0.7	30 (27.0%)												
Nera 18mg		26	5.7	0.9	26 (25.2%)												
Week 88																	
Placebo		12	3.8	0.8	12 (10.8%)												
Nera 18mg		9	7.4	1.2	9 (8.7%)												
Week 100																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Depression total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		1	2.0	NC	1 (0.9%)												
Nera 18mg		1	3.0	NC	1 (1.0%)												
Female																	
Baseline																	
Placebo	55	55	3.9	0.4	53 (100.0%)												
Nera 18mg	62	62	3.6	0.4	61 (100.0%)												
Week 12																	
Placebo		52	4.1	0.5	52 (98.1%)	0.3	0.3	-0.4	0.9								
Nera 18mg		60	3.7	0.4	60 (98.4%)	0.0	0.3	-0.6	0.6	-0.2	0.4	-1.1	0.6	0.5943			
Week 26																	
Placebo		52	4.3	0.5	52 (98.1%)	0.5	0.4	-0.2	1.2								
Nera 18mg		56	3.8	0.4	56 (91.8%)	0.3	0.3	-0.4	0.9	-0.2	0.5	-1.2	0.8	0.6681			
Week 36																	
Placebo		51	4.2	0.5	51 (96.2%)	0.4	0.3	-0.2	1.1								
Nera 18mg		57	3.5	0.4	57 (93.4%)	-0.0	0.3	-0.6	0.6	-0.4	0.5	-1.3	0.5	0.3418			
Week 44																	
Placebo		50	3.7	0.4	50 (94.3%)	0.0	0.4	-0.7	0.7								
Nera 18mg		57	4.0	0.5	57 (93.4%)	0.4	0.3	-0.3	1.1	0.4	0.5	-0.6	1.4	0.4302			
Week 52																	
Placebo		51	4.1	0.5	51 (96.2%)	0.3	0.4	-0.5	1.1								
Nera 18mg		55	3.9	0.5	55 (90.2%)	0.5	0.4	-0.2	1.3	0.2	0.6	-0.9	1.3	0.7106			
Week 64																	
Placebo		40	4.5	0.6	40 (75.5%)	0.7	0.4	-0.0	1.4								
Nera 18mg		43	3.6	0.5	43 (70.5%)	0.5	0.4	-0.2	1.2	-0.2	0.5	-1.2	0.8	0.6916			
Week 76																	
Placebo		16	3.2	0.7	16 (30.2%)												
Nera 18mg		19	3.5	0.8	19 (31.1%)												
Week 88																	
Placebo		5	3.8	1.2	5 (9.4%)												
Nera 18mg		7	5.6	1.4	7 (11.5%)												
Week 100																	
Placebo		2	4.0	2.0	2 (3.8%)												
Nera 18mg		1	9.0	NC	1 (1.6%)												
Baseline FVC percent predicted																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Depression total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Test for homogeneity (H0)^																	
Week 12														0.0135			
Week 26														0.9858			
Week 36														0.5409			
Week 44														0.7539			
Week 52														0.3206			
Week 64														0.2830			
<=70%																	
Baseline																	
Placebo	95	95	3.6	0.3	91 (100.0%)												
Nera 18mg	97	97	3.7	0.3	95 (100.0%)												
Week 12																	
Placebo		87	3.8	0.3	87 (95.6%)	0.3	0.2	-0.2	0.8								
Nera 18mg		92	4.8	0.3	92 (96.8%)	1.1	0.2	0.6	1.5	0.7	0.3	0.1	1.4	0.0315	0.32	0.03	0.61
Week 26																	
Placebo		85	4.5	0.4	85 (93.4%)	0.9	0.3	0.4	1.4								
Nera 18mg		85	4.5	0.4	85 (89.5%)	0.8	0.3	0.2	1.3	-0.1	0.4	-0.9	0.7	0.7795			
Week 36																	
Placebo		82	4.1	0.3	82 (90.1%)	0.6	0.3	0.1	1.1								
Nera 18mg		83	4.6	0.4	83 (87.4%)	0.9	0.3	0.4	1.4	0.4	0.4	-0.4	1.1	0.3294			
Week 44																	
Placebo		81	4.1	0.3	81 (89.0%)	0.7	0.3	0.1	1.2								
Nera 18mg		80	4.7	0.4	80 (84.2%)	1.1	0.3	0.5	1.6	0.4	0.4	-0.4	1.2	0.2941			
Week 52																	
Placebo		80	4.3	0.4	80 (87.9%)	0.9	0.3	0.3	1.5								
Nera 18mg		79	5.0	0.4	79 (83.2%)	1.5	0.3	0.9	2.1	0.6	0.4	-0.3	1.5	0.1697			
Week 64																	
Placebo		56	4.0	0.4	56 (61.5%)	0.8	0.3	0.2	1.4								
Nera 18mg		60	4.6	0.5	60 (63.2%)	1.5	0.3	0.9	2.0	0.7	0.4	-0.1	1.5	0.1004			
Week 76																	
Placebo		26	3.9	0.7	26 (28.6%)												
Nera 18mg		25	5.2	0.9	25 (26.3%)												
Week 88																	
Placebo		10	4.9	0.9	10 (11.0%)												
Nera 18mg		9	6.8	1.4	9 (9.5%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 100																	
Placebo		2	4.0	2.0	2 (2.2%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	74	74	3.7	0.3	73 (100.0%)												
Nera 18mg	73	73	3.1	0.3	69 (100.0%)												
Week 12																	
Placebo		72	3.8	0.4	72 (98.6%)	0.1	0.3	-0.4	0.6								
Nera 18mg		68	2.8	0.3	68 (98.6%)	-0.5	0.3	-1.0	0.1	-0.5	0.4	-1.3	0.2	0.1588			
Week 26																	
Placebo		70	3.8	0.4	70 (95.9%)	0.3	0.3	-0.3	0.9								
Nera 18mg		63	3.2	0.4	63 (91.3%)	0.2	0.3	-0.5	0.8	-0.1	0.4	-1.0	0.8	0.8240			
Week 36																	
Placebo		68	3.5	0.4	68 (93.2%)	-0.0	0.3	-0.6	0.5								
Nera 18mg		60	3.2	0.3	60 (87.0%)	-0.0	0.3	-0.6	0.6	0.0	0.4	-0.8	0.8	0.9662			
Week 44																	
Placebo		66	3.5	0.4	66 (90.4%)	-0.0	0.3	-0.6	0.6								
Nera 18mg		60	3.4	0.4	60 (87.0%)	0.2	0.3	-0.4	0.9	0.2	0.5	-0.7	1.1	0.6110			
Week 52																	
Placebo		68	3.8	0.4	68 (93.2%)	0.3	0.3	-0.4	0.9								
Nera 18mg		59	3.3	0.4	59 (85.5%)	0.2	0.4	-0.5	0.9	-0.1	0.5	-1.0	0.9	0.9130			
Week 64																	
Placebo		51	3.9	0.5	51 (69.9%)	0.3	0.3	-0.3	1.0								
Nera 18mg		45	3.4	0.5	45 (65.2%)	0.3	0.3	-0.3	1.0	0.0	0.5	-0.9	0.9	0.9740			
Week 76																	
Placebo		20	3.2	0.7	20 (27.4%)												
Nera 18mg		20	4.2	0.9	20 (29.0%)												
Week 88																	
Placebo		7	2.1	0.6	7 (9.6%)												
Nera 18mg		7	6.4	1.2	7 (10.1%)												
Week 100																	
Placebo		1	2.0	NC	1 (1.4%)												
Nera 18mg		2	6.0	3.0	2 (2.9%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Baseline HRCT pattern																	
Test for homogeneity (H0)^																	
Week 12														0.9494			
Week 26														0.8497			
Week 36														0.9164			
Week 44														0.6223			
Week 52														0.5687			
Week 64														0.3171			
UIP-like																	
Baseline																	
Placebo	116	116	3.6	0.3	113 (100.0%)												
Nera 18mg	121	121	3.6	0.3	118 (100.0%)												
Week 12																	
Placebo		110	3.7	0.3	110 (97.3%)	0.2	0.2	-0.2	0.6								
Nera 18mg		117	3.9	0.3	117 (99.2%)	0.4	0.2	-0.0	0.8	0.2	0.3	-0.4	0.8	0.5325			
Week 26																	
Placebo		106	4.0	0.3	106 (93.8%)	0.5	0.2	-0.0	0.9								
Nera 18mg		106	3.8	0.3	106 (89.8%)	0.3	0.2	-0.1	0.8	-0.1	0.3	-0.8	0.6	0.7360			
Week 36																	
Placebo		102	3.6	0.3	102 (90.3%)	0.2	0.2	-0.3	0.7								
Nera 18mg		102	3.9	0.3	102 (86.4%)	0.4	0.2	-0.0	0.9	0.2	0.3	-0.4	0.9	0.5092			
Week 44																	
Placebo		99	3.6	0.3	99 (87.6%)	0.3	0.3	-0.2	0.8								
Nera 18mg		100	4.2	0.4	100 (84.7%)	0.8	0.3	0.3	1.3	0.5	0.4	-0.3	1.2	0.2039			
Week 52																	
Placebo		100	3.7	0.4	100 (88.5%)	0.5	0.3	-0.1	1.0								
Nera 18mg		99	4.2	0.4	99 (83.9%)	0.9	0.3	0.4	1.5	0.5	0.4	-0.3	1.3	0.2340			
Week 64																	
Placebo		75	3.6	0.4	75 (66.4%)	0.2	0.3	-0.3	0.8								
Nera 18mg		76	4.0	0.4	76 (64.4%)	0.9	0.3	0.4	1.4	0.6	0.4	-0.1	1.4	0.0973			
Week 76																	
Placebo		30	2.9	0.5	30 (26.5%)												
Nera 18mg		32	4.8	0.7	32 (27.1%)												
Week 88																	
Placebo		14	3.4	0.7	14 (12.4%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Depression total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		15	6.5	1.0	15 (12.7%)												
Week 100																	
Placebo		2	2.0	0.0	2 (1.8%)												
Nera 18mg		2	6.0	3.0	2 (1.7%)												
Other fibrotic patterns																	
Baseline																	
Placebo	53	53	3.7	0.4	51 (100.0%)												
Nera 18mg	49	49	3.2	0.4	46 (100.0%)												
Week 12																	
Placebo		49	4.0	0.4	49 (96.1%)	0.2	0.3	-0.4	0.9								
Nera 18mg		43	3.8	0.4	43 (93.5%)	0.5	0.4	-0.2	1.2	0.2	0.5	-0.7	1.2	0.6359			
Week 26																	
Placebo		49	4.7	0.5	49 (96.1%)	1.0	0.4	0.3	1.7								
Nera 18mg		42	4.3	0.5	42 (91.3%)	1.0	0.4	0.2	1.8	0.0	0.5	-1.1	1.1	0.9946			
Week 36																	
Placebo		48	4.3	0.5	48 (94.1%)	0.5	0.3	-0.2	1.2								
Nera 18mg		41	4.0	0.5	41 (89.1%)	0.8	0.4	0.1	1.5	0.3	0.5	-0.7	1.3	0.5766			
Week 44																	
Placebo		48	4.2	0.5	48 (94.1%)	0.4	0.4	-0.3	1.2								
Nera 18mg		40	4.0	0.5	40 (87.0%)	0.6	0.4	-0.2	1.4	0.1	0.6	-0.9	1.2	0.8050			
Week 52																	
Placebo		48	4.7	0.6	48 (94.1%)	0.9	0.4	0.1	1.7								
Nera 18mg		39	4.4	0.6	39 (84.8%)	1.0	0.4	0.1	1.9	0.1	0.6	-1.1	1.3	0.9213			
Week 64																	
Placebo		32	4.9	0.6	32 (62.7%)	1.3	0.4	0.5	2.1								
Nera 18mg		29	4.3	0.7	29 (63.0%)	1.3	0.4	0.4	2.1	-0.1	0.6	-1.2	1.1	0.9013			
Week 76																	
Placebo		16	4.8	1.0	16 (31.4%)												
Nera 18mg		13	4.5	1.3	13 (28.3%)												
Week 88																	
Placebo		3	5.7	1.9	3 (5.9%)												
Nera 18mg		1	8.0	NC	1 (2.2%)												
Week 100																	
Placebo		1	6.0	NC	1 (2.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Depression total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Underlying ILD diagnosis																	
Test for homogeneity (H0)^																	
Week 12														0.9085			
Week 26														0.7907			
Week 36														0.0346			
Week 44														0.3327			
Week 52														0.1690			
Week 64														0.2115			
iNSIP																	
Baseline																	
Placebo	32	32	4.5	0.6	31 (100.0%)												
Nera 18mg	27	27	3.0	0.5	25 (100.0%)												
Week 12																	
Placebo		29	4.3	0.7	29 (93.5%)	0.3	0.4	-0.6	1.2								
Nera 18mg		23	3.6	0.6	23 (92.0%)	0.4	0.5	-0.6	1.4	0.1	0.7	-1.2	1.4	0.8747			
Week 26																	
Placebo		29	3.9	0.7	29 (93.5%)	-0.2	0.5	-1.2	0.7								
Nera 18mg		23	2.9	0.5	23 (92.0%)	-0.2	0.5	-1.2	0.9	0.1	0.7	-1.3	1.5	0.9216			
Week 36																	
Placebo		28	3.7	0.6	28 (90.3%)	-0.1	0.4	-1.0	0.7								
Nera 18mg		20	4.2	0.5	20 (80.0%)	1.4	0.5	0.4	2.4	1.6	0.7	0.2	2.9	0.0241	0.65	0.07	1.23
Week 44																	
Placebo		28	4.3	0.7	28 (90.3%)	0.3	0.5	-0.7	1.3								
Nera 18mg		19	4.3	1.1	19 (76.0%)	1.4	0.6	0.3	2.6	1.1	0.8	-0.4	2.6	0.1529			
Week 52																	
Placebo		27	4.0	0.7	27 (87.1%)	0.2	0.5	-0.9	1.3								
Nera 18mg		17	4.2	0.9	17 (68.0%)	1.6	0.7	0.3	2.9	1.4	0.9	-0.3	3.1	0.0961			
Week 64																	
Placebo		19	4.6	0.8	19 (61.3%)	0.3	0.5	-0.8	1.3								
Nera 18mg		13	4.0	0.9	13 (52.0%)	1.6	0.6	0.4	2.9	1.3	0.8	-0.3	3.0	0.1074			
Week 76																	
Placebo		10	4.4	0.9	10 (32.3%)												
Nera 18mg		6	6.5	2.1	6 (24.0%)												
Week 88																	
Placebo		5	4.2	1.2	5 (16.1%)												

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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		2	6.5	1.5	2 (8.0%)												
Week 100																	
Placebo		1	2.0	NC	1 (3.2%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Unclassifiable IIP																	
Baseline																	
Placebo	46	46	3.0	0.3	44 (100.0%)												
Nera 18mg	32	32	4.6	0.6	32 (100.0%)												
Week 12																	
Placebo		44	3.3	0.4	44 (100.0%)	0.2	0.4	-0.5	0.9								
Nera 18mg		32	4.3	0.6	32 (100.0%)	-0.0	0.4	-0.8	0.8	-0.2	0.6	-1.3	0.9	0.6993			
Week 26																	
Placebo		40	3.7	0.5	40 (90.9%)	0.5	0.4	-0.3	1.3								
Nera 18mg		28	4.4	0.6	28 (87.5%)	-0.1	0.5	-1.0	0.9	-0.5	0.6	-1.8	0.7	0.3848			
Week 36																	
Placebo		38	3.4	0.4	38 (86.4%)	0.5	0.4	-0.3	1.2								
Nera 18mg		27	4.4	0.6	27 (84.4%)	-0.1	0.5	-1.0	0.8	-0.6	0.6	-1.8	0.6	0.3218			
Week 44																	
Placebo		37	3.5	0.5	37 (84.1%)	0.6	0.4	-0.3	1.4								
Nera 18mg		27	4.8	0.7	27 (84.4%)	0.1	0.5	-0.9	1.1	-0.4	0.7	-1.7	0.9	0.4993			
Week 52																	
Placebo		38	3.7	0.6	38 (86.4%)	0.8	0.5	-0.1	1.7								
Nera 18mg		28	4.6	0.7	28 (87.5%)	-0.0	0.5	-1.1	1.1	-0.8	0.7	-2.3	0.6	0.2430			
Week 64																	
Placebo		30	2.8	0.4	30 (68.2%)	0.4	0.4	-0.5	1.2								
Nera 18mg		20	4.7	0.7	20 (62.5%)	0.4	0.5	-0.6	1.5	0.1	0.7	-1.3	1.4	0.9212			
Week 76																	
Placebo		13	2.7	0.7	13 (29.5%)												
Nera 18mg		14	5.2	1.4	14 (43.8%)												
Week 88																	
Placebo		3	4.3	1.9	3 (6.8%)												
Nera 18mg		5	7.8	1.8	5 (15.6%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	9.0	NC	1 (3.1%)												
HP																	

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Baseline																	
Placebo	38	38	2.7	0.3	38 (100.0%)												
Nera 18mg	43	43	4.0	0.4	40 (100.0%)												
Week 12																	
Placebo		37	3.0	0.4	37 (97.4%)	0.0	0.4	-0.8	0.8								
Nera 18mg		38	4.4	0.5	38 (95.0%)	0.4	0.4	-0.4	1.1	0.4	0.6	-0.7	1.5	0.5003			
Week 26																	
Placebo		38	4.3	0.6	38 (100.0%)	1.4	0.4	0.5	2.2								
Nera 18mg		36	4.8	0.6	36 (90.0%)	0.7	0.4	-0.1	1.6	-0.6	0.6	-1.8	0.5	0.2876			
Week 36																	
Placebo		37	2.9	0.3	37 (97.4%)	-0.1	0.4	-0.9	0.6								
Nera 18mg		36	4.1	0.4	36 (90.0%)	0.1	0.4	-0.6	0.9	0.3	0.6	-0.8	1.4	0.6204			
Week 44																	
Placebo		37	3.2	0.4	37 (97.4%)	0.2	0.4	-0.6	1.1								
Nera 18mg		35	4.5	0.6	35 (87.5%)	0.7	0.4	-0.2	1.5	0.4	0.6	-0.8	1.7	0.4652			
Week 52																	
Placebo		37	3.5	0.5	37 (97.4%)	0.5	0.5	-0.4	1.4								
Nera 18mg		35	4.9	0.6	35 (87.5%)	0.9	0.5	-0.0	1.9	0.4	0.7	-0.9	1.8	0.5279			
Week 64																	
Placebo		24	3.8	0.7	24 (63.2%)	0.8	0.5	-0.2	1.7								
Nera 18mg		27	5.0	0.8	27 (67.5%)	1.2	0.5	0.3	2.1	0.5	0.7	-0.8	1.7	0.4753			
Week 76																	
Placebo		10	2.1	0.7	10 (26.3%)												
Nera 18mg		8	6.3	1.2	8 (20.0%)												
Week 88																	
Placebo		1	0.0	NC	1 (2.6%)												
Nera 18mg		2	6.5	2.5	2 (5.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	3.0	NC	1 (2.5%)												
Autoimmune ILD																	
Baseline																	
Placebo	29	29	3.9	0.5	28 (100.0%)												
Nera 18mg	43	43	2.6	0.3	43 (100.0%)												
Week 12																	
Placebo		27	4.1	0.6	27 (96.4%)	0.3	0.5	-0.6	1.2								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		43	3.6	0.5	43 (100.0%)	0.7	0.4	-0.0	1.4	0.4	0.6	-0.7	1.6	0.4683			
Week 26																	
Placebo		27	4.4	0.7	27 (96.4%)	0.5	0.5	-0.4	1.5								
Nera 18mg		39	3.6	0.6	39 (90.7%)	1.0	0.4	0.2	1.8	0.5	0.6	-0.8	1.7	0.4683			
Week 36																	
Placebo		26	4.2	0.8	26 (92.9%)	0.4	0.5	-0.5	1.3								
Nera 18mg		38	3.2	0.5	38 (88.4%)	0.5	0.4	-0.3	1.2	0.1	0.6	-1.1	1.3	0.8430			
Week 44																	
Placebo		24	3.3	0.7	24 (85.7%)	-0.2	0.5	-1.2	0.9								
Nera 18mg		37	3.1	0.5	37 (86.0%)	0.4	0.4	-0.4	1.2	0.6	0.7	-0.8	1.9	0.3968			
Week 52																	
Placebo		25	4.3	0.8	25 (89.3%)	0.8	0.6	-0.4	1.9								
Nera 18mg		36	3.6	0.6	36 (83.7%)	1.1	0.5	0.2	2.1	0.4	0.7	-1.1	1.8	0.6001			
Week 64																	
Placebo		17	4.2	0.8	17 (60.7%)	0.3	0.6	-0.7	1.4								
Nera 18mg		28	3.0	0.6	28 (65.1%)	0.8	0.4	-0.1	1.7	0.5	0.7	-0.9	1.9	0.5161			
Week 76																	
Placebo		7	2.3	0.9	7 (25.0%)												
Nera 18mg		8	1.1	0.4	8 (18.6%)												
Week 88																	
Placebo		4	3.5	1.6	4 (14.3%)												
Nera 18mg		3	3.7	1.5	3 (7.0%)												
Week 100																	
Placebo		2	4.0	2.0	2 (7.1%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Other ILD																	
Baseline																	
Placebo	24	24	4.7	0.6	23 (100.0%)												
Nera 18mg	25	25	3.0	0.5	24 (100.0%)												
Week 12																	
Placebo		22	4.9	0.7	22 (95.7%)	0.4	0.5	-0.6	1.4								
Nera 18mg		24	3.6	0.6	24 (100.0%)	0.6	0.5	-0.4	1.5	0.2	0.7	-1.2	1.6	0.8096			
Week 26																	
Placebo		21	5.3	0.7	21 (91.3%)	0.7	0.6	-0.4	1.8								
Nera 18mg		22	3.6	0.5	22 (91.7%)	0.9	0.5	-0.2	1.9	0.2	0.8	-1.4	1.7	0.8349			
Week 36																	

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		21	5.6	0.9	21 (91.3%)	1.2	0.5	0.2	2.2								
Nera 18mg		22	4.2	0.8	22 (91.7%)	1.3	0.5	0.3	2.2	0.0	0.7	-1.4	1.4	0.9754			
Week 44																	
Placebo		21	5.3	0.8	21 (91.3%)	0.9	0.6	-0.2	2.1								
Nera 18mg		22	4.4	0.8	22 (91.7%)	1.5	0.6	0.4	2.6	0.6	0.8	-1.0	2.1	0.4855			
Week 52																	
Placebo		21	5.2	0.8	21 (91.3%)	0.8	0.6	-0.5	2.0								
Nera 18mg		22	4.1	0.6	22 (91.7%)	1.4	0.6	0.2	2.5	0.6	0.9	-1.1	2.3	0.5056			
Week 64																	
Placebo		17	5.2	0.9	17 (73.9%)	1.3	0.6	0.1	2.4								
Nera 18mg		17	3.9	0.7	17 (70.8%)	1.1	0.6	-0.0	2.2	-0.2	0.8	-1.8	1.4	0.8378			
Week 76																	
Placebo		6	8.0	2.0	6 (26.1%)												
Nera 18mg		9	4.8	1.2	9 (37.5%)												
Week 88																	
Placebo		4	4.0	1.6	4 (17.4%)												
Nera 18mg		4	7.5	2.4	4 (16.7%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Region																	
Test for homogeneity (H0)^																	
Week 12														0.9955			
Week 26														0.7520			
Week 36														0.7385			
Week 44														0.4256			
Week 52														0.8123			
Week 64														0.8835			
Europe																	
Baseline																	
Placebo	78	78	3.9	0.3	77 (100.0%)												
Nera 18mg	67	67	3.8	0.3	64 (100.0%)												
Week 12																	

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo		76	4.2	0.4	76 (98.7%)	0.4	0.3	-0.1	1.0								
Nera 18mg		61	4.4	0.4	61 (95.3%)	0.7	0.3	0.1	1.3	0.2	0.4	-0.6	1.0	0.5834			
Week 26																	
Placebo		73	4.9	0.4	73 (94.8%)	1.1	0.3	0.5	1.7								
Nera 18mg		56	4.6	0.4	56 (87.5%)	1.0	0.3	0.3	1.6	-0.2	0.4	-1.0	0.7	0.7261			
Week 36																	
Placebo		68	4.2	0.4	68 (88.3%)	0.6	0.3	0.0	1.2								
Nera 18mg		54	4.5	0.4	54 (84.4%)	0.9	0.3	0.3	1.6	0.3	0.4	-0.5	1.2	0.4382			
Week 44																	
Placebo		68	4.0	0.4	68 (88.3%)	0.4	0.3	-0.3	1.0								
Nera 18mg		54	4.6	0.4	54 (84.4%)	1.0	0.3	0.3	1.7	0.6	0.5	-0.3	1.6	0.1789			
Week 52																	
Placebo		69	4.6	0.4	69 (89.6%)	1.0	0.3	0.3	1.6								
Nera 18mg		53	5.0	0.5	53 (82.8%)	1.4	0.4	0.6	2.1	0.4	0.5	-0.6	1.4	0.4023			
Week 64																	
Placebo		50	4.4	0.5	50 (64.9%)	0.9	0.3	0.3	1.6								
Nera 18mg		42	5.1	0.6	42 (65.6%)	1.5	0.4	0.8	2.2	0.6	0.5	-0.4	1.5	0.2217			
Week 76																	
Placebo		19	4.1	0.8	19 (24.7%)												
Nera 18mg		15	6.6	1.2	15 (23.4%)												
Week 88																	
Placebo		5	3.6	1.3	5 (6.5%)												
Nera 18mg		3	8.0	0.6	3 (4.7%)												
Week 100																	
Placebo		1	6.0	NC	1 (1.3%)												
Nera 18mg		1	9.0	NC	1 (1.6%)												
Asia																	
Baseline																	
Placebo	45	45	3.2	0.4	43 (100.0%)												
Nera 18mg	41	41	3.0	0.5	39 (100.0%)												
Week 12																	
Placebo		41	3.0	0.4	41 (95.3%)	-0.3	0.4	-1.0	0.4								
Nera 18mg		39	3.1	0.5	39 (100.0%)	-0.1	0.4	-0.8	0.7	0.2	0.5	-0.8	1.3	0.6584			
Week 26																	
Placebo		42	3.1	0.5	42 (97.7%)	-0.1	0.4	-0.9	0.7								
Nera 18mg		34	3.2	0.6	34 (87.2%)	0.3	0.4	-0.6	1.1	0.4	0.6	-0.8	1.5	0.5007			

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 36																	
Placebo		41	3.0	0.5	41 (95.3%)	-0.2	0.4	-0.9	0.6								
Nera 18mg		33	3.4	0.6	33 (84.6%)	0.3	0.4	-0.5	1.1	0.4	0.5	-0.7	1.5	0.4478			
Week 44																	
Placebo		38	3.1	0.6	38 (88.4%)	0.1	0.4	-0.7	0.9								
Nera 18mg		31	4.2	0.9	31 (79.5%)	1.0	0.5	0.1	1.9	0.9	0.6	-0.3	2.1	0.1292			
Week 52																	
Placebo		39	3.1	0.6	39 (90.7%)	0.1	0.4	-0.8	1.0								
Nera 18mg		32	3.6	0.7	32 (82.1%)	0.9	0.5	-0.1	1.9	0.8	0.7	-0.5	2.2	0.2040			
Week 64																	
Placebo		28	3.1	0.6	28 (65.1%)	0.1	0.4	-0.7	1.0								
Nera 18mg		26	3.2	0.7	26 (66.7%)	0.5	0.5	-0.4	1.4	0.4	0.6	-0.8	1.7	0.5077			
Week 76																	
Placebo		16	2.9	0.9	16 (37.2%)												
Nera 18mg		12	4.4	1.5	12 (30.8%)												
Week 88																	
Placebo		7	4.3	1.3	7 (16.3%)												
Nera 18mg		8	7.0	1.7	8 (20.5%)												
Week 100																	
Placebo		1	2.0	NC	1 (2.3%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	
Baseline																	
Placebo	30	30	2.8	0.4	30 (100.0%)												
Nera 18mg	37	37	3.1	0.4	37 (100.0%)												
Week 12																	
Placebo		28	3.6	0.5	28 (93.3%)	0.5	0.4	-0.4	1.3								
Nera 18mg		37	3.7	0.5	37 (100.0%)	0.5	0.4	-0.3	1.2	0.0	0.6	-1.1	1.2	0.9829			
Week 26																	
Placebo		26	3.5	0.6	26 (86.7%)	0.4	0.5	-0.6	1.3								
Nera 18mg		34	3.2	0.5	34 (91.9%)	-0.1	0.4	-1.0	0.7	-0.5	0.7	-1.8	0.8	0.4533			
Week 36																	
Placebo		27	3.2	0.4	27 (90.0%)	0.1	0.5	-0.8	1.0								
Nera 18mg		34	3.7	0.5	34 (91.9%)	0.3	0.4	-0.5	1.1	0.2	0.6	-1.0	1.4	0.6860			
Week 44																	
Placebo		27	3.7	0.5	27 (90.0%)	0.6	0.5	-0.4	1.6								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Depression total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		33	3.5	0.5	33 (89.2%)	0.2	0.5	-0.7	1.1	-0.4	0.7	-1.7	0.9	0.5350			
Week 52																	
Placebo		26	3.2	0.4	26 (86.7%)	0.2	0.6	-0.9	1.3								
Nera 18mg		33	3.6	0.5	33 (89.2%)	0.3	0.5	-0.6	1.3	0.1	0.7	-1.3	1.6	0.8484			
Week 64																	
Placebo		19	3.3	0.5	19 (63.3%)	0.3	0.5	-0.8	1.3								
Nera 18mg		25	3.3	0.6	25 (67.6%)	0.4	0.5	-0.6	1.3	0.1	0.7	-1.3	1.5	0.8948			
Week 76																	
Placebo		9	3.8	0.9	9 (30.0%)												
Nera 18mg		13	3.3	0.8	13 (35.1%)												
Week 88																	
Placebo		5	3.2	1.0	5 (16.7%)												
Nera 18mg		4	5.5	0.9	4 (10.8%)												
Week 100																	
Placebo		1	2.0	NC	1 (3.3%)												
Nera 18mg		1	3.0	NC	1 (2.7%)												
Rest of the World																	
Baseline																	
Placebo	16	16	5.2	0.8	14 (100.0%)												
Nera 18mg	25	25	3.7	0.5	24 (100.0%)												
Week 12																	
Placebo		14	4.6	0.9	14 (100.0%)	0.0	0.6	-1.2	1.3								
Nera 18mg		23	4.2	0.6	23 (95.8%)	0.5	0.5	-0.5	1.4	0.4	0.8	-1.1	2.0	0.5918			
Week 26																	
Placebo		14	5.3	1.0	14 (100.0%)	0.6	0.7	-0.7	2.0								
Nera 18mg		24	4.5	0.7	24 (100.0%)	0.8	0.5	-0.2	1.8	0.2	0.9	-1.5	1.9	0.8121			
Week 36																	
Placebo		14	5.1	1.0	14 (100.0%)	0.4	0.6	-0.8	1.7								
Nera 18mg		22	4.0	0.7	22 (91.7%)	0.2	0.5	-0.8	1.2	-0.2	0.8	-1.8	1.4	0.7629			
Week 44																	
Placebo		14	5.2	1.1	14 (100.0%)	0.5	0.7	-0.9	1.9								
Nera 18mg		22	4.0	0.6	22 (91.7%)	0.4	0.6	-0.7	1.5	-0.1	0.9	-1.9	1.6	0.8771			
Week 52																	
Placebo		14	5.8	1.2	14 (100.0%)	1.0	0.8	-0.5	2.6								
Nera 18mg		20	4.5	0.9	20 (83.3%)	0.9	0.6	-0.4	2.1	-0.2	1.0	-2.1	1.7	0.8441			
Week 64																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Depression total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.1.2.1.7: 2 Adjusted mean (SE) of absolute change from baseline in HADS for Depression total score (MMRM) over the whole trial - 18mg - TS (NIN background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		10	5.4	1.4	10 (71.4%)	0.5	0.7	-0.9	2.0								
Nera 18mg		12	4.3	1.0	12 (50.0%)	1.5	0.6	0.2	2.7	1.0	1.0	-0.9	2.9	0.3144			
Week 76																	
Placebo		2	3.0	2.0	2 (14.3%)												
Nera 18mg		5	3.8	1.8	5 (20.8%)												
Week 88																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	4.0	NC	1 (4.2%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline HADS for Depression total score at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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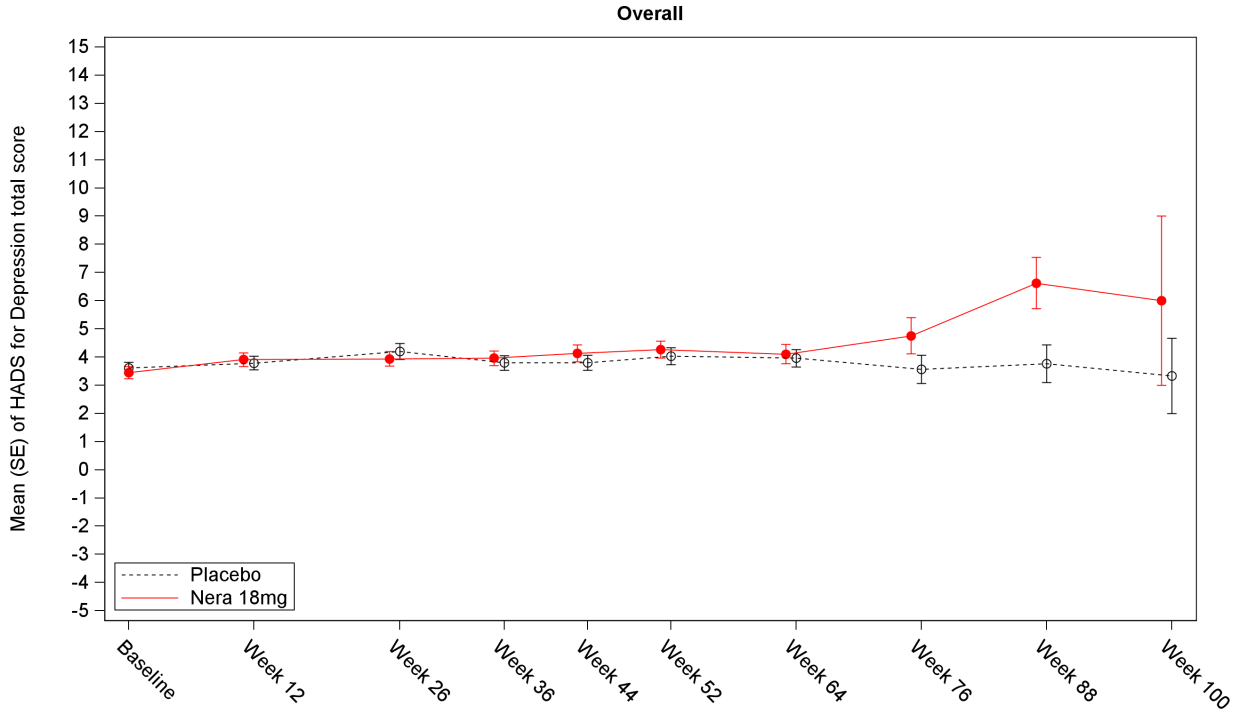

Number of patients

Placebo	169	159	155	150	147	148	107	46	17	3
Nera 18mg	170	160	148	143	140	138	105	45	16	2

Study: 1305-0023. Number of patients refers to the number of patients with observed data at visit.

Figure I.1.1.2.1.7: 2 Mean (SE) of HADS for Depression total score over the whole trial - 18mg - TS (NIN background)

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Figure I.1.1.2.1.7: 2

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I.1.1.3 Further analysis

I.1.1.3.1 Time to event analyses: treatment policy approach to lung transplant

Table I.1.1.3.1: 1 Cox model for time to first confirmed acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n (e/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (e/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	38 (18/ 20)	22.5	16.62	170	25 (14/ 11)	14.7	10.66	0.59	(0.36, 0.99)	0.0448	
Age												0.6015
<65 years	65	8 (4/ 4)	12.3	8.73	64	6 (4/ 2)	9.4	6.68	0.76	(0.26, 2.21)	0.6177	
>=65 years	104	30 (14/ 16)	28.8	21.90	106	19 (10/ 9)	17.9	13.14	0.55	(0.31, 0.98)	0.0442	
Sex												0.9168
Male	114	31 (15/ 16)	27.2	20.44	108	20 (12/ 8)	18.5	13.61	0.62	(0.35, 1.09)	0.0960	
Female	55	7 (3/ 4)	12.7	9.09	62	5 (2/ 3)	8.1	5.72	0.58	(0.18, 1.83)	0.3521	
Baseline FVC percent predicted												0.1635
<=70%	95	25 (13/ 12)	26.3	19.95	97	13 (9/ 4)	13.4	9.56	0.45	(0.23, 0.88)	0.0195	
>70%	74	13 (5/ 8)	17.6	12.58	73	12 (5/ 7)	16.4	12.18	0.94	(0.43, 2.07)	0.8751	
Baseline HRCT pattern												0.1801
UIP-like	116	24 (13/ 11)	20.7	15.22	121	21 (12/ 9)	17.4	12.59	0.74	(0.41, 1.33)	0.3112	
Other fibrotic patterns	53	14 (5/ 9)	26.4	19.71	49	4 (2/ 2)	8.2	5.92	0.31	(0.10, 0.95)	0.0399	
Underlying ILD diagnosis												0.2763
iNSIP	32	5 (0/ 5)	15.6	10.84	27	8 (5/ 3)	29.6	23.63	1.78	(0.58, 5.53)	0.3150	
Unclassifiable IIP	46	14 (8/ 6)	30.4	23.35	32	6 (3/ 3)	18.8	12.86	0.57	(0.22, 1.49)	0.2531	
HP	38	6 (3/ 3)	15.8	11.49	43	5 (2/ 3)	11.6	8.66	0.59	(0.18, 1.95)	0.3830	
Autoimmune ILD	29	7 (3/ 4)	24.1	17.93	43	4 (2/ 2)	9.3	6.75	0.31	(0.09, 1.05)	0.0604	
Other ILD	24	6 (4/ 2)	25.0	19.13	25	2 (2/ 0)	8.0	5.41	0.35	(0.07, 1.76)	0.2037	
Region												0.8160
Europe	78	17 (8/ 9)	21.8	16.17	67	8 (4/ 4)	11.9	8.83	0.48	(0.21, 1.12)	0.0910	
Asia	45	12 (7/ 5)	26.7	19.74	41	8 (5/ 3)	19.5	14.21	0.55	(0.22, 1.34)	0.1891	
Canada and USA	30	5 (2/ 3)	16.7	11.57	37	5 (4/ 1)	13.5	9.28	0.99	(0.29, 3.45)	0.9929	
Rest of the World	16	4 (1/ 3)	25.0	20.45	25	4 (1/ 3)	16.0	11.90	0.64	(0.16, 2.61)	0.5326	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed acute ILD exacerbations, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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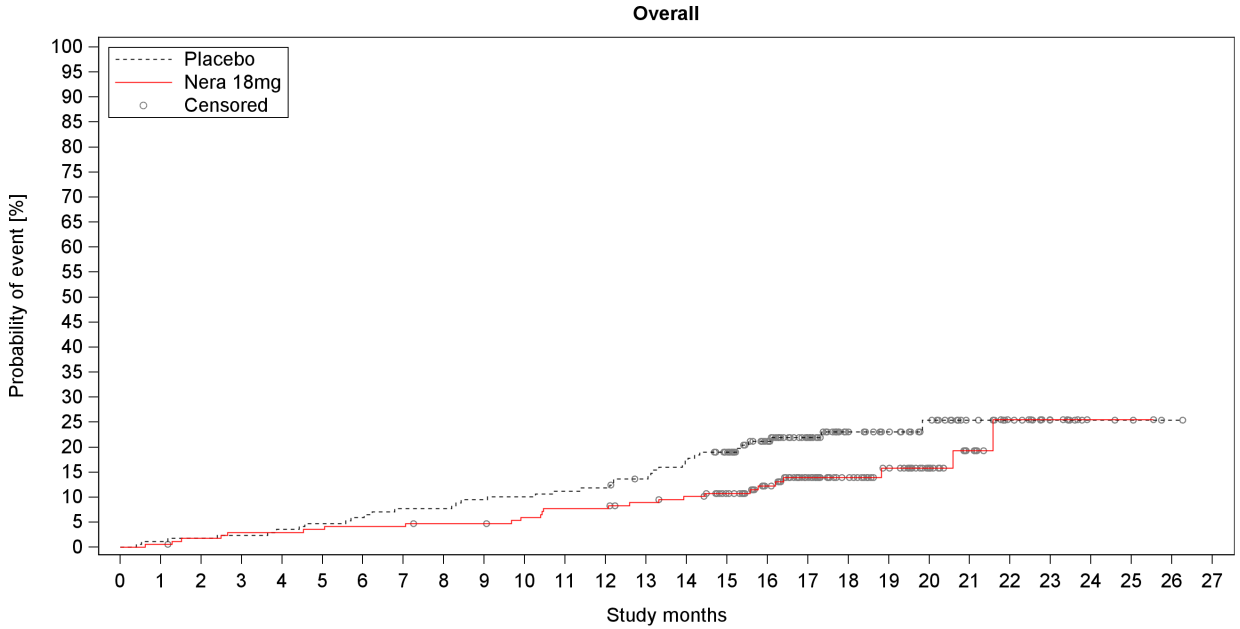

Number at risk (percentage relative to baseline)

Placebo	169	167	166	165	163	161	159	156	156	153	152	150	149	144	138	127	102	80	52	43	32	19	14	8	4	3	1	0
%	100.0	98.8	98.2	97.6	96.4	95.3	94.1	92.3	92.3	90.5	89.9	88.8	88.2	85.2	81.7	75.1	60.4	47.3	30.8	25.4	18.9	11.2	8.3	4.7	2.4	1.8	0.6	0.0
Nera 18mg	170	169	166	164	164	163	162	162	160	160	157	154	154	150	146	135	108	84	57	43	31	17	10	5	1	1	0	0
%	100.0	99.4	97.6	96.5	96.5	95.9	95.3	95.3	94.1	94.1	92.4	90.6	90.6	88.2	85.9	79.4	63.5	49.4	33.5	25.3	18.2	10.0	5.9	2.9	0.6	0.6	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	10	32	53	80	89	99	112	117	123	127	128	130	131
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.2	1.2	5.9	18.9	31.4	47.3	52.7	58.6	66.3	69.2	72.8	75.1	75.7	76.9	77.5
Nera 18mg	0	0	1	1	1	1	1	1	2	2	3	3	3	5	7	17	42	64	91	104	116	129	135	140	144	144	145	145
%	0.0	0.0	0.6	0.6	0.6	0.6	0.6	0.6	1.2	1.2	1.8	1.8	1.8	2.9	4.1	10.0	24.7	37.6	53.5	61.2	68.2	75.9	79.4	82.4	84.7	84.7	85.3	85.3

Study: 1305-0023

Figure I.1.1.3.1: 1 Time to first confirmed acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate - 18mg - FAS (NIN background)

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Table I.1.1.3.1: 2 Cox model for time to first confirmed or suspected acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n (e/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (e/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	42 (24/ 18)	24.9	18.69	170	28 (17/ 11)	16.5	12.03	0.60	(0.37, 0.96)	0.0346	
Age												0.3112
<65 years	65	9 (5/ 4)	13.8	9.86	64	8 (6/ 2)	12.5	9.05	0.92	(0.35, 2.38)	0.8558	
>=65 years	104	33 (19/ 14)	31.7	24.73	106	20 (11/ 9)	18.9	13.86	0.52	(0.29, 0.90)	0.0205	
Sex												0.7720
Male	114	34 (19/ 15)	29.8	22.79	108	21 (13/ 8)	19.4	14.31	0.59	(0.34, 1.01)	0.0556	
Female	55	8 (5/ 3)	14.5	10.60	62	7 (4/ 3)	11.3	8.14	0.70	(0.25, 1.93)	0.4855	
Baseline FVC percent predicted												0.2169
<=70%	95	28 (18/ 10)	29.5	22.74	97	16 (12/ 4)	16.5	11.92	0.47	(0.25, 0.88)	0.0175	
>70%	74	14 (6/ 8)	18.9	13.79	73	12 (5/ 7)	16.4	12.18	0.88	(0.41, 1.92)	0.7560	
Baseline HRCT pattern												0.4368
UIP-like	116	27 (17/ 10)	23.3	17.40	121	22 (13/ 9)	18.2	13.25	0.67	(0.38, 1.18)	0.1696	
Other fibrotic patterns	53	15 (7/ 8)	28.3	21.57	49	6 (4/ 2)	12.2	9.00	0.43	(0.17, 1.12)	0.0840	
Underlying ILD diagnosis												0.3017
iNSIP	32	6 (2/ 4)	18.8	13.56	27	9 (6/ 3)	33.3	26.80	1.65	(0.58, 4.69)	0.3484	
Unclassifiable IIP	46	15 (9/ 6)	32.6	25.05	32	6 (3/ 3)	18.8	12.86	0.54	(0.21, 1.39)	0.2018	
HP	38	7 (4/ 3)	18.4	13.51	43	5 (2/ 3)	11.6	8.66	0.51	(0.16, 1.62)	0.2501	
Autoimmune ILD	29	7 (4/ 3)	24.1	18.44	43	6 (4/ 2)	14.0	10.38	0.45	(0.15, 1.34)	0.1512	
Other ILD	24	7 (5/ 2)	29.2	22.72	25	2 (2/ 0)	8.0	5.41	0.28	(0.06, 1.34)	0.1109	
Region												0.8983
Europe	78	19 (12/ 7)	24.4	18.35	67	9 (5/ 4)	13.4	10.02	0.48	(0.22, 1.07)	0.0745	
Asia	45	12 (7/ 5)	26.7	19.74	41	9 (6/ 3)	22.0	16.16	0.62	(0.26, 1.47)	0.2733	
Canada and USA	30	7 (4/ 3)	23.3	17.15	37	6 (5/ 1)	16.2	11.19	0.82	(0.27, 2.45)	0.7176	
Rest of the World	16	4 (1/ 3)	25.0	20.45	25	4 (1/ 3)	16.0	11.90	0.61	(0.15, 2.50)	0.4952	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed or suspected acute ILD exacerbations, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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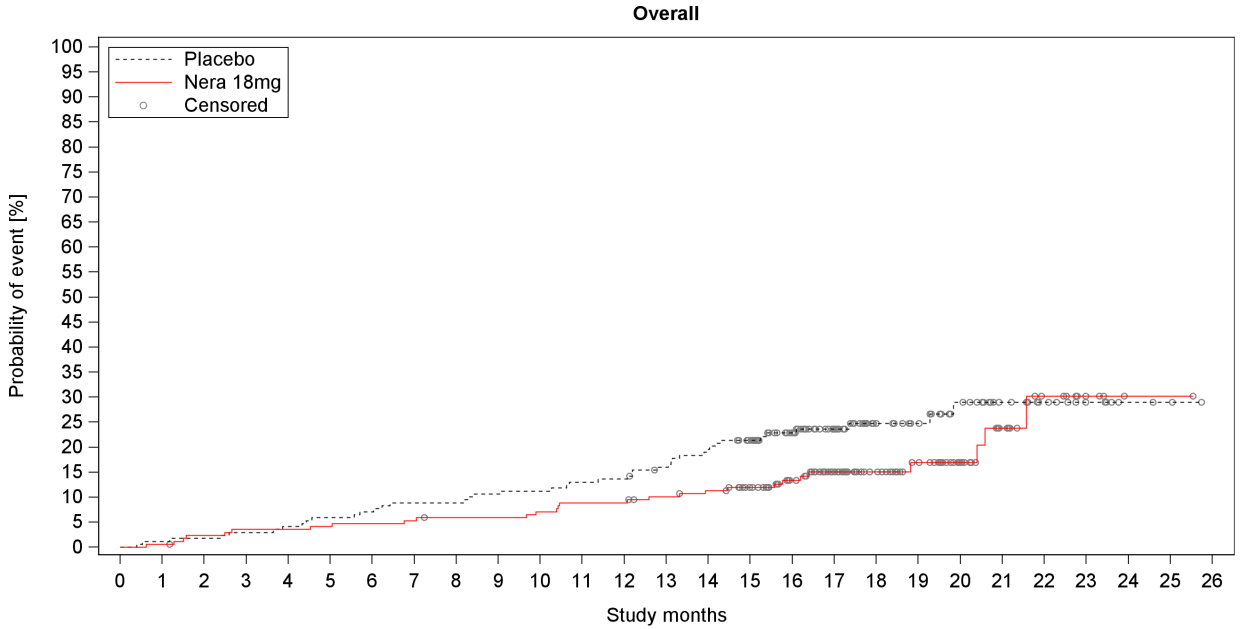

Number at risk (percentage relative to baseline)

Placebo	169	167	166	164	162	159	157	154	154	151	150	147	146	140	134	123	99	77	51	42	30	18	13	7	3	2	0
%	100.0	98.8	98.2	97.0	95.9	94.1	92.9	91.1	91.1	89.3	88.8	87.0	86.4	82.8	79.3	72.8	58.6	45.6	30.2	24.9	17.8	10.7	7.7	4.1	1.8	1.2	0.0
Nera 18mg	170	169	165	163	163	162	161	160	158	158	156	153	153	149	145	134	107	84	57	43	31	16	9	4	1	1	0
%	100.0	99.4	97.1	95.9	95.9	95.3	94.7	94.1	92.9	92.9	91.8	90.0	90.0	87.6	85.3	78.8	62.9	49.4	33.5	25.3	18.2	9.4	5.3	2.4	0.6	0.6	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	10	32	53	78	87	97	109	114	120	124	125	127
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.2	1.2	5.9	18.9	31.4	46.2	51.5	57.4	64.5	67.5	71.0	73.4	74.0	75.1
Nera 18mg	0	0	1	1	1	1	1	1	2	2	2	2	2	4	6	16	41	62	89	102	114	127	133	138	141	141	142
%	0.0	0.0	0.6	0.6	0.6	0.6	0.6	0.6	1.2	1.2	1.2	1.2	1.2	2.4	3.5	9.4	24.1	36.5	52.4	60.0	67.1	74.7	78.2	81.2	82.9	82.9	83.5

Study: 1305-0023

Figure I.1.1.3.1: 2 Time to first confirmed or suspected acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate - 18mg - FAS (NIN background)

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Figure I.1.1.3.1: 2

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Table I.1.1.3.1: 3 Cox model for time to death - treatment policy approach to lung transplant - over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	28	16.6	11.71	170	18	10.6	7.49	0.57	(0.31, 1.03)	0.0647	
Age												0.7471
<65 years	65	5	7.7	5.25	64	3	4.7	3.27	0.71	(0.17, 3.02)	0.6469	
>=65 years	104	23	22.1	15.97	106	15	14.2	10.09	0.55	(0.29, 1.06)	0.0735	
Sex												0.9359
Male	114	23	20.2	14.41	108	14	13.0	9.19	0.58	(0.30, 1.12)	0.1054	
Female	55	5	9.1	6.28	62	4	6.5	4.54	0.61	(0.16, 2.30)	0.4682	
Baseline FVC percent predicted												0.2185
<=70%	95	18	18.9	13.54	97	9	9.3	6.43	0.43	(0.19, 0.96)	0.0397	
>70%	74	10	13.5	9.41	73	9	12.3	8.97	0.92	(0.37, 2.29)	0.8609	
Baseline HRCT pattern												0.4858
UIP-like	116	19	16.4	11.63	121	15	12.4	8.69	0.64	(0.33, 1.27)	0.2032	
Other fibrotic patterns	53	9	17.0	11.86	49	3	6.1	4.43	0.38	(0.10, 1.41)	0.1484	
Underlying ILD diagnosis												0.4884
iNSIP	32	5	15.6	10.84	27	7	25.9	19.74	1.32	(0.41, 4.26)	0.6370	
Unclassifiable IIP	46	9	19.6	13.75	32	4	12.5	8.08	0.61	(0.19, 2.02)	0.4215	
HP	38	3	7.9	5.55	43	4	9.3	6.88	0.84	(0.18, 3.85)	0.8195	
Autoimmune ILD	29	6	20.7	14.74	43	3	7.0	4.98	0.25	(0.06, 1.00)	0.0493	
Other ILD	24	5	20.8	15.22	25	0	0.0	0.00	0.00	(NC, NC)	0.9878	
Region												0.9906
Europe	78	12	15.4	11.03	67	6	9.0	6.60	0.50	(0.18, 1.35)	0.1688	
Asia	45	9	20.0	13.96	41	6	14.6	10.21	0.58	(0.20, 1.64)	0.3042	
Canada and USA	30	3	10.0	6.48	37	2	5.4	3.51	0.63	(0.10, 3.82)	0.6177	
Rest of the World	16	4	25.0	20.41	25	4	16.0	11.89	0.64	(0.15, 2.64)	0.5355	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb). The subgroup model additionally includes the subgroup and treatment by subgroup interaction. Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined). N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk. NC=not calculable.

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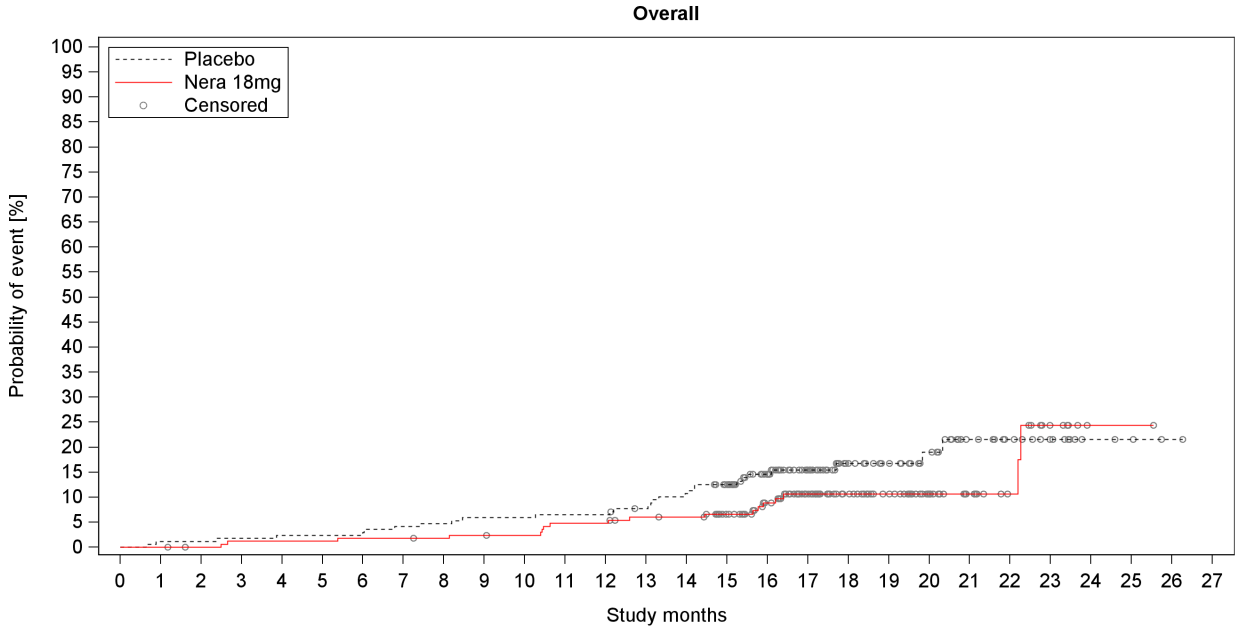

Number at risk (percentage relative to baseline)

Placebo	169	167	167	166	165	165	165	162	161	159	159	158	158	154	149	138	112	88	58	47	36	22	17	10	4	3	1	0
%	100.0	98.8	98.8	98.2	97.6	97.6	97.6	95.9	95.3	94.1	94.1	93.5	93.5	91.1	88.2	81.7	66.3	52.1	34.3	27.8	21.3	13.0	10.1	5.9	2.4	1.8	0.6	0.0
Nera 18mg	170	170	168	166	166	166	165	165	164	163	162	158	158	154	152	140	112	87	59	46	33	19	13	6	1	1	0	0
%	100.0	100.0	98.8	97.6	97.6	97.6	97.1	97.1	96.5	95.9	95.3	92.9	92.9	90.6	89.4	82.4	65.9	51.2	34.7	27.1	19.4	11.2	7.6	3.5	0.6	0.6	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	10	33	56	85	96	106	119	124	131	137	138	140	141
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.2	1.2	5.9	19.5	33.1	50.3	56.8	62.7	70.4	73.4	77.5	81.1	81.7	82.8	83.4
Nera 18mg	0	0	2	2	2	2	2	2	3	3	4	4	4	6	8	19	44	67	95	108	121	135	141	146	151	151	152	152
%	0.0	0.0	1.2	1.2	1.2	1.2	1.2	1.2	1.8	1.8	2.4	2.4	2.4	3.5	4.7	11.2	25.9	39.4	55.9	63.5	71.2	79.4	82.9	85.9	88.8	88.8	89.4	89.4

Study: 1305-0023

Figure I.1.1.3.1: 3 Time to death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate - 18mg - FAS (NIN background)

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Figure I.1.1.3.1: 3

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Table I.1.1.3.1: 4 Cox model for time to first confirmed acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	18	10.7	7.87	170	14	8.2	5.97	0.72	(0.36, 1.44)	0.3510	
Age												0.5803
<65 years	65	4	6.2	4.36	64	4	6.3	4.45	1.00	(0.25, 4.01)	0.9946	
>=65 years	104	14	13.5	10.22	106	10	9.4	6.92	0.63	(0.28, 1.43)	0.2684	
Sex												0.6525
Male	114	15	13.2	9.89	108	12	11.1	8.16	0.81	(0.38, 1.73)	0.5794	
Female	55	3	5.5	3.90	62	2	3.2	2.29	0.52	(0.09, 3.10)	0.4686	
Baseline FVC percent predicted												0.5226
<=70%	95	13	13.7	10.38	97	9	9.3	6.62	0.62	(0.26, 1.44)	0.2643	
>70%	74	5	6.8	4.84	73	5	6.8	5.08	1.01	(0.29, 3.49)	0.9923	
Baseline HRCT pattern												0.4902
UIP-like	116	13	11.2	8.25	121	12	9.9	7.19	0.82	(0.37, 1.80)	0.6139	
Other fibrotic patterns	53	5	9.4	7.05	49	2	4.1	2.96	0.43	(0.08, 2.22)	0.3131	
Underlying ILD diagnosis												0.9992
iNSIP	32	0	0.0	0.00	27	5	18.5	14.77	>10	(NC, NC)	0.9884	
Unclassifiable IIP	46	8	17.4	13.35	32	3	9.4	6.43	0.47	(0.12, 1.81)	0.2744	
HP	38	3	7.9	5.75	43	2	4.7	3.46	0.53	(0.09, 3.19)	0.4867	
Autoimmune ILD	29	3	10.3	7.69	43	2	4.7	3.38	0.37	(0.06, 2.26)	0.2842	
Other ILD	24	4	16.7	12.75	25	2	8.0	5.41	0.43	(0.08, 2.38)	0.3328	
Region												0.6679
Europe	78	8	10.3	7.61	67	4	6.0	4.41	0.51	(0.15, 1.70)	0.2714	
Asia	45	7	15.6	11.52	41	5	12.2	8.88	0.64	(0.20, 2.03)	0.4457	
Canada and USA	30	2	6.7	4.63	37	4	10.8	7.42	1.87	(0.34, 10.25)	0.4717	
Rest of the World	16	1	6.3	5.11	25	1	4.0	2.98	0.72	(0.04, 11.65)	0.8151	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb). The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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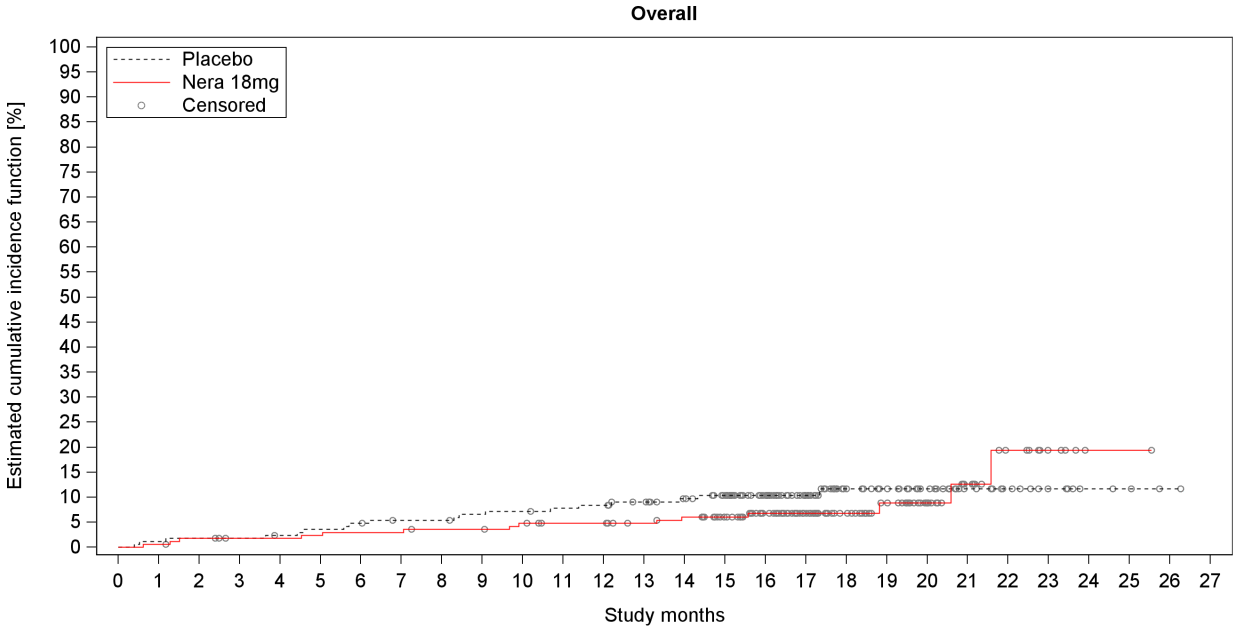

Number at risk (percentage relative to baseline)

Placebo	169	167	166	165	163	161	159	156	156	153	152	150	149	144	138	127	101	80	52	43	32	19	14	8	4	3	1	0
%	100.0	98.8	98.2	97.6	96.4	95.3	94.1	92.3	92.3	90.5	89.9	88.8	88.2	85.2	81.7	75.1	59.8	47.3	30.8	25.4	18.9	11.2	8.3	4.7	2.4	1.8	0.6	0.0
Nera 18mg	170	169	166	164	164	163	162	162	160	160	157	154	154	150	146	135	108	84	57	43	31	17	10	5	1	1	0	0
%	100.0	99.4	97.6	96.5	96.5	95.9	95.3	95.3	94.1	94.1	92.4	90.6	90.6	88.2	85.9	79.4	63.5	49.4	33.5	25.3	18.2	10.0	5.9	2.9	0.6	0.6	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	1	2	2	2	4	4	5	5	6	6	10	15	25	51	72	99	108	119	132	137	143	147	148	150	151
%	0.0	0.0	0.0	0.6	1.2	1.2	1.2	2.4	2.4	3.0	3.0	3.6	3.6	5.9	8.9	14.8	30.2	42.6	58.6	63.9	70.4	78.1	81.1	84.6	87.0	87.6	88.8	89.3
Nera 18mg	0	0	1	3	3	3	3	3	4	4	5	8	8	12	14	25	51	75	102	115	127	140	146	151	155	155	156	156
%	0.0	0.0	0.6	1.8	1.8	1.8	1.8	1.8	2.4	2.4	2.9	4.7	4.7	7.1	8.2	14.7	30.0	44.1	60.0	67.6	74.7	82.4	85.9	88.8	91.2	91.2	91.8	91.8

Study: 1305-0023

Figure I.1.1.3.1: 4 Time to first confirmed acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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Figure I.1.1.3.1: 4

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Table I.1.1.3.1: 5 Cox model for time to first confirmed or suspected acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial - 18mg - FAS (NIN background)

Subgroup	Placebo				Nera 18mg				Nera 18mg vs Placebo			
Category	N	n	%	Rate°	N	n	%	Rate°	Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	24	14.2	10.68	170	17	10.0	7.30	0.65	(0.35, 1.21)	0.1723	
Age												0.2287
<65 years	65	5	7.7	5.48	64	6	9.4	6.79	1.20	(0.36, 3.95)	0.7676	
>=65 years	104	19	18.3	14.24	106	11	10.4	7.62	0.50	(0.24, 1.06)	0.0722	
Sex												0.9282
Male	114	19	16.7	12.74	108	13	12.0	8.86	0.67	(0.33, 1.37)	0.2754	
Female	55	5	9.1	6.62	62	4	6.5	4.65	0.63	(0.17, 2.36)	0.4925	
Baseline FVC percent predicted												0.5568
<=70%	95	18	18.9	14.62	97	12	12.4	8.94	0.57	(0.28, 1.20)	0.1389	
>70%	74	6	8.1	5.91	73	5	6.8	5.08	0.87	(0.27, 2.88)	0.8248	
Baseline HRCT pattern												0.9545
UIP-like	116	17	14.7	10.96	121	13	10.7	7.83	0.65	(0.32, 1.35)	0.2527	
Other fibrotic patterns	53	7	13.2	10.07	49	4	8.2	6.00	0.63	(0.18, 2.15)	0.4587	
Underlying ILD diagnosis												0.2122
iNSIP	32	2	6.3	4.52	27	6	22.2	17.87	3.75	(0.75, 18.76)	0.1083	
Unclassifiable IIP	46	9	19.6	15.04	32	3	9.4	6.43	0.44	(0.12, 1.65)	0.2250	
HP	38	4	10.5	7.72	43	2	4.7	3.46	0.39	(0.07, 2.14)	0.2771	
Autoimmune ILD	29	4	13.8	10.54	43	4	9.3	6.92	0.55	(0.14, 2.24)	0.4046	
Other ILD	24	5	20.8	16.23	25	2	8.0	5.41	0.33	(0.06, 1.75)	0.1933	
Region												0.7067
Europe	78	12	15.4	11.59	67	5	7.5	5.57	0.43	(0.15, 1.23)	0.1173	
Asia	45	7	15.6	11.52	41	6	14.6	10.78	0.75	(0.25, 2.24)	0.6003	
Canada and USA	30	4	13.3	9.80	37	5	13.5	9.32	1.17	(0.31, 4.40)	0.8141	
Rest of the World	16	1	6.3	5.11	25	1	4.0	2.98	0.64	(0.04, 10.39)	0.7546	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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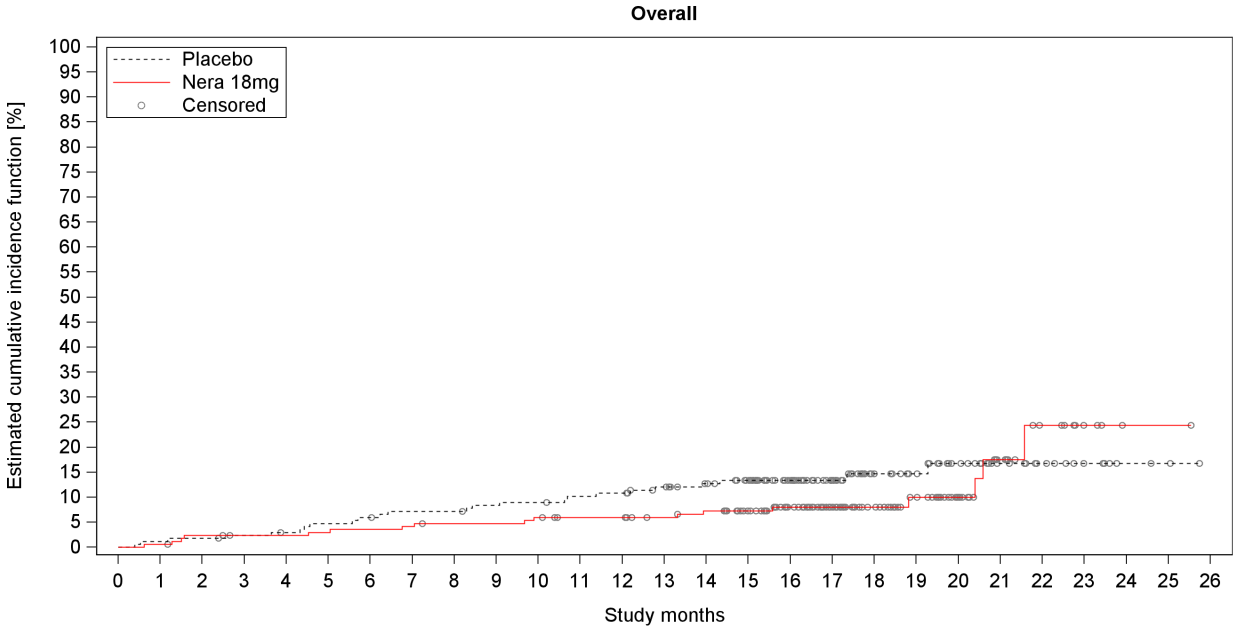

Number at risk (percentage relative to baseline)

Placebo	169	167	166	164	162	159	157	154	154	151	150	147	146	140	134	123	98	77	51	42	30	18	13	7	3	2	0
%	100.0	98.8	98.2	97.0	95.9	94.1	92.9	91.1	91.1	89.3	88.8	87.0	86.4	82.8	79.3	72.8	58.0	45.6	30.2	24.9	17.8	10.7	7.7	4.1	1.8	1.2	0.0
Nera 18mg	170	169	165	163	163	162	161	160	158	158	156	153	153	149	145	134	107	84	57	43	31	16	9	4	1	1	0
%	100.0	99.4	97.1	95.9	95.9	95.3	94.7	94.1	92.9	92.9	91.8	90.0	90.0	87.6	85.3	78.8	62.9	49.4	33.5	25.3	18.2	9.4	5.3	2.4	0.6	0.6	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	1	2	2	2	3	3	4	4	5	5	9	14	24	49	70	95	104	115	127	132	138	142	143	145
%	0.0	0.0	0.0	0.6	1.2	1.2	1.2	1.8	1.8	2.4	2.4	3.0	3.0	5.3	8.3	14.2	29.0	41.4	56.2	61.5	68.0	75.1	78.1	81.7	84.0	84.6	85.8
Nera 18mg	0	0	1	3	3	3	3	3	4	4	4	7	7	11	13	24	50	73	100	113	125	138	144	149	152	152	153
%	0.0	0.0	0.6	1.8	1.8	1.8	1.8	1.8	2.4	2.4	2.4	4.1	4.1	6.5	7.6	14.1	29.4	42.9	58.8	66.5	73.5	81.2	84.7	87.6	89.4	89.4	90.0

Study: 1305-0023

Figure I.1.1.3.1: 5 Time to first confirmed or suspected acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial, estimated cumulative incidence function - 18mg - FAS (NIN background)

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I.1.2 Population with non-AF background

I.1.2.1 Efficacy Analysis

I.1.2.1.1 Time to event analyses

I.1.2.1.1.1 Analyses of composite endpoints

I.1.2.1.1.1.1 Time to first confirmed acute ILD exacerbation or death

Table I.1.2.1.1.1.1: 1 Cox model for time to first confirmed acute ILD exacerbation or death over the whole trial - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n (e/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (e/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	222	50 (22/ 28)	22.5	16.83	220	26 (13/ 13)	11.8	8.40	0.57	(0.35, 0.92)	0.0207	
Age												0.3165
<65 years	83	12 (6/ 6)	14.5	10.25	88	9 (5/ 4)	10.2	7.08	0.82	(0.34, 1.94)	0.6445	
>=65 years	139	38 (16/ 22)	27.3	21.11	132	17 (8/ 9)	12.9	9.33	0.48	(0.27, 0.85)	0.0126	
Sex												0.4817
Male	116	30 (14/ 16)	25.9	19.99	111	13 (5/ 8)	11.7	8.43	0.48	(0.25, 0.94)	0.0319	
Female	106	20 (8/ 12)	18.9	13.60	109	13 (8/ 5)	11.9	8.38	0.68	(0.34, 1.38)	0.2876	
Baseline FVC percent predicted												0.1722
<=70%	118	39 (17/ 22)	33.1	25.76	96	15 (9/ 6)	15.6	11.31	0.45	(0.25, 0.82)	0.0093	
>70%	104	11 (5/ 6)	10.6	7.55	124	11 (4/ 7)	8.9	6.22	0.93	(0.40, 2.20)	0.8777	
Baseline HRCT pattern												0.6824
UIP-like	158	36 (17/ 19)	22.8	17.29	154	18 (7/ 11)	11.7	8.32	0.53	(0.30, 0.94)	0.0307	
Other fibrotic patterns	64	14 (5/ 9)	21.9	15.76	66	8 (6/ 2)	12.1	8.60	0.66	(0.27, 1.61)	0.3629	
Underlying ILD diagnosis												0.4631
iNSIP	40	8 (4/ 4)	20.0	13.90	55	8 (3/ 5)	14.5	10.48	0.84	(0.32, 2.26)	0.7354	
Unclassifiable IIP	36	6 (1/ 5)	16.7	11.96	40	5 (4/ 1)	12.5	9.03	0.92	(0.28, 3.02)	0.8842	
HP	39	12 (7/ 5)	30.8	27.52	30	3 (1/ 2)	10.0	7.20	0.32	(0.09, 1.15)	0.0811	
Autoimmune ILD	71	14 (6/ 8)	19.7	14.27	70	5 (1/ 4)	7.1	4.91	0.34	(0.12, 0.94)	0.0384	
Other ILD	36	10 (4/ 6)	27.8	21.00	25	5 (4/ 1)	20.0	14.64	0.90	(0.31, 2.64)	0.8445	
Region												0.2290
Europe	40	7 (2/ 5)	17.5	13.33	53	10 (5/ 5)	18.9	14.56	1.20	(0.45, 3.16)	0.7139	
Asia	106	20 (12/ 8)	18.9	13.17	107	13 (6/ 7)	12.1	8.41	0.70	(0.35, 1.42)	0.3235	
Canada and USA	30	9 (3/ 6)	30.0	23.79	17	0 (0/ 0)	0.0	0.00	0.00	(NC, NC)	0.9831	
Rest of the World	46	14 (5/ 9)	30.4	25.50	43	3 (2/ 1)	7.0	4.94	0.22	(0.06, 0.79)	0.0199	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed acute ILD exacerbations, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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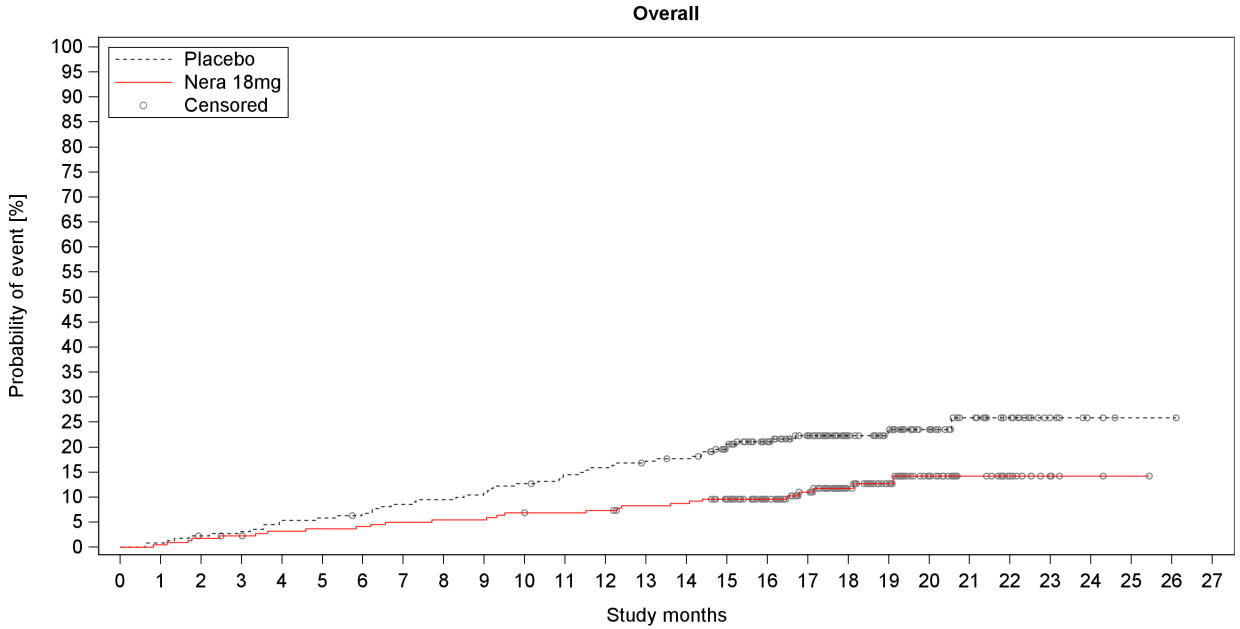

Number at risk (percentage relative to baseline)

Placebo	222	220	216	214	210	208	205	201	199	196	192	187	184	180	178	161	136	114	80	64	43	29	20	7	3	1	1	0
%	100.0	99.1	97.3	96.4	94.6	93.7	92.3	90.5	89.6	88.3	86.5	84.2	82.9	81.1	80.2	72.5	61.3	51.4	36.0	28.8	19.4	13.1	9.0	3.2	1.4	0.5	0.5	0.0
Nera 18mg	220	219	216	214	211	210	209	207	206	206	203	202	201	197	196	186	149	127	87	65	41	23	16	4	2	1	0	0
%	100.0	99.5	98.2	97.3	95.9	95.5	95.0	94.1	93.6	93.6	92.3	91.8	91.4	89.5	89.1	84.5	67.7	57.7	39.5	29.5	18.6	10.5	7.3	1.8	0.9	0.5	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	1	1	1	1	2	2	2	2	2	3	3	4	5	16	40	60	94	109	130	143	152	165	169	171	171	172
%	0.0	0.0	0.5	0.5	0.5	0.5	0.9	0.9	0.9	0.9	0.9	1.4	1.4	1.8	2.3	7.2	18.0	27.0	42.3	49.1	58.6	64.4	68.5	74.3	76.1	77.0	77.0	77.5
Nera 18mg	0	0	0	1	2	2	2	2	2	2	2	3	3	5	5	13	50	70	109	130	153	171	178	190	192	193	194	194
%	0.0	0.0	0.0	0.5	0.9	0.9	0.9	0.9	0.9	0.9	0.9	1.4	1.4	2.3	2.3	5.9	22.7	31.8	49.5	59.1	69.5	77.7	80.9	86.4	87.3	87.7	88.2	88.2

Study: 1305-0023

Figure I.1.2.1.1.1.1: 1 Time to first confirmed acute ILD exacerbation or death over the whole trial, Kaplan-Meier estimate - 18mg - FAS (non-AF background)

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Figure I.1.2.1.1.1.1: 1

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I.1.2.1.1.1.2 Time to first confirmed or suspected acute ILD exacerbation or death

Table I.1.2.1.1.1.2: 1 Cox model for time to first confirmed or suspected acute ILD exacerbation or death over the whole trial - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n (e/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (e/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	222	55 (33/ 22)	24.8	18.98	220	30 (18/ 12)	13.6	9.83	0.58	(0.37, 0.91)	0.0172	
Age												0.2382
<65 years	83	15 (12/ 3)	18.1	13.29	88	12 (9/ 3)	13.6	9.63	0.84	(0.39, 1.81)	0.6581	
>=65 years	139	40 (21/ 19)	28.8	22.60	132	18 (9/ 9)	13.6	9.96	0.48	(0.27, 0.84)	0.0097	
Sex												0.7124
Male	116	32 (21/ 11)	27.6	21.86	111	16 (9/ 7)	14.4	10.58	0.54	(0.29, 0.99)	0.0447	
Female	106	23 (12/ 11)	21.7	16.04	109	14 (9/ 5)	12.8	9.09	0.63	(0.33, 1.23)	0.1805	
Baseline FVC percent predicted												0.2549
<=70%	118	41 (23/ 18)	34.7	27.80	96	17 (12/ 5)	17.7	13.03	0.48	(0.27, 0.85)	0.0112	
>70%	104	14 (10/ 4)	13.5	9.83	124	13 (6/ 7)	10.5	7.43	0.84	(0.39, 1.81)	0.6485	
Baseline HRCT pattern												0.7819
UIP-like	158	38 (23/ 15)	24.1	18.51	154	20 (10/ 10)	13.0	9.32	0.55	(0.32, 0.96)	0.0342	
Other fibrotic patterns	64	17 (10/ 7)	26.6	20.11	66	10 (8/ 2)	15.2	11.01	0.64	(0.29, 1.40)	0.2611	
Underlying ILD diagnosis												0.7464
iNSIP	40	10 (8/ 2)	25.0	18.16	55	9 (4/ 5)	16.4	11.89	0.68	(0.27, 1.67)	0.3937	
Unclassifiable IIP	36	6 (2/ 4)	16.7	11.99	40	5 (4/ 1)	12.5	9.03	0.87	(0.27, 2.88)	0.8250	
HP	39	13 (9/ 4)	33.3	30.56	30	4 (2/ 2)	13.3	9.81	0.39	(0.13, 1.22)	0.1073	
Autoimmune ILD	71	16 (9/ 7)	22.5	16.78	70	7 (3/ 4)	10.0	7.05	0.43	(0.18, 1.05)	0.0638	
Other ILD	36	10 (5/ 5)	27.8	21.36	25	5 (5/ 0)	20.0	14.65	0.86	(0.29, 2.53)	0.7823	
Region												0.3226
Europe	40	8 (6/ 2)	20.0	15.86	53	12 (7/ 5)	22.6	18.01	1.17	(0.48, 2.88)	0.7244	
Asia	106	21 (14/ 7)	19.8	13.98	107	13 (7/ 6)	12.1	8.41	0.66	(0.33, 1.32)	0.2428	
Canada and USA	30	10 (4/ 6)	33.3	27.04	17	0 (0/ 0)	0.0	0.00	0.00	(NC, NC)	0.9817	
Rest of the World	46	16 (9/ 7)	34.8	30.63	43	5 (4/ 1)	11.6	8.51	0.32	(0.12, 0.90)	0.0297	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed or suspected acute ILD exacerbations, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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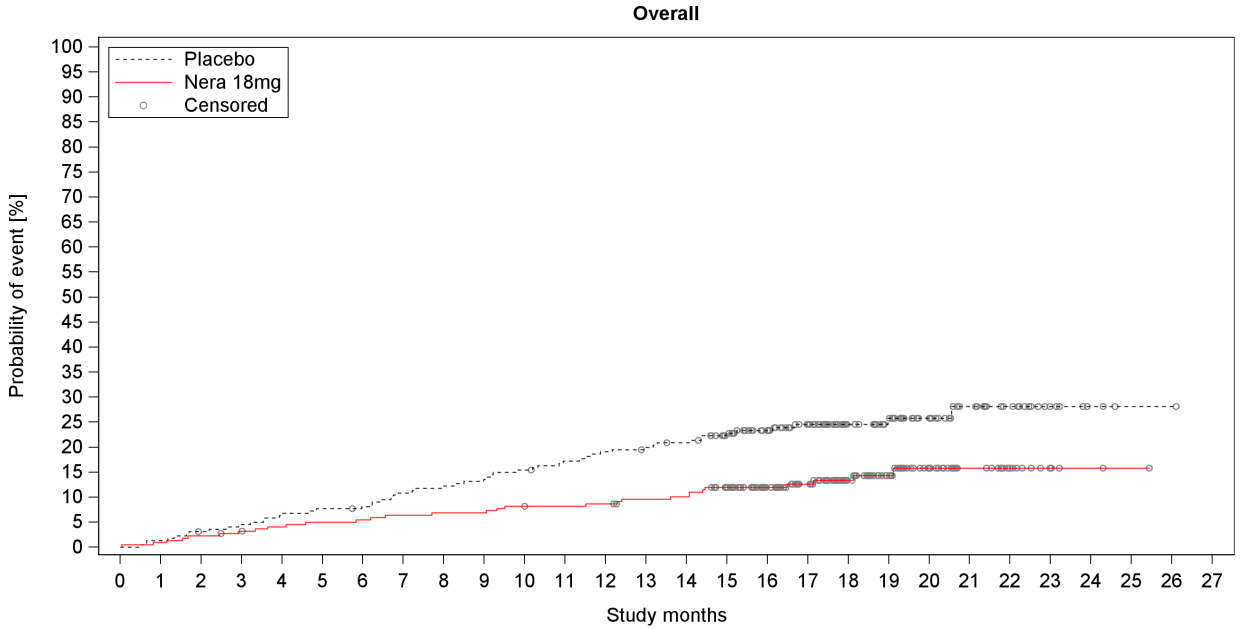

Number at risk (percentage relative to baseline)

Placebo	222	219	214	211	207	204	202	196	193	190	186	181	177	174	171	156	132	110	76	61	42	28	19	7	3	1	1	0
%	100.0	98.6	96.4	95.0	93.2	91.9	91.0	88.3	86.9	85.6	83.8	81.5	79.7	78.4	77.0	70.3	59.5	49.5	34.2	27.5	18.9	12.6	8.6	3.2	1.4	0.5	0.5	0.0
Nera 18mg	220	218	215	212	209	207	206	204	203	203	200	199	198	194	193	182	145	125	86	65	41	23	16	4	2	1	0	0
%	100.0	99.1	97.7	96.4	95.0	94.1	93.6	92.7	92.3	92.3	90.9	90.5	90.0	88.2	87.7	82.7	65.9	56.8	39.1	29.5	18.6	10.5	7.3	1.8	0.9	0.5	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	1	1	1	1	2	2	2	2	2	3	3	4	5	16	39	59	93	107	126	139	148	160	164	166	166	167
%	0.0	0.0	0.5	0.5	0.5	0.5	0.9	0.9	0.9	0.9	0.9	1.4	1.4	1.8	2.3	7.2	17.6	26.6	41.9	48.2	56.8	62.6	66.7	72.1	73.9	74.8	74.8	75.2
Nera 18mg	0	0	0	1	2	2	2	2	2	2	2	3	3	5	5	12	49	68	106	126	149	167	174	186	188	189	190	190
%	0.0	0.0	0.0	0.5	0.9	0.9	0.9	0.9	0.9	0.9	0.9	1.4	1.4	2.3	2.3	5.5	22.3	30.9	48.2	57.3	67.7	75.9	79.1	84.5	85.5	85.9	86.4	86.4

Study: 1305-0023

Figure I.1.2.1.1.1.2: 1 Time to first confirmed or suspected acute ILD exacerbation or death over the whole trial, Kaplan-Meier estimate - 18mg - FAS (non-AF background)

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Figure I.1.2.1.1.1.2: 1

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I.1.2.1.1.2 Analyses of single endpoints

I.1.2.1.1.2.1 Time to death

Table I.1.2.1.1.2.1: 1 Cox model for time to death over the whole trial
- 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	222	36	16.2	11.58	220	15	6.8	4.71	0.45	(0.24,	0.82)	0.0092	
Age													0.2744
<65 years	83	7	8.4	5.77	88	5	5.7	3.85	0.77	(0.24,	2.45)	0.6610	
>=65 years	139	29	20.9	15.30	132	10	7.6	5.30	0.36	(0.18,	0.75)	0.0062	
Sex													0.9895
Male	116	22	19.0	13.89	111	9	8.1	5.72	0.45	(0.20,	0.98)	0.0446	
Female	106	14	13.2	9.18	109	6	5.5	3.73	0.45	(0.17,	1.17)	0.1014	
Baseline FVC percent predicted													0.1532
<=70%	118	29	24.6	17.93	96	8	8.3	5.77	0.32	(0.15,	0.71)	0.0050	
>70%	104	7	6.7	4.69	124	7	5.6	3.89	0.84	(0.29,	2.41)	0.7476	
Baseline HRCT pattern													0.9660
UIP-like	158	26	16.5	11.87	154	11	7.1	4.95	0.45	(0.22,	0.91)	0.0275	
Other fibrotic patterns	64	10	15.6	10.88	66	4	6.1	4.15	0.44	(0.14,	1.40)	0.1620	
Underlying ILD diagnosis													0.5469
iNSIP	40	4	10.0	6.61	55	5	9.1	6.42	1.15	(0.31,	4.33)	0.8308	
Unclassifiable IIP	36	5	13.9	9.77	40	3	7.5	5.13	0.61	(0.15,	2.59)	0.5065	
HP	39	9	23.1	19.19	30	2	6.7	4.79	0.31	(0.07,	1.45)	0.1374	
Autoimmune ILD	71	10	14.1	9.75	70	4	5.7	3.90	0.35	(0.11,	1.12)	0.0776	
Other ILD	36	8	22.2	16.09	25	1	4.0	2.64	0.20	(0.03,	1.64)	0.1347	
Region													0.3012
Europe	40	6	15.0	10.96	53	6	11.3	8.43	0.84	(0.27,	2.60)	0.7575	
Asia	106	11	10.4	6.86	107	8	7.5	5.02	0.78	(0.31,	1.95)	0.5937	
Canada and USA	30	9	30.0	23.51	17	0	0.0	0.00	0.00	(NC,	NC)	0.9811	
Rest of the World	46	10	21.7	17.41	43	1	2.3	1.60	0.10	(0.01,	0.75)	0.0257	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment,
baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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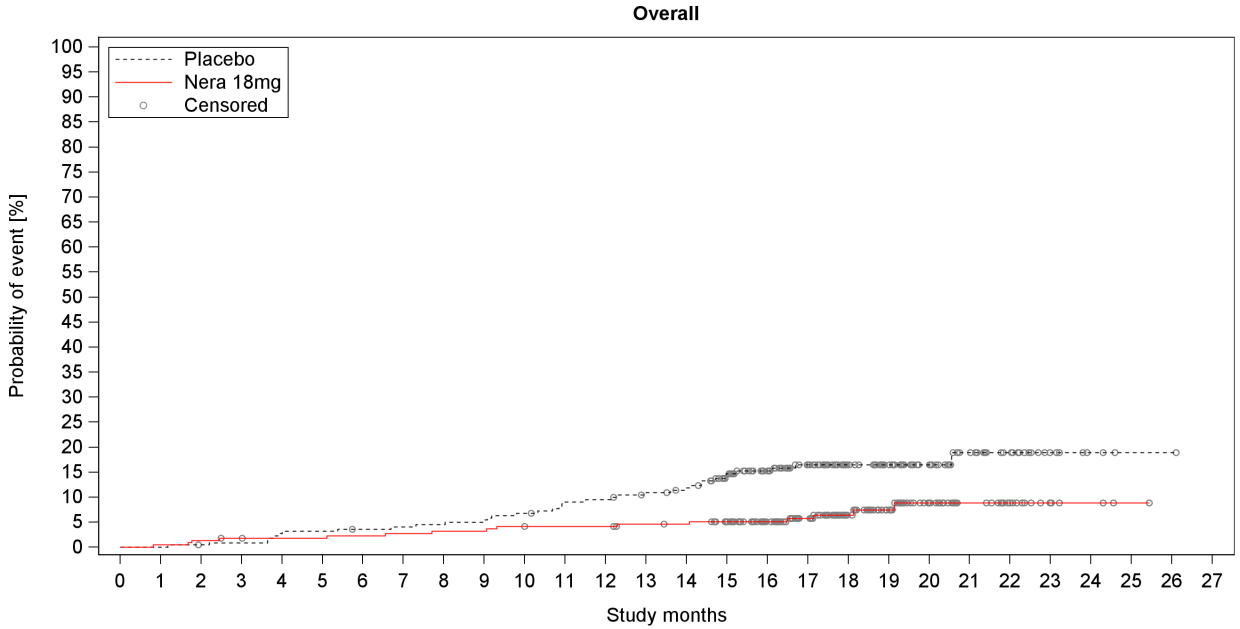

Number at risk (percentage relative to baseline)

Placebo	222	222	220	219	215	214	212	211	210	208	205	199	198	193	190	171	145	120	85	69	47	30	20	7	3	1	1	0
%	100.0	100.0	99.1	98.6	96.8	96.4	95.5	95.0	94.6	93.7	92.3	89.6	89.2	86.9	85.6	77.0	65.3	54.1	38.3	31.1	21.2	13.5	9.0	3.2	1.4	0.5	0.5	0.0
Nera 18mg	220	219	217	215	214	214	213	212	211	211	209	208	208	205	204	194	157	134	93	71	45	26	19	5	3	1	0	0
%	100.0	99.5	98.6	97.7	97.3	97.3	96.8	96.4	95.9	95.9	95.0	94.5	94.5	93.2	92.7	88.2	71.4	60.9	42.3	32.3	20.5	11.8	8.6	2.3	1.4	0.5	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	1	1	1	1	2	2	2	2	2	3	3	5	7	19	44	67	102	118	140	156	166	179	183	185	185	186
%	0.0	0.0	0.5	0.5	0.5	0.5	0.9	0.9	0.9	0.9	0.9	1.4	1.4	2.3	3.2	8.6	19.8	30.2	45.9	53.2	63.1	70.3	74.8	80.6	82.4	83.3	83.3	83.8
Nera 18mg	0	0	0	1	2	2	2	2	2	2	2	3	3	5	6	15	52	74	114	135	160	179	186	200	202	204	205	205
%	0.0	0.0	0.0	0.5	0.9	0.9	0.9	0.9	0.9	0.9	0.9	1.4	1.4	2.3	2.7	6.8	23.6	33.6	51.8	61.4	72.7	81.4	84.5	90.9	91.8	92.7	93.2	93.2

Study: 1305-0023

Figure I.1.2.1.1.2.1: 1 Time to death over the whole trial, Kaplan-Meier estimate
- 18mg - FAS (non-AF background)

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I.1.2.1.1.2.2 Time to first confirmed acute ILD exacerbation

Table I.1.2.1.1.2.2: 1 Cox model for time to first confirmed acute ILD exacerbation over the whole trial - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	222	22	9.9	7.42	220	13	5.9	4.20	0.69	(0.34, 1.38)	0.2963	
Age												0.4747
<65 years	83	6	7.2	5.12	88	5	5.7	3.93	0.98	(0.29, 3.25)	0.9709	
>=65 years	139	16	11.5	8.91	132	8	6.1	4.39	0.57	(0.24, 1.35)	0.2003	
Sex												0.2405
Male	116	14	12.1	9.34	111	5	4.5	3.25	0.45	(0.16, 1.27)	0.1302	
Female	106	8	7.5	5.45	109	8	7.3	5.16	1.05	(0.40, 2.81)	0.9162	
Baseline FVC percent predicted												0.7506
<=70%	118	17	14.4	11.25	96	9	9.4	6.79	0.65	(0.29, 1.46)	0.2997	
>70%	104	5	4.8	3.44	124	4	3.2	2.27	0.84	(0.21, 3.38)	0.8117	
Baseline HRCT pattern												0.1599
UIP-like	158	17	10.8	8.17	154	7	4.5	3.24	0.48	(0.20, 1.17)	0.1077	
Other fibrotic patterns	64	5	7.8	5.64	66	6	9.1	6.45	1.47	(0.41, 5.25)	0.5517	
Underlying ILD diagnosis												
iNSIP	40	4	10.0		55	3	5.5					
Unclassifiable IIP	36	1	2.8		40	4	10.0					
HP	39	7	17.9		30	1	3.3					
Autoimmune ILD	71	6	8.5		70	1	1.4					
Other ILD	36	4	11.1		25	4	16.0					
Region												0.5736
Europe	40	2	5.0	3.81	53	5	9.4	7.30	2.10	(0.41, 10.90)	0.3755	
Asia	106	12	11.3	7.90	107	6	5.6	3.88	0.59	(0.22, 1.58)	0.2909	
Canada and USA	30	3	10.0	8.02	17	0	0.0	0.00	0.00	(NC, NC)	0.9880	
Rest of the World	46	5	10.9	9.11	43	2	4.7	3.30	0.49	(0.09, 2.68)	0.4089	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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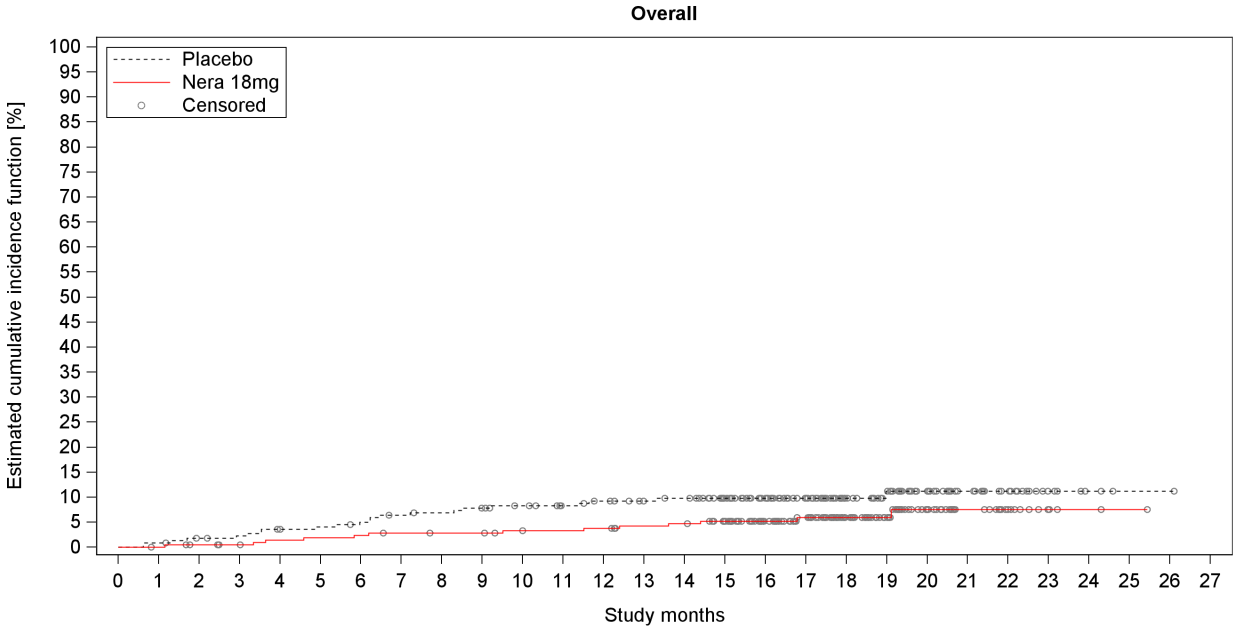

Number at risk (percentage relative to baseline)

Placebo	222	220	216	214	210	208	205	201	199	196	192	187	183	178	176	161	136	114	80	64	43	29	20	7	3	1	1	0
%	100.0	99.1	97.3	96.4	94.6	93.7	92.3	90.5	89.6	88.3	86.5	84.2	82.4	80.2	79.3	72.5	61.3	51.4	36.0	28.8	19.4	13.1	9.0	3.2	1.4	0.5	0.5	0.0
Nera 18mg	220	219	216	214	211	210	209	207	206	206	203	202	201	197	196	185	148	126	87	65	41	23	16	4	2	1	0	0
%	100.0	99.5	98.2	97.3	95.9	95.5	95.0	94.1	93.6	93.6	92.3	91.8	91.4	89.5	89.1	84.1	67.3	57.3	39.5	29.5	18.6	10.5	7.3	1.8	0.9	0.5	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	2	3	4	5	6	7	8	9	12	17	19	24	25	40	65	87	121	136	157	171	180	193	197	199	199	200
%	0.0	0.0	0.9	1.4	1.8	2.3	2.7	3.2	3.6	4.1	5.4	7.7	8.6	10.8	11.3	18.0	29.3	39.2	54.5	61.3	70.7	77.0	81.1	86.9	88.7	89.6	89.6	90.1
Nera 18mg	0	1	3	5	6	6	6	7	8	8	10	11	11	14	14	24	61	82	121	143	166	184	191	203	205	206	207	207
%	0.0	0.5	1.4	2.3	2.7	2.7	2.7	3.2	3.6	3.6	4.5	5.0	5.0	6.4	6.4	10.9	27.7	37.3	55.0	65.0	75.5	83.6	86.8	92.3	93.2	93.6	94.1	94.1

Study: 1305-0023

Figure I.1.2.1.1.2.2: 1 Time to first confirmed acute ILD exacerbation over the whole trial, estimated cumulative incidence function - 18mg - FAS (non-AF background)

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Figure I.1.2.1.1.2.2: 1

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I.1.2.1.1.2.3 Time to first confirmed or suspected acute ILD exacerbation

Table I.1.2.1.1.2.3: 1 Cox model for time to first confirmed or suspected acute ILD exacerbation over the whole trial - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	222	33	14.9	11.40	220	18	8.2	5.90	0.59	(0.33,	1.06)	0.0756	
Age													0.3657
<65 years	83	12	14.5	10.63	88	9	10.2	7.23	0.80	(0.34,	1.92)	0.6186	
>=65 years	139	21	15.1	11.89	132	9	6.8	4.98	0.47	(0.21,	1.03)	0.0579	
Sex													0.3998
Male	116	21	18.1	14.36	111	9	8.1	5.96	0.47	(0.21,	1.04)	0.0634	
Female	106	12	11.3	8.38	109	9	8.3	5.84	0.78	(0.33,	1.86)	0.5752	
Baseline FVC percent predicted													0.8543
<=70%	118	23	19.5	15.62	96	12	12.5	9.20	0.61	(0.30,	1.23)	0.1683	
>70%	104	10	9.6	7.04	124	6	4.8	3.44	0.54	(0.19,	1.53)	0.2486	
Baseline HRCT pattern													0.3449
UIP-like	158	23	14.6	11.22	154	10	6.5	4.67	0.48	(0.23,	1.01)	0.0522	
Other fibrotic patterns	64	10	15.6	11.86	66	8	12.1	8.81	0.86	(0.33,	2.23)	0.7503	
Underlying ILD diagnosis													0.1650
iNSIP	40	8	20.0	14.58	55	4	7.3	5.28	0.35	(0.10,	1.17)	0.0874	
Unclassifiable IIP	36	2	5.6	4.01	40	4	10.0	7.24	1.93	(0.35,	10.59)	0.4507	
HP	39	9	23.1	21.16	30	2	6.7	4.90	0.28	(0.06,	1.31)	0.1062	
Autoimmune ILD	71	9	12.7	9.44	70	3	4.3	3.02	0.38	(0.10,	1.40)	0.1458	
Other ILD	36	5	13.9	10.68	25	5	20.0	14.65	1.65	(0.47,	5.72)	0.4317	
Region													0.8802
Europe	40	6	15.0	11.90	53	7	13.2	10.53	0.89	(0.30,	2.64)	0.8303	
Asia	106	14	13.2	9.32	107	7	6.5	4.53	0.57	(0.23,	1.41)	0.2240	
Canada and USA	30	4	13.3	10.94	17	0	0.0	0.00	0.00	(NC,	NC)	0.9857	
Rest of the World	46	9	19.6	17.23	43	4	9.3	6.82	0.47	(0.14,	1.55)	0.2130	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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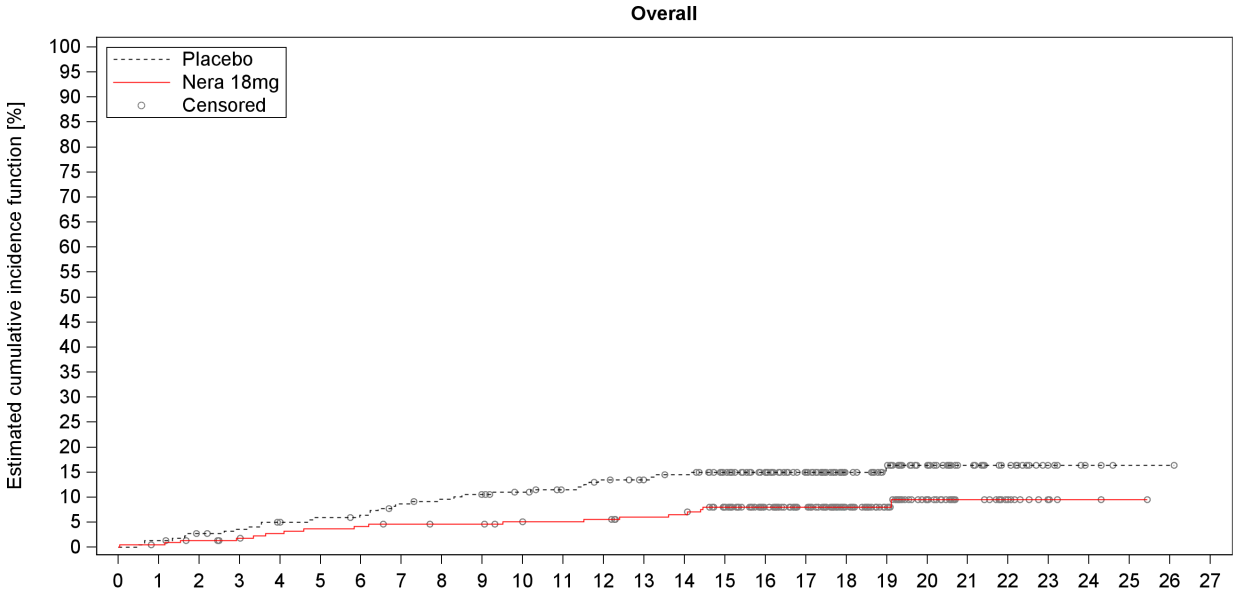

Number at risk (percentage relative to baseline)

Placebo	222	219	214	211	207	204	202	196	193	190	186	181	176	172	169	156	132	110	76	61	42	28	19	7	3	1	1	0
%	100.0	98.6	96.4	95.0	93.2	91.9	91.0	88.3	86.9	85.6	83.8	81.5	79.3	77.5	76.1	70.3	59.5	49.5	34.2	27.5	18.9	12.6	8.6	3.2	1.4	0.5	0.5	0.0
Nera 18mg	220	218	215	212	209	207	206	204	203	203	200	199	198	194	193	181	144	124	86	65	41	23	16	4	2	1	0	0
%	100.0	99.1	97.7	96.4	95.0	94.1	93.6	92.7	92.3	92.3	90.9	90.5	90.0	88.2	87.7	82.3	65.5	56.4	39.1	29.5	18.6	10.5	7.3	1.8	0.9	0.5	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	2	3	4	5	6	7	8	9	12	16	17	21	22	34	58	80	114	128	147	161	170	182	186	188	188	189
%	0.0	0.0	0.9	1.4	1.8	2.3	2.7	3.2	3.6	4.1	5.4	7.2	7.7	9.5	9.9	15.3	26.1	36.0	51.4	57.7	66.2	72.5	76.6	82.0	83.8	84.7	84.7	85.1
Nera 18mg	0	1	2	4	5	5	5	6	7	7	9	10	10	13	13	22	59	79	117	138	161	179	186	198	200	201	202	202
%	0.0	0.5	0.9	1.8	2.3	2.3	2.3	2.7	3.2	3.2	4.1	4.5	4.5	5.9	5.9	10.0	26.8	35.9	53.2	62.7	73.2	81.4	84.5	90.0	90.9	91.4	91.8	91.8

Study: 1305-0023

Figure I.1.2.1.1.2.3: 1 Time to first confirmed or suspected acute ILD exacerbation over the whole trial, estimated cumulative incidence function - 18mg - FAS (non-AF background)

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Figure I.1.2.1.1.2.3: 1

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I.1.2.1.2 Analyses of continuous variables

I.1.2.1.2.1 MMRM Analysis

Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Overall																	
Baseline																	
Placebo	222	218	72.2	1.2	215 (100.0%)												
Nera 18mg	220	218	72.5	1.1	213 (100.0%)												
Week 6																	
Placebo		218	75.0	1.1	215 (100.0%)	2.2	0.9	0.5	4.0								
Nera 18mg		213	74.2	1.1	211 (99.1%)	1.7	0.9	-0.1	3.4	-0.6	1.3	-3.1	1.9	0.6484			
Week 12																	
Placebo		210	73.5	1.1	207 (96.3%)	0.2	1.0	-1.6	2.1								
Nera 18mg		208	73.0	1.2	206 (96.7%)	0.6	1.0	-1.3	2.5	0.4	1.4	-2.3	3.0	0.7869			
Week 18																	
Placebo		207	74.5	1.2	204 (94.9%)	1.2	1.0	-0.9	3.2								
Nera 18mg		202	75.4	1.1	200 (93.9%)	2.5	1.0	0.4	4.5	1.3	1.5	-1.6	4.2	0.3738			
Week 26																	
Placebo		202	73.4	1.2	199 (92.6%)	-0.0	1.0	-2.0	1.9								
Nera 18mg		197	74.3	1.1	195 (91.5%)	1.0	1.0	-0.9	3.0	1.1	1.4	-1.7	3.8	0.4557			
Week 36																	
Placebo		193	72.2	1.3	190 (88.4%)	-2.0	1.1	-4.1	0.1								
Nera 18mg		190	74.0	1.3	189 (88.7%)	0.7	1.1	-1.4	2.8	2.7	1.5	-0.3	5.7	0.0769			
Week 44																	
Placebo		187	73.0	1.3	184 (85.6%)	-1.4	1.1	-3.6	0.8								
Nera 18mg		191	74.0	1.2	190 (89.2%)	0.6	1.1	-1.5	2.8	2.0	1.6	-1.0	5.1	0.1934			
Week 52																	
Placebo		183	73.1	1.4	180 (83.7%)	-1.8	1.1	-4.0	0.4								
Nera 18mg		189	73.7	1.3	187 (87.8%)	0.3	1.1	-1.9	2.5	2.1	1.6	-1.0	5.2	0.1793			
Week 64																	
Placebo		167	72.8	1.4	164 (76.3%)	-2.8	1.1	-5.0	-0.5								
Nera 18mg		179	74.3	1.3	178 (83.6%)	0.6	1.1	-1.6	2.8	3.4	1.6	0.3	6.5	0.0340	0.23	0.02	0.44
Week 76																	
Placebo		114	72.7	1.6	112 (52.1%)												
Nera 18mg		125	74.1	1.6	124 (58.2%)												
Week 88																	
Placebo		59	71.3	2.5	59 (27.4%)												
Nera 18mg		64	74.9	2.2	64 (30.0%)												
Week 100																	
Placebo		18	66.9	5.6	18 (8.4%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		21	76.7	3.6	21 (9.9%)												
Week 112																	
Placebo		1	77.0	NC	1 (0.5%)												
Nera 18mg		2	85.0	5.0	2 (0.9%)												
Age																	
Test for homogeneity (H0)^																	
Week 6														0.7956			
Week 12														0.4227			
Week 18														0.3148			
Week 26														0.1027			
Week 36														0.3668			
Week 44														0.2618			
Week 52														0.4080			
Week 64														0.9776			
<65 years																	
Baseline																	
Placebo	83	80	71.9	2.0	79 (100.0%)												
Nera 18mg	88	88	74.5	1.7	86 (100.0%)												
Week 6																	
Placebo		82	76.6	1.7	79 (100.0%)	4.3	1.5	1.4	7.2								
Nera 18mg		86	76.6	1.8	86 (100.0%)	3.2	1.4	0.4	6.0	-1.1	2.0	-5.1	2.9	0.5917			
Week 12																	
Placebo		80	73.8	1.8	77 (97.5%)	0.9	1.6	-2.2	4.0								
Nera 18mg		83	75.9	1.9	83 (96.5%)	2.6	1.5	-0.4	5.6	1.7	2.2	-2.6	6.0	0.4459			
Week 18																	
Placebo		81	74.7	1.9	78 (98.7%)	1.7	1.7	-1.6	5.0								
Nera 18mg		80	78.6	1.6	80 (93.0%)	4.8	1.6	1.6	8.0	3.1	2.3	-1.5	7.7	0.1908			
Week 26																	
Placebo		79	73.6	2.0	76 (96.2%)	0.4	1.6	-2.8	3.5								
Nera 18mg		80	78.3	1.7	80 (93.0%)	4.2	1.6	1.1	7.3	3.8	2.2	-0.6	8.2	0.0900			
Week 36																	
Placebo		77	72.8	2.2	74 (93.7%)	-0.3	1.7	-3.7	3.1								
Nera 18mg		78	78.3	1.9	78 (90.7%)	4.0	1.7	0.7	7.3	4.3	2.4	-0.5	9.0	0.0767			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 44																	
Placebo		75	72.6	2.2	72 (91.1%)	-1.4	1.8	-5.0	2.1								
Nera 18mg		80	76.7	2.0	80 (93.0%)	2.7	1.7	-0.7	6.1	4.2	2.5	-0.7	9.1	0.0956			
Week 52																	
Placebo		74	73.9	2.2	71 (89.9%)	-0.4	1.8	-4.0	3.1								
Nera 18mg		77	77.1	1.9	77 (89.5%)	3.2	1.7	-0.2	6.6	3.6	2.5	-1.3	8.5	0.1459			
Week 64																	
Placebo		65	74.4	2.1	62 (78.5%)	-0.8	1.8	-4.4	2.9								
Nera 18mg		74	77.2	2.1	74 (86.0%)	2.6	1.7	-0.8	6.0	3.3	2.5	-1.6	8.3	0.1872			
Week 76																	
Placebo		47	73.0	2.6	45 (57.0%)												
Nera 18mg		55	77.1	2.4	55 (64.0%)												
Week 88																	
Placebo		26	68.0	4.3	26 (32.9%)												
Nera 18mg		29	76.6	3.4	29 (33.7%)												
Week 100																	
Placebo		7	74.1	8.3	7 (8.9%)												
Nera 18mg		7	81.9	4.6	7 (8.1%)												
Week 112																	
Placebo		1	77.0	NC	1 (1.3%)												
Nera 18mg		1	90.0	NC	1 (1.2%)												
>=65 years																	
Baseline																	
Placebo	139	138	72.4	1.5	136 (100.0%)												
Nera 18mg	132	130	71.1	1.4	127 (100.0%)												
Week 6																	
Placebo		136	74.1	1.4	136 (100.0%)	1.0	1.1	-1.2	3.2								
Nera 18mg		127	72.6	1.4	125 (98.4%)	0.6	1.2	-1.7	2.9	-0.4	1.6	-3.6	2.8	0.7956			
Week 12																	
Placebo		130	73.2	1.4	130 (95.6%)	-0.2	1.2	-2.5	2.2								
Nera 18mg		125	71.1	1.5	123 (96.9%)	-0.7	1.2	-3.2	1.7	-0.6	1.7	-4.0	2.8	0.7404			
Week 18																	
Placebo		126	74.3	1.5	126 (92.6%)	0.8	1.3	-1.7	3.4								
Nera 18mg		122	73.3	1.4	120 (94.5%)	0.9	1.3	-1.7	3.5	0.0	1.9	-3.6	3.7	0.9788			
Week 26																	
Placebo		123	73.3	1.6	123 (90.4%)	-0.2	1.3	-2.7	2.3								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		117	71.7	1.5	115 (90.6%)	-1.1	1.3	-3.7	1.5	-0.9	1.8	-4.5	2.6	0.6174			
Week 36																	
Placebo		116	71.9	1.6	116 (85.3%)	-3.1	1.4	-5.7	-0.4								
Nera 18mg		112	71.0	1.7	111 (87.4%)	-1.6	1.4	-4.3	1.2	1.5	1.9	-2.4	5.3	0.4500			
Week 44																	
Placebo		112	73.3	1.6	112 (82.4%)	-1.4	1.4	-4.1	1.4								
Nera 18mg		111	72.1	1.5	110 (86.6%)	-0.8	1.4	-3.7	2.0	0.5	2.0	-3.4	4.5	0.7892			
Week 52																	
Placebo		109	72.6	1.7	109 (80.1%)	-2.6	1.4	-5.4	0.2								
Nera 18mg		112	71.4	1.6	110 (86.6%)	-1.6	1.4	-4.5	1.2	1.0	2.0	-3.0	4.9	0.6325			
Week 64																	
Placebo		102	71.8	1.8	102 (75.0%)	-4.0	1.4	-6.8	-1.2								
Nera 18mg		105	72.3	1.6	104 (81.9%)	-0.7	1.5	-3.6	2.1	3.3	2.0	-0.8	7.3	0.1120			
Week 76																	
Placebo		67	72.6	2.1	67 (49.3%)												
Nera 18mg		70	71.7	2.1	69 (54.3%)												
Week 88																	
Placebo		33	73.9	2.8	33 (24.3%)												
Nera 18mg		35	73.6	2.9	35 (27.6%)												
Week 100																	
Placebo		11	62.3	7.5	11 (8.1%)												
Nera 18mg		14	74.1	4.9	14 (11.0%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	80.0	NC	1 (0.8%)												
Sex																	
Test for homogeneity (H0)^																	
Week 6														0.1149			
Week 12														0.8931			
Week 18														0.0879			
Week 26														0.0740			
Week 36														0.5413			
Week 44														0.8291			
Week 52														0.3766			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 64														0.9102			
Male																	
Baseline																	
Placebo	116	114	72.4	1.6	113 (100.0%)												
Nera 18mg	111	110	73.2	1.5	105 (100.0%)												
Week 6																	
Placebo		115	74.0	1.6	113 (100.0%)	0.9	1.2	-1.6	3.3								
Nera 18mg		105	75.1	1.6	104 (99.0%)	2.2	1.3	-0.3	4.7	1.4	1.8	-2.1	4.9	0.4424			
Week 12																	
Placebo		111	72.5	1.6	109 (96.5%)	-1.1	1.3	-3.7	1.5								
Nera 18mg		102	71.9	1.8	101 (96.2%)	-0.6	1.4	-3.3	2.0	0.5	1.9	-3.3	4.2	0.8054			
Week 18																	
Placebo		107	72.4	1.8	105 (92.9%)	-1.4	1.4	-4.2	1.4								
Nera 18mg		100	75.4	1.6	99 (94.3%)	2.3	1.5	-0.6	5.2	3.7	2.0	-0.3	7.7	0.0702			
Week 26																	
Placebo		104	72.7	1.9	102 (90.3%)	-1.1	1.4	-3.8	1.6								
Nera 18mg		97	76.0	1.5	96 (91.4%)	2.5	1.4	-0.3	5.3	3.6	2.0	-0.3	7.5	0.0737			
Week 36																	
Placebo		97	71.7	2.0	95 (84.1%)	-3.8	1.5	-6.8	-0.8								
Nera 18mg		96	73.1	1.8	95 (90.5%)	-0.2	1.5	-3.2	2.8	3.6	2.1	-0.6	7.8	0.0941			
Week 44																	
Placebo		93	74.0	1.9	91 (80.5%)	-1.5	1.6	-4.6	1.6								
Nera 18mg		97	74.0	1.8	96 (91.4%)	0.2	1.6	-2.9	3.2	1.6	2.2	-2.7	6.0	0.4605			
Week 52																	
Placebo		91	73.6	2.0	89 (78.8%)	-2.5	1.6	-5.6	0.6								
Nera 18mg		94	75.0	1.7	93 (88.6%)	1.0	1.6	-2.1	4.1	3.4	2.2	-0.9	7.8	0.1215			
Week 64																	
Placebo		83	73.4	2.1	81 (71.7%)	-3.4	1.6	-6.6	-0.3								
Nera 18mg		89	75.1	1.9	88 (83.8%)	0.1	1.6	-3.0	3.2	3.5	2.3	-0.9	7.9	0.1218			
Week 76																	
Placebo		63	72.1	2.4	62 (54.9%)												
Nera 18mg		59	73.2	2.4	58 (55.2%)												
Week 88																	
Placebo		33	69.7	3.9	33 (29.2%)												
Nera 18mg		28	75.6	3.4	28 (26.7%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 100																	
Placebo		10	72.7	6.6	10 (8.8%)												
Nera 18mg		7	73.3	8.6	7 (6.7%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Female																	
Baseline																	
Placebo	106	104	72.0	1.7	102 (100.0%)												
Nera 18mg	109	108	71.7	1.6	108 (100.0%)												
Week 6																	
Placebo		103	76.2	1.4	102 (100.0%)	3.7	1.3	1.2	6.3								
Nera 18mg		108	73.3	1.5	107 (99.1%)	1.1	1.3	-1.4	3.6	-2.7	1.8	-6.2	0.9	0.1441			
Week 12																	
Placebo		99	74.5	1.5	98 (96.1%)	1.7	1.4	-1.0	4.5								
Nera 18mg		106	74.1	1.5	105 (97.2%)	1.8	1.3	-0.8	4.5	0.1	1.9	-3.7	3.9	0.9573			
Week 18																	
Placebo		100	76.7	1.5	99 (97.1%)	3.9	1.5	1.0	6.8								
Nera 18mg		102	75.5	1.5	101 (93.5%)	2.6	1.5	-0.2	5.5	-1.3	2.1	-5.3	2.8	0.5394			
Week 26																	
Placebo		98	74.2	1.6	97 (95.1%)	1.2	1.4	-1.6	4.0								
Nera 18mg		100	72.7	1.7	99 (91.7%)	-0.3	1.4	-3.1	2.5	-1.5	2.0	-5.4	2.4	0.4544			
Week 36																	
Placebo		96	72.7	1.7	95 (93.1%)	-0.1	1.5	-3.1	2.9								
Nera 18mg		94	74.9	1.9	94 (87.0%)	1.6	1.5	-1.4	4.6	1.7	2.2	-2.5	6.0	0.4215			
Week 44																	
Placebo		94	72.0	1.7	93 (91.2%)	-1.2	1.6	-4.3	1.9								
Nera 18mg		94	74.0	1.7	94 (87.0%)	1.1	1.6	-2.0	4.2	2.3	2.2	-2.1	6.7	0.2983			
Week 52																	
Placebo		92	72.7	1.8	91 (89.2%)	-1.0	1.6	-4.1	2.1								
Nera 18mg		95	72.5	1.9	94 (87.0%)	-0.3	1.6	-3.4	2.7	0.7	2.2	-3.7	5.0	0.7652			
Week 64																	
Placebo		84	72.2	1.8	83 (81.4%)	-2.0	1.6	-5.2	1.2								
Nera 18mg		90	73.6	1.8	90 (83.3%)	1.1	1.6	-2.0	4.2	3.1	2.3	-1.3	7.6	0.1644			
Week 76																	
Placebo		51	73.6	2.0	50 (49.0%)												

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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		66	74.9	2.1	66 (61.1%)												
Week 88																	
Placebo		26	73.3	2.7	26 (25.5%)												
Nera 18mg		36	74.4	3.0	36 (33.3%)												
Week 100																	
Placebo		8	59.6	9.4	8 (7.8%)												
Nera 18mg		14	78.4	3.6	14 (13.0%)												
Week 112																	
Placebo		1	77.0	NC	1 (1.0%)												
Nera 18mg		2	85.0	5.0	2 (1.9%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 6														0.6742			
Week 12														0.6818			
Week 18														0.8373			
Week 26														0.0888			
Week 36														0.4033			
Week 44														0.9081			
Week 52														0.1465			
Week 64														0.5867			
<=70%																	
Baseline																	
Placebo	118	117	70.4	1.6	115 (100.0%)												
Nera 18mg	96	96	68.9	1.6	94 (100.0%)												
Week 6																	
Placebo		115	72.3	1.5	115 (100.0%)	0.9	1.2	-1.5	3.3								
Nera 18mg		93	71.1	1.8	93 (98.9%)	0.6	1.4	-2.1	3.3	-0.3	1.8	-3.8	3.3	0.8867			
Week 12																	
Placebo		110	71.2	1.6	110 (95.7%)	-0.4	1.3	-3.0	2.2								
Nera 18mg		92	71.1	1.8	92 (97.9%)	0.4	1.5	-2.4	3.3	0.9	2.0	-3.0	4.7	0.6623			
Week 18																	
Placebo		106	73.3	1.7	106 (92.2%)	1.3	1.4	-1.5	4.1								
Nera 18mg		88	73.8	1.7	88 (93.6%)	2.3	1.6	-0.8	5.4	1.0	2.1	-3.2	5.1	0.6506			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 26																	
Placebo		102	69.7	1.9	102 (88.7%)	-2.5	1.4	-5.3	0.2								
Nera 18mg		84	72.3	1.9	84 (89.4%)	0.8	1.5	-2.2	3.8	3.3	2.0	-0.7	7.4	0.1028			
Week 36																	
Placebo		100	67.8	2.0	100 (87.0%)	-4.7	1.5	-7.5	-1.8								
Nera 18mg		83	70.3	2.1	83 (88.3%)	-1.0	1.6	-4.2	2.1	3.6	2.2	-0.7	7.9	0.0978			
Week 44																	
Placebo		94	70.3	1.9	94 (81.7%)	-2.7	1.5	-5.7	0.4								
Nera 18mg		83	70.7	1.8	83 (88.3%)	-0.7	1.7	-4.0	2.6	2.0	2.3	-2.5	6.5	0.3834			
Week 52																	
Placebo		92	69.9	2.0	92 (80.0%)	-3.2	1.5	-6.2	-0.3								
Nera 18mg		80	67.1	2.1	80 (85.1%)	-4.0	1.7	-7.3	-0.8	-0.8	2.2	-5.2	3.6	0.7211			
Week 64																	
Placebo		82	71.2	2.0	82 (71.3%)	-3.2	1.6	-6.3	-0.1								
Nera 18mg		78	70.4	2.2	78 (83.0%)	-1.0	1.7	-4.3	2.4	2.2	2.3	-2.3	6.8	0.3328			
Week 76																	
Placebo		61	69.7	2.5	61 (53.0%)												
Nera 18mg		53	69.1	2.3	53 (56.4%)												
Week 88																	
Placebo		31	65.7	3.8	31 (27.0%)												
Nera 18mg		26	67.6	3.9	26 (27.7%)												
Week 100																	
Placebo		13	68.8	6.4	13 (11.3%)												
Nera 18mg		9	72.4	5.5	9 (9.6%)												
Week 112																	
Placebo		1	77.0	NC	1 (0.9%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	104	101	74.2	1.7	100 (100.0%)												
Nera 18mg	124	122	75.3	1.5	119 (100.0%)												
Week 6																	
Placebo		103	78.0	1.4	100 (100.0%)	3.8	1.3	1.2	6.4								
Nera 18mg		120	76.6	1.3	118 (99.2%)	2.5	1.2	0.1	4.8	-1.3	1.8	-4.8	2.2	0.4542			
Week 12																	
Placebo		100	75.9	1.4	97 (97.0%)	1.0	1.4	-1.8	3.8								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		116	74.5	1.6	114 (95.8%)	0.7	1.3	-1.8	3.3	-0.3	1.9	-4.0	3.5	0.8892			
Week 18																	
Placebo		101	75.7	1.7	98 (98.0%)	1.1	1.5	-1.9	4.0								
Nera 18mg		114	76.6	1.4	112 (94.1%)	2.6	1.4	-0.1	5.4	1.6	2.0	-2.5	5.6	0.4444			
Week 26																	
Placebo		100	77.3	1.5	97 (97.0%)	2.7	1.4	-0.1	5.6								
Nera 18mg		113	75.8	1.4	111 (93.3%)	1.3	1.3	-1.4	3.9	-1.5	1.9	-5.3	2.4	0.4492			
Week 36																	
Placebo		93	77.0	1.5	90 (90.0%)	1.0	1.6	-2.1	4.0								
Nera 18mg		107	76.9	1.6	106 (89.1%)	2.0	1.4	-0.8	4.9	1.1	2.1	-3.0	5.2	0.6074			
Week 44																	
Placebo		93	75.8	1.7	90 (90.0%)	0.1	1.6	-3.1	3.2								
Nera 18mg		108	76.5	1.7	107 (89.9%)	1.7	1.5	-1.2	4.6	1.6	2.2	-2.7	5.9	0.4574			
Week 52																	
Placebo		91	76.4	1.7	88 (88.0%)	-0.1	1.6	-3.2	3.0								
Nera 18mg		109	78.6	1.4	107 (89.9%)	3.6	1.4	0.8	6.5	3.7	2.1	-0.5	7.9	0.0841			
Week 64																	
Placebo		85	74.3	1.8	82 (82.0%)	-2.2	1.6	-5.4	1.0								
Nera 18mg		101	77.3	1.5	100 (84.0%)	1.8	1.5	-1.2	4.7	4.0	2.2	-0.4	8.3	0.0721			
Week 76																	
Placebo		53	76.2	1.8	51 (51.0%)												
Nera 18mg		72	77.7	2.0	71 (59.7%)												
Week 88																	
Placebo		28	77.5	2.6	28 (28.0%)												
Nera 18mg		38	79.9	2.4	38 (31.9%)												
Week 100																	
Placebo		5	62.0	12.4	5 (5.0%)												
Nera 18mg		12	79.8	4.8	12 (10.1%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		2	85.0	5.0	2 (1.7%)												
Baseline HRCT pattern																	
Test for homogeneity (H0)^																	
Week 6														0.8739			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 12														0.8584			
Week 18														0.5331			
Week 26														0.0601			
Week 36														0.5253			
Week 44														0.0141			
Week 52														0.0719			
Week 64														0.2169			
UIP-like																	
Baseline																	
Placebo	158	156	71.6		1.4 153 (100.0%)												
Nera 18mg	154	152	73.5		1.3 148 (100.0%)												
Week 6																	
Placebo		155	76.0		1.2 153 (100.0%)	3.5	1.1	1.4	5.6								
Nera 18mg		148	75.9		1.2 146 (98.6%)	2.8	1.1	0.7	4.9	-0.7	1.5	-3.7	2.3	0.6413			
Week 12																	
Placebo		150	73.9		1.3 148 (96.7%)	1.1	1.1	-1.2	3.3								
Nera 18mg		143	74.2		1.4 141 (95.3%)	1.3	1.2	-1.0	3.6	0.2	1.6	-3.0	3.4	0.8977			
Week 18																	
Placebo		147	75.4		1.4 145 (94.8%)	2.4	1.2	0.0	4.8								
Nera 18mg		139	76.6		1.3 137 (92.6%)	3.1	1.3	0.7	5.6	0.7	1.7	-2.7	4.1	0.6892			
Week 26																	
Placebo		143	73.8		1.5 141 (92.2%)	1.1	1.2	-1.2	3.4								
Nera 18mg		138	74.3		1.4 136 (91.9%)	0.4	1.2	-1.9	2.8	-0.7	1.7	-4.0	2.6	0.6867			
Week 36																	
Placebo		133	72.8		1.5 131 (85.6%)	-1.3	1.3	-3.9	1.2								
Nera 18mg		131	74.6		1.6 130 (87.8%)	0.8	1.3	-1.8	3.3	2.1	1.8	-1.5	5.7	0.2550			
Week 44																	
Placebo		131	74.2		1.5 129 (84.3%)	0.1	1.3	-2.5	2.7								
Nera 18mg		132	73.3		1.6 131 (88.5%)	-0.4	1.3	-3.0	2.2	-0.5	1.9	-4.2	3.2	0.7868			
Week 52																	
Placebo		129	74.2		1.6 127 (83.0%)	-0.3	1.3	-2.9	2.3								
Nera 18mg		130	73.6		1.6 128 (86.5%)	-0.1	1.3	-2.7	2.5	0.2	1.9	-3.4	3.9	0.8973			
Week 64																	
Placebo		119	72.9		1.6 117 (76.5%)	-1.9	1.3	-4.5	0.8								
Nera 18mg		124	74.4		1.6 123 (83.1%)	0.2	1.3	-2.4	2.8	2.1	1.9	-1.7	5.8	0.2765			

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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 76																	
Placebo		82	73.5	1.8	81 (52.9%)												
Nera 18mg		92	74.0	1.9	91 (61.5%)												
Week 88																	
Placebo		42	73.0	2.8	42 (27.5%)												
Nera 18mg		45	76.5	2.4	45 (30.4%)												
Week 100																	
Placebo		13	66.3	6.9	13 (8.5%)												
Nera 18mg		16	77.6	4.3	16 (10.8%)												
Week 112																	
Placebo		1	77.0	NC	1 (0.7%)												
Nera 18mg		2	85.0	5.0	2 (1.4%)												
Other fibrotic patterns																	
Baseline																	
Placebo	64	62	73.7	2.1	62 (100.0%)												
Nera 18mg	66	66	70.0	2.0	65 (100.0%)												
Week 6																	
Placebo		63	72.7	2.0	62 (100.0%)	-0.8	1.7	-4.0	2.5								
Nera 18mg		65	70.3	2.1	65 (100.0%)	-1.0	1.6	-4.2	2.2	-0.3	2.3	-4.8	4.3	0.9097			
Week 12																	
Placebo		60	72.2	1.9	59 (95.2%)	-1.7	1.8	-5.2	1.8								
Nera 18mg		65	70.4	2.1	65 (100.0%)	-1.0	1.7	-4.4	2.4	0.7	2.5	-4.2	5.6	0.7664			
Week 18																	
Placebo		60	72.3	2.2	59 (95.2%)	-1.8	1.9	-5.6	2.0								
Nera 18mg		63	72.7	2.0	63 (96.9%)	0.9	1.9	-2.8	4.6	2.7	2.7	-2.6	7.9	0.3138			
Week 26																	
Placebo		59	72.6	2.2	58 (93.5%)	-2.7	1.8	-6.3	0.9								
Nera 18mg		59	74.5	2.0	59 (90.8%)	2.5	1.8	-1.1	6.0	5.1	2.6	0.1	10.2	0.0473	0.37	0.00	0.73
Week 36																	
Placebo		60	70.9	2.6	59 (95.2%)	-3.6	2.0	-7.5	0.2								
Nera 18mg		59	72.6	2.3	59 (90.8%)	0.6	1.9	-3.3	4.4	4.2	2.8	-1.2	9.6	0.1295			
Week 44																	
Placebo		56	70.3	2.5	55 (88.7%)	-4.9	2.0	-8.9	-1.0								
Nera 18mg		59	75.6	1.9	59 (90.8%)	2.9	2.0	-1.0	6.8	7.9	2.8	2.3	13.4	0.0058	0.52	0.15	0.89
Week 52																	
Placebo		54	70.5	2.7	53 (85.5%)	-5.2	2.0	-9.2	-1.2								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		59	73.9	2.2	59 (90.8%)	1.2	2.0	-2.7	5.0	6.4	2.8	0.8	12.0	0.0253	0.42	0.05	0.79
Week 64																	
Placebo		48	72.5	2.5	47 (75.8%)	-4.8	2.1	-9.0	-0.7								
Nera 18mg		55	74.2	2.1	55 (84.6%)	1.5	2.0	-2.4	5.5	6.4	2.9	0.7	12.1	0.0291	0.43	0.04	0.82
Week 76																	
Placebo		32	70.8	3.3	31 (50.0%)												
Nera 18mg		33	74.4	3.0	33 (50.8%)												
Week 88																	
Placebo		17	67.1	5.0	17 (27.4%)												
Nera 18mg		19	71.2	5.0	19 (29.2%)												
Week 100																	
Placebo		5	68.4	10.4	5 (8.1%)												
Nera 18mg		5	73.8	7.1	5 (7.7%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Underlying ILD diagnosis																	
Test for homogeneity (H0)^																	
Week 6														0.3315			
Week 12														0.7631			
Week 18														0.2545			
Week 26														0.1668			
Week 36														0.4775			
Week 44														0.3299			
Week 52														0.0704			
Week 64														0.3424			
iNSIP																	
Baseline																	
Placebo	40	39	73.9	2.6	39 (100.0%)												
Nera 18mg	55	55	70.1	2.3	54 (100.0%)												
Week 6																	
Placebo		39	77.8	2.3	39 (100.0%)	4.4	2.1	0.3	8.5								
Nera 18mg		52	73.3	2.3	52 (96.3%)	1.8	1.8	-1.7	5.3	-2.6	2.7	-8.0	2.8	0.3398			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Week 12																	
Placebo		38	77.3	2.4	38 (97.4%)	3.5	2.2	-0.8	7.9								
Nera 18mg		50	74.4	2.4	50 (92.6%)	3.1	1.9	-0.6	6.9	-0.4	2.9	-6.1	5.4	0.8942			
Week 18																	
Placebo		39	79.3	2.3	39 (100.0%)	6.1	2.4	1.4	10.7								
Nera 18mg		50	76.5	2.0	50 (92.6%)	4.1	2.1	0.0	8.1	-2.0	3.1	-8.2	4.2	0.5238			
Week 26																	
Placebo		37	77.6	2.4	37 (94.9%)	2.7	2.3	-1.8	7.2								
Nera 18mg		47	73.7	2.1	47 (87.0%)	0.7	2.0	-3.2	4.7	-2.0	3.0	-8.0	4.0	0.5122			
Week 36																	
Placebo		38	74.2	3.0	38 (97.4%)	-0.2	2.4	-5.0	4.6								
Nera 18mg		44	74.3	2.5	44 (81.5%)	0.8	2.2	-3.5	5.1	1.0	3.3	-5.4	7.4	0.7617			
Week 44																	
Placebo		37	77.7	2.7	37 (94.9%)	3.3	2.5	-1.6	8.2								
Nera 18mg		45	75.8	2.2	45 (83.3%)	2.8	2.2	-1.6	7.1	-0.6	3.3	-7.2	6.0	0.8663			
Week 52																	
Placebo		35	76.8	2.7	35 (89.7%)	2.0	2.5	-3.0	6.9								
Nera 18mg		43	72.3	2.6	43 (79.6%)	-0.9	2.2	-5.3	3.5	-2.9	3.4	-9.6	3.7	0.3913			
Week 64																	
Placebo		34	76.1	2.7	34 (87.2%)	0.8	2.5	-4.1	5.7								
Nera 18mg		41	74.7	2.4	41 (75.9%)	1.9	2.2	-2.5	6.3	1.1	3.4	-5.5	7.7	0.7509			
Week 76																	
Placebo		28	76.4	2.7	28 (71.8%)												
Nera 18mg		28	74.5	3.0	28 (51.9%)												
Week 88																	
Placebo		14	78.7	3.9	14 (35.9%)												
Nera 18mg		14	70.9	4.1	14 (25.9%)												
Week 100																	
Placebo		3	50.0	20.8	3 (7.7%)												
Nera 18mg		5	75.6	7.8	5 (9.3%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Unclassifiable IIP																	
Baseline																	
Placebo	36	36	73.3	2.8	36 (100.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg	40	39	72.3	2.6	39 (100.0%)												
Week 6																	
Placebo		36	74.6	2.5	36 (100.0%)	1.3	2.2	-3.0	5.5								
Nera 18mg		40	71.5	2.7	39 (100.0%)	-1.2	2.1	-5.3	2.9	-2.5	3.0	-8.3	3.4	0.4139			
Week 12																	
Placebo		35	75.2	2.2	35 (97.2%)	2.1	2.3	-2.5	6.6								
Nera 18mg		40	69.6	2.8	39 (100.0%)	-3.2	2.2	-7.5	1.1	-5.3	3.2	-11.5	1.0	0.0991			
Week 18																	
Placebo		35	74.2	2.6	35 (97.2%)	1.0	2.5	-3.9	5.9								
Nera 18mg		37	74.5	2.6	36 (92.3%)	1.2	2.4	-3.6	5.9	0.1	3.5	-6.7	7.0	0.9675			
Week 26																	
Placebo		33	70.5	3.1	33 (91.7%)	-2.1	2.4	-6.8	2.7								
Nera 18mg		35	73.2	3.2	34 (87.2%)	-1.0	2.4	-5.6	3.7	1.1	3.4	-5.5	7.7	0.7475			
Week 36																	
Placebo		31	69.2	3.3	31 (86.1%)	-3.9	2.6	-9.0	1.3								
Nera 18mg		34	72.6	3.3	34 (87.2%)	-1.7	2.5	-6.6	3.3	2.2	3.6	-5.0	9.3	0.5486			
Week 44																	
Placebo		30	68.4	3.7	30 (83.3%)	-4.0	2.7	-9.4	1.3								
Nera 18mg		33	73.1	2.9	33 (84.6%)	-1.6	2.6	-6.7	3.5	2.5	3.8	-5.0	9.9	0.5159			
Week 52																	
Placebo		30	73.6	3.5	30 (83.3%)	0.1	2.7	-5.2	5.4								
Nera 18mg		35	73.5	3.1	34 (87.2%)	-1.1	2.6	-6.2	3.9	-1.2	3.7	-8.6	6.1	0.7420			
Week 64																	
Placebo		28	72.2	3.6	28 (77.8%)	-1.3	2.7	-6.7	4.0								
Nera 18mg		30	76.2	2.7	30 (76.9%)	-0.5	2.6	-5.7	4.7	0.8	3.8	-6.6	8.3	0.8228			
Week 76																	
Placebo		18	67.6	4.3	18 (50.0%)												
Nera 18mg		23	70.0	4.3	23 (59.0%)												
Week 88																	
Placebo		9	75.6	6.4	9 (25.0%)												
Nera 18mg		12	71.5	6.6	12 (30.8%)												
Week 100																	
Placebo		5	79.4	8.6	5 (13.9%)												
Nera 18mg		5	68.0	9.2	5 (12.8%)												
Week 112																	
Placebo		1	77.0	NC	1 (2.8%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg		0	NC	NC	0 (0.0%)												
HP																	
Baseline																	
Placebo	39	39	69.3	2.9	38 (100.0%)												
Nera 18mg	30	29	70.4	3.1	28 (100.0%)												
Week 6																	
Placebo		38	71.6	3.2	38 (100.0%)	1.4	2.1	-2.8	5.5								
Nera 18mg		29	70.7	3.2	28 (100.0%)	0.5	2.5	-4.3	5.3	-0.9	3.2	-7.2	5.5	0.7861			
Week 12																	
Placebo		36	67.4	3.0	36 (94.7%)	-4.3	2.3	-8.8	0.2								
Nera 18mg		28	67.5	3.5	27 (96.4%)	-2.5	2.6	-7.7	2.6	1.7	3.5	-5.1	8.6	0.6173			
Week 18																	
Placebo		34	69.9	3.2	34 (89.5%)	-1.8	2.5	-6.7	3.1								
Nera 18mg		28	68.5	3.3	27 (96.4%)	-1.7	2.8	-7.3	3.9	0.1	3.8	-7.3	7.5	0.9731			
Week 26																	
Placebo		34	71.5	3.2	34 (89.5%)	-0.7	2.4	-5.4	4.1								
Nera 18mg		27	76.4	2.4	26 (92.9%)	5.7	2.7	0.3	11.1	6.3	3.6	-0.8	13.4	0.0818			
Week 36																	
Placebo		29	73.8	2.8	29 (76.3%)	-1.6	2.7	-6.9	3.7								
Nera 18mg		27	68.8	3.8	26 (92.9%)	-0.9	2.9	-6.7	4.8	0.7	4.0	-7.1	8.5	0.8620			
Week 44																	
Placebo		29	74.2	3.0	29 (76.3%)	-0.7	2.8	-6.2	4.8								
Nera 18mg		27	68.6	3.6	26 (92.9%)	-2.2	3.0	-8.1	3.7	-1.5	4.1	-9.5	6.5	0.7068			
Week 52																	
Placebo		28	69.5	3.7	28 (73.7%)	-6.0	2.8	-11.4	-0.5								
Nera 18mg		27	71.0	3.8	26 (92.9%)	0.2	3.0	-5.7	6.1	6.2	4.1	-1.8	14.1	0.1298			
Week 64																	
Placebo		25	70.2	4.1	25 (65.8%)	-6.4	2.8	-11.9	-0.8								
Nera 18mg		27	68.1	3.7	26 (92.9%)	-2.5	3.0	-8.3	3.3	3.9	4.1	-4.1	11.8	0.3427			
Week 76																	
Placebo		13	71.9	4.3	13 (34.2%)												
Nera 18mg		14	69.7	5.2	13 (46.4%)												
Week 88																	
Placebo		6	58.3	7.8	6 (15.8%)												
Nera 18mg		6	65.0	8.2	6 (21.4%)												
Week 100																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Placebo		1	30.0	NC	1 (2.6%)												
Nera 18mg		1	75.0	NC	1 (3.6%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Autoimmune ILD																	
Baseline																	
Placebo	71	69	72.7	2.2	67 (100.0%)												
Nera 18mg	70	70	75.3	1.8	68 (100.0%)												
Week 6																	
Placebo		69	79.0	1.5	67 (100.0%)	5.3	1.6	2.2	8.4								
Nera 18mg		68	77.7	1.7	68 (100.0%)	3.1	1.6	0.0	6.3	-2.2	2.2	-6.5	2.2	0.3330			
Week 12																	
Placebo		67	76.7	1.5	65 (97.0%)	2.8	1.7	-0.5	6.1								
Nera 18mg		66	76.1	1.8	66 (97.1%)	1.8	1.7	-1.5	5.1	-1.0	2.4	-5.7	3.7	0.6757			
Week 18																	
Placebo		67	76.0	2.1	65 (97.0%)	2.2	1.8	-1.4	5.8								
Nera 18mg		65	77.5	1.8	65 (95.6%)	3.1	1.8	-0.5	6.7	0.9	2.6	-4.2	5.9	0.7306			
Week 26																	
Placebo		66	76.8	1.8	64 (95.5%)	3.0	1.7	-0.4	6.5								
Nera 18mg		65	75.6	1.9	65 (95.6%)	1.1	1.7	-2.3	4.5	-1.9	2.5	-6.8	2.9	0.4364			
Week 36																	
Placebo		65	75.1	2.0	63 (94.0%)	1.1	1.9	-2.6	4.8								
Nera 18mg		62	76.7	2.1	62 (91.2%)	2.0	1.9	-1.7	5.7	0.9	2.6	-4.3	6.1	0.7412			
Week 44																	
Placebo		65	74.3	2.0	63 (94.0%)	0.2	1.9	-3.6	4.0								
Nera 18mg		63	75.0	2.4	63 (92.6%)	0.5	1.9	-3.3	4.3	0.3	2.7	-5.0	5.6	0.9062			
Week 52																	
Placebo		63	76.1	2.0	61 (91.0%)	1.2	1.9	-2.6	5.0								
Nera 18mg		62	76.5	2.1	62 (91.2%)	1.8	1.9	-2.0	5.6	0.6	2.7	-4.7	6.0	0.8229			
Week 64																	
Placebo		56	76.8	1.9	54 (80.6%)	1.2	2.0	-2.6	5.1								
Nera 18mg		60	76.6	2.3	60 (88.2%)	1.7	1.9	-2.1	5.4	0.4	2.7	-4.9	5.8	0.8780			
Week 76																	
Placebo		40	77.5	2.2	38 (56.7%)												
Nera 18mg		46	77.3	2.5	46 (67.6%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 88																	
Placebo		21	75.2	2.9	21 (31.3%)												
Nera 18mg		22	83.0	2.4	22 (32.4%)												
Week 100																	
Placebo		5	77.0	3.0	5 (7.5%)												
Nera 18mg		5	85.6	5.6	5 (7.4%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	90.0	NC	1 (1.5%)												
Other ILD																	
Baseline																	
Placebo	36	35	71.5	3.0	35 (100.0%)												
Nera 18mg	25	25	72.3	3.4	24 (100.0%)												
Week 6																	
Placebo		36	68.4	2.8	35 (100.0%)	-4.1	2.2	-8.5	0.2								
Nera 18mg		24	75.2	2.9	24 (100.0%)	3.0	2.7	-2.2	8.2	7.2	3.4	0.4	13.9	0.0373	0.55	0.02	1.07
Week 12																	
Placebo		34	67.4	3.5	33 (94.3%)	-5.4	2.4	-10.0	-0.8								
Nera 18mg		24	74.0	3.7	24 (100.0%)	1.6	2.8	-3.9	7.1	7.0	3.7	-0.2	14.2	0.0566			
Week 18																	
Placebo		32	70.5	3.4	31 (88.6%)	-3.2	2.6	-8.3	1.9								
Nera 18mg		22	77.0	3.3	22 (91.7%)	4.1	3.1	-2.0	10.2	7.3	4.0	-0.7	15.2	0.0732			
Week 26																	
Placebo		32	66.8	3.7	31 (88.6%)	-6.2	2.5	-11.0	-1.3								
Nera 18mg		23	71.5	4.1	23 (95.8%)	-0.4	2.9	-6.1	5.4	5.8	3.8	-1.7	13.3	0.1303			
Week 36																	
Placebo		30	65.0	4.0	29 (82.9%)	-8.4	2.7	-13.7	-3.1								
Nera 18mg		23	74.2	3.7	23 (95.8%)	2.4	3.1	-3.8	8.5	10.8	4.1	2.7	18.9	0.0090	0.72	0.17	1.28
Week 44																	
Placebo		26	67.0	3.6	25 (71.4%)	-8.0	2.9	-13.7	-2.3								
Nera 18mg		23	75.5	2.9	23 (95.8%)	3.5	3.2	-2.7	9.8	11.5	4.3	3.0	20.0	0.0080	0.76	0.18	1.34
Week 52																	
Placebo		27	64.9	4.3	26 (74.3%)	-10.0	2.8	-15.6	-4.4								
Nera 18mg		22	72.3	3.5	22 (91.7%)	0.9	3.2	-5.4	7.2	10.9	4.3	2.5	19.4	0.0114	0.73	0.15	1.30
Week 64																	
Placebo		24	62.2	4.0	23 (65.7%)	-13.2	2.9	-18.9	-7.5								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Nera 18mg		21	72.6	4.1	21 (87.5%)	0.6	3.2	-5.7	6.9	13.8	4.3	5.3	22.3	0.0015	0.95	0.33	1.56
Week 76																	
Placebo		15	60.1	6.0	15 (42.9%)												
Nera 18mg		14	73.6	4.2	14 (58.3%)												
Week 88																	
Placebo		9	55.0	8.4	9 (25.7%)												
Nera 18mg		10	72.9	6.8	10 (41.7%)												
Week 100																	
Placebo		4	60.5	11.9	4 (11.4%)												
Nera 18mg		5	77.8	7.7	5 (20.8%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	80.0	NC	1 (4.2%)												
Region																	
Test for homogeneity (H0)^																	
Week 6														0.8154			
Week 12														0.9522			
Week 18														0.2613			
Week 26														0.2361			
Week 36														0.8955			
Week 44														0.5383			
Week 52														0.7094			
Week 64														0.9943			
Europe																	
Baseline																	
Placebo	40	38	67.0	3.0	38 (100.0%)												
Nera 18mg	53	52	68.7	2.3	51 (100.0%)												
Week 6																	
Placebo		40	67.7	2.7	38 (100.0%)	-2.4	2.1	-6.6	1.8								
Nera 18mg		51	67.8	2.4	50 (98.0%)	-2.0	1.8	-5.7	1.6	0.4	2.8	-5.1	5.9	0.8861			
Week 12																	
Placebo		36	66.0	2.6	34 (89.5%)	-5.4	2.3	-10.0	-0.8								
Nera 18mg		50	65.9	2.7	49 (96.1%)	-3.6	2.0	-7.5	0.2	1.8	3.0	-4.1	7.7	0.5508			

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 18																	
Placebo		38	66.3	2.9	36 (94.7%)	-6.3	2.4	-11.0	-1.6								
Nera 18mg		48	64.9	2.5	47 (92.2%)	-6.3	2.1	-10.3	-2.2	0.0	3.1	-6.1	6.2	0.9920			
Week 26																	
Placebo		36	64.0	3.4	34 (89.5%)	-7.9	2.4	-12.5	-3.2								
Nera 18mg		45	68.7	2.3	44 (86.3%)	-2.8	2.1	-6.9	1.3	5.0	3.1	-1.1	11.2	0.1072			
Week 36																	
Placebo		33	68.5	2.9	31 (81.6%)	-6.2	2.6	-11.4	-1.1								
Nera 18mg		45	66.6	3.0	44 (86.3%)	-4.2	2.2	-8.6	0.2	2.0	3.4	-4.7	8.7	0.5520			
Week 44																	
Placebo		33	68.0	3.5	31 (81.6%)	-5.9	2.7	-11.2	-0.6								
Nera 18mg		44	69.1	2.7	43 (84.3%)	-2.6	2.3	-7.1	1.9	3.3	3.5	-3.6	10.2	0.3516			
Week 52																	
Placebo		33	68.5	3.6	31 (81.6%)	-5.0	2.7	-10.3	0.4								
Nera 18mg		44	68.6	2.7	43 (84.3%)	-3.3	2.3	-7.8	1.2	1.6	3.5	-5.3	8.6	0.6410			
Week 64																	
Placebo		29	65.1	3.6	27 (71.1%)	-9.3	2.8	-14.8	-3.9								
Nera 18mg		42	67.1	2.9	41 (80.4%)	-5.2	2.3	-9.7	-0.7	4.1	3.6	-2.9	11.1	0.2448			
Week 76																	
Placebo		18	63.5	4.9	16 (42.1%)												
Nera 18mg		28	65.2	3.6	27 (52.9%)												
Week 88																	
Placebo		8	52.6	8.6	8 (21.1%)												
Nera 18mg		8	57.4	8.6	8 (15.7%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	49.0	NC	1 (2.0%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Asia																	
Baseline																	
Placebo	106	106	77.1	1.5	106 (100.0%)												
Nera 18mg	107	106	76.9	1.4	102 (100.0%)												
Week 6																	
Placebo		106	79.3	1.3	106 (100.0%)	4.1	1.3	1.6	6.6								

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g 95% CI value	lower	upper
Nera 18mg		102	79.2	1.3	101 (99.0%)	3.8	1.3	1.3	6.4	-0.3	1.8	-3.8	3.3	0.8817			
Week 12																	
Placebo		103	78.9	1.2	103 (97.2%)	3.6	1.4	0.9	6.2								
Nera 18mg		99	77.5	1.5	98 (96.1%)	2.5	1.4	-0.2	5.2	-1.1	1.9	-4.8	2.7	0.5800			
Week 18																	
Placebo		103	78.7	1.5	103 (97.2%)	3.9	1.4	1.1	6.7								
Nera 18mg		96	80.1	1.4	95 (93.1%)	5.0	1.5	2.2	7.9	1.1	2.0	-2.8	5.1	0.5746			
Week 26																	
Placebo		100	76.8	1.6	100 (94.3%)	1.1	1.4	-1.6	3.9								
Nera 18mg		94	78.4	1.4	93 (91.2%)	2.3	1.4	-0.6	5.1	1.1	2.0	-2.8	5.0	0.5697			
Week 36																	
Placebo		97	73.9	1.8	97 (91.5%)	-1.8	1.5	-4.8	1.1								
Nera 18mg		92	78.7	1.5	92 (90.2%)	2.0	1.6	-1.1	5.1	3.8	2.2	-0.4	8.1	0.0742			
Week 44																	
Placebo		93	74.2	1.8	93 (87.7%)	-1.8	1.6	-4.9	1.3								
Nera 18mg		92	77.1	1.6	92 (90.2%)	1.0	1.6	-2.1	4.2	2.8	2.2	-1.5	7.2	0.2023			
Week 52																	
Placebo		93	75.6	1.7	93 (87.7%)	-1.3	1.6	-4.4	1.8								
Nera 18mg		89	77.4	1.5	88 (86.3%)	0.7	1.6	-2.5	3.9	2.0	2.2	-2.4	6.4	0.3757			
Week 64																	
Placebo		85	75.8	1.8	85 (80.2%)	-1.7	1.6	-4.8	1.5								
Nera 18mg		87	78.0	1.7	87 (85.3%)	1.5	1.6	-1.6	4.7	3.2	2.2	-1.2	7.6	0.1502			
Week 76																	
Placebo		70	74.7	2.0	70 (66.0%)												
Nera 18mg		71	75.2	2.1	71 (69.6%)												
Week 88																	
Placebo		42	74.9	2.5	42 (39.6%)												
Nera 18mg		43	77.1	2.5	43 (42.2%)												
Week 100																	
Placebo		13	69.9	5.4	13 (12.3%)												
Nera 18mg		15	77.7	4.6	15 (14.7%)												
Week 112																	
Placebo		1	77.0	NC	1 (0.9%)												
Nera 18mg		2	85.0	5.0	2 (2.0%)												
Canada and USA																	
Baseline																	

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo	30	28	69.1	3.8	28 (100.0%)												
Nera 18mg	17	17	67.7	5.0	17 (100.0%)												
Week 6																	
Placebo		29	73.3	3.7	28 (100.0%)	2.1	2.5	-2.7	7.0								
Nera 18mg		17	72.9	3.1	17 (100.0%)	2.8	3.2	-3.4	9.0	0.7	4.0	-7.2	8.5	0.8698			
Week 12																	
Placebo		28	69.5	4.1	27 (96.4%)	-1.8	2.6	-6.9	3.4								
Nera 18mg		17	72.2	3.6	17 (100.0%)	1.9	3.3	-4.7	8.4	3.6	4.2	-4.7	11.9	0.3909			
Week 18																	
Placebo		24	73.7	3.9	23 (82.1%)	2.4	2.9	-3.2	8.1								
Nera 18mg		17	82.2	2.5	17 (100.0%)	11.3	3.5	4.5	18.1	8.8	4.5	0.0	17.7	0.0499	0.62	-0.01	1.25
Week 26																	
Placebo		23	70.9	4.2	22 (78.6%)	-1.5	2.9	-7.2	4.2								
Nera 18mg		17	71.5	4.5	17 (100.0%)	1.4	3.4	-5.3	8.1	2.9	4.5	-5.9	11.7	0.5160			
Week 36																	
Placebo		23	73.4	4.1	22 (78.6%)	1.6	3.1	-4.6	7.7								
Nera 18mg		16	71.5	3.8	16 (94.1%)	2.2	3.7	-5.1	9.5	0.7	4.8	-8.8	10.1	0.8927			
Week 44																	
Placebo		22	77.0	3.3	21 (75.0%)	3.1	3.2	-3.3	9.4								
Nera 18mg		17	69.0	4.7	17 (100.0%)	-1.1	3.8	-8.5	6.3	-4.1	5.0	-13.9	5.6	0.4030			
Week 52																	
Placebo		20	74.1	4.7	19 (67.9%)	-0.6	3.3	-7.1	6.0								
Nera 18mg		17	73.6	3.8	17 (100.0%)	4.0	3.8	-3.4	11.4	4.6	5.0	-5.3	14.4	0.3638			
Week 64																	
Placebo		20	73.8	4.4	19 (67.9%)	-0.7	3.3	-7.1	5.8								
Nera 18mg		14	72.4	4.8	14 (82.4%)	3.6	3.9	-4.0	11.1	4.2	5.1	-5.7	14.2	0.4020			
Week 76																	
Placebo		11	72.7	4.7	11 (39.3%)												
Nera 18mg		7	75.4	4.3	7 (41.2%)												
Week 88																	
Placebo		7	71.4	7.5	7 (25.0%)												
Nera 18mg		4	76.8	8.4	4 (23.5%)												
Week 100																	
Placebo		5	59.0	15.2	5 (17.9%)												
Nera 18mg		3	81.7	3.3	3 (17.6%)												
Week 112																	

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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	Change from baseline n2 (%)	adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Rest of the World																	
Baseline																	
Placebo	46	46	67.1	2.5	43 (100.0%)												
Nera 18mg	43	43	67.8	2.4	43 (100.0%)												
Week 6																	
Placebo		43	72.5	2.1	43 (100.0%)	1.8	2.0	-2.1	5.7								
Nera 18mg		43	70.5	2.6	43 (100.0%)	0.3	2.0	-3.6	4.2	-1.5	2.8	-7.0	4.0	0.5953			
Week 12																	
Placebo		43	69.2	2.5	43 (100.0%)	-1.6	2.1	-5.7	2.5								
Nera 18mg		42	71.2	2.5	42 (97.7%)	0.6	2.1	-3.6	4.7	2.2	3.0	-3.6	8.0	0.4607			
Week 18																	
Placebo		42	71.8	2.7	42 (97.7%)	0.4	2.2	-3.9	4.7								
Nera 18mg		41	73.8	1.9	41 (95.3%)	2.9	2.2	-1.4	7.3	2.5	3.1	-3.6	8.6	0.4169			
Week 26																	
Placebo		43	74.9	2.1	43 (100.0%)	4.5	2.1	0.2	8.7								
Nera 18mg		41	72.5	3.0	41 (95.3%)	2.5	2.2	-1.8	6.8	-2.0	3.0	-7.9	4.0	0.5219			
Week 36																	
Placebo		40	70.5	2.8	40 (93.0%)	-0.5	2.3	-5.2	4.1								
Nera 18mg		37	72.3	3.3	37 (86.0%)	2.6	2.4	-2.1	7.4	3.2	3.3	-3.4	9.7	0.3462			
Week 44																	
Placebo		39	72.0	2.6	39 (90.7%)	0.9	2.4	-3.8	5.7								
Nera 18mg		38	74.6	2.7	38 (88.4%)	4.5	2.5	-0.4	9.4	3.5	3.5	-3.3	10.3	0.3061			
Week 52																	
Placebo		37	70.5	3.0	37 (86.0%)	-0.9	2.5	-5.8	3.9								
Nera 18mg		39	71.2	3.5	39 (90.7%)	2.1	2.5	-2.8	6.9	3.0	3.5	-3.8	9.8	0.3853			
Week 64																	
Placebo		33	71.2	2.7	33 (76.7%)	-0.8	2.5	-5.7	4.1								
Nera 18mg		36	74.5	2.7	36 (83.7%)	4.1	2.5	-0.8	8.9	4.9	3.5	-2.0	11.8	0.1625			
Week 76																	
Placebo		15	74.6	4.0	15 (34.9%)												
Nera 18mg		19	82.5	2.8	19 (44.2%)												
Week 88																	
Placebo		2	70.0	0.0	2 (4.7%)												
Nera 18mg		9	79.4	3.1	9 (20.9%)												

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Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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Table I.1.2.1.2.1: 1 Adjusted mean (SE) of absolute change from baseline in EQ-5D VAS (MMRM) over the whole trial - 18mg - FAS (non-AF background)

Subgroup / Category / Visit / Treatment	N	Descriptive statistics n1	Mean	SE	n2 (%)	Change from baseline adj Mean	SE	95% CI lower	upper	Nera 18mg vs. Placebo adj mean diff	SE	95% CI lower	upper	p-value	Hedges'g value	95% CI lower	upper
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		2	75.0	5.0	2 (4.7%)												
Week 112																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0023. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
n2: Number of patients analysed at visit, i.e. patients with measured baseline and at least one post-baseline (% based on baseline n2)
Model is based on fixed, categorical effects of treatment at each visit, baseline HRCT pattern (UIP-like/Other fibrotic patterns) at each visit, continuous baseline EQ-5D VAS at each visit as fixed effect(s) and unstructured covariance for repeated measures.
Data up until week 64 is included and analysed in the model.
Subgroup models include treatment by subgroup by visit interaction. Covariate removed from model if also used as the subgroup.
Hedges´g will be presented in case of a significant treatment comparison. NC: Not calculable

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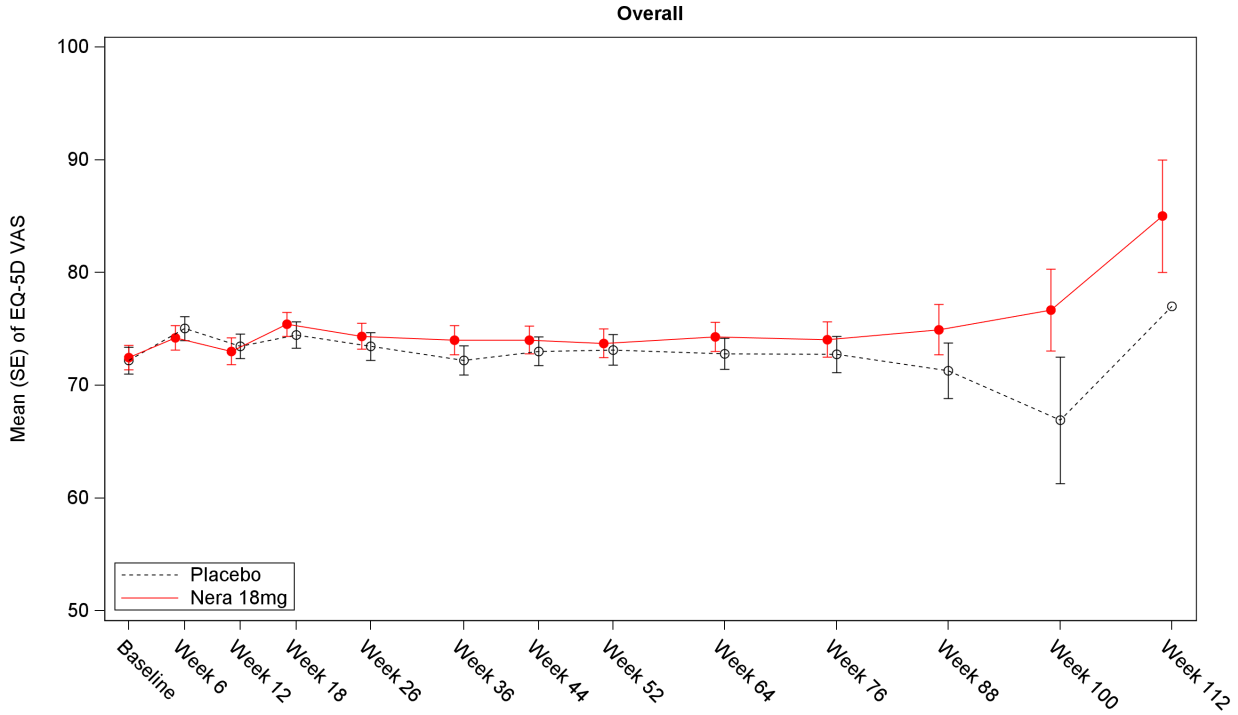

Number of patients

Placebo	218	218	210	207	202	193	187	183	167	114	59	18	1
Nera 18mg	218	213	208	202	197	190	191	189	179	125	64	21	2

Study: 1305-0023. Number of patients refers to the number of patients with observed data at visit.

Figure I.1.2.1.2.1: 1 Mean (SE) of EQ-5D VAS
over the whole trial - 18mg - FAS (non-AF background)

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Boehringer Ingelheim
BI Trial No.: x1305p3.hta

Figure I.1.2.1.2.1: 1

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I.1.2.2 Safety analysis

I.1.2.2.1 Safety analysis over the whole trial

I.1.2.2.1.1 Adverse events overall over the whole trial

Table I.1.2.2.1.1: 1 Proportion of patients with any adverse events over the whole trial - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	213	95.9	220	207	94.1	0.3699	0.98 (0.94, 1.02)	0.67 (0.28, 1.61)	-1.86 (-6.23, 2.38)	
Age											0.1898
<65 years	83	79	95.2	88	79	89.8	0.1823	0.94 (0.87, 1.03)	0.44 (0.13, 1.50)	-5.41 (-14.00, 2.99)	
>=65 years	139	134	96.4	132	128	97.0	0.7946	1.01 (0.96, 1.05)	1.19 (0.31, 4.55)	0.57 (-4.38, 5.47)	
Sex											0.7001
Male	116	112	96.6	111	106	95.5	0.6835	0.99 (0.94, 1.04)	0.76 (0.20, 2.90)	-1.06 (-7.05, 4.64)	
Female	106	101	95.3	109	101	92.7	0.4199	0.97 (0.91, 1.04)	0.63 (0.20, 1.98)	-2.62 (-9.64, 4.24)	
Baseline FVC percent predicted											0.0824
<=70%	118	115	97.5	96	88	91.7	0.0564	0.94 (0.88, 1.01)	0.29 (0.07, 1.11)	-5.79 (-13.24, 0.39)	
>70%	104	98	94.2	124	119	96.0	0.5421	1.02 (0.96, 1.08)	1.46 (0.43, 4.92)	1.74 (-4.20, 8.40)	
Baseline HRCT pattern											0.8568
UIP-like	158	150	94.9	154	143	92.9	0.4425	0.98 (0.92, 1.04)	0.69 (0.27, 1.77)	-2.08 (-7.83, 3.48)	
Other fibrotic patterns	64	63	98.4	66	64	97.0	0.5774	0.99 (0.93, 1.04)	0.51 (0.04, 5.74)	-1.47 (-8.94, 5.65)	
Underlying ILD diagnosis											0.7083
iNSIP	40	39	97.5	55	50	90.9	0.1923	0.93 (0.85, 1.03)	0.26 (0.03, 2.29)	-6.59 (-17.28, 5.00)	
Unclassifiable IIP	36	34	94.4	40	38	95.0	0.9138	1.01 (0.90, 1.12)	1.12 (0.15, 8.37)	0.56 (-11.63, 13.65)	
HP	39	38	97.4	30	28	93.3	0.4074	0.96 (0.86, 1.07)	0.37 (0.03, 4.27)	-4.10 (-18.91, 7.56)	
Autoimmune ILD	71	66	93.0	70	66	94.3	0.7471	1.01 (0.93, 1.11)	1.25 (0.32, 4.86)	1.33 (-7.68, 10.42)	
Other ILD	36	36	100.0	25	25	100.0	0.8581	0.99 (0.93, 1.06)	NC (NC, NC)	0.00 (NC, NC)	
Region											0.9561
Europe	40	40	100.0	53	51	96.2	0.2142	0.96 (0.91, 1.01)	0.00 (NC, NC)	-3.77 (-12.75, 5.40)	
Asia	106	103	97.2	107	102	95.3	0.4794	0.98 (0.93, 1.03)	0.59 (0.14, 2.55)	-1.84 (-7.94, 3.96)	
Canada and USA	30	29	96.7	17	16	94.1	0.6774	0.97 (0.85, 1.12)	0.55 (0.03, 9.43)	-2.55 (-23.83, 11.64)	
Rest of the World	46	41	89.1	43	38	88.4	0.9099	0.99 (0.85, 1.15)	0.93 (0.25, 3.46)	-0.76 (-15.00, 13.06)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.2.1.1: 2 Proportion of patients with any adverse events (excluding disease-related events) over the whole trial - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	211	95.0	220	207	94.1	0.6581	0.99 (0.95, 1.04)	0.83 (0.36, 1.90)	-0.95 (-5.45, 3.47)	
Age											0.4594
<65 years	83	77	92.8	88	79	89.8	0.4885	0.97 (0.88, 1.06)	0.68 (0.23, 2.01)	-3.00 (-11.96, 6.01)	
>=65 years	139	134	96.4	132	128	97.0	0.7946	1.01 (0.96, 1.05)	1.19 (0.31, 4.55)	0.57 (-4.38, 5.47)	
Sex											0.9465
Male	116	112	96.6	111	106	95.5	0.6835	0.99 (0.94, 1.04)	0.76 (0.20, 2.90)	-1.06 (-7.05, 4.64)	
Female	106	99	93.4	109	101	92.7	0.8323	0.99 (0.92, 1.07)	0.89 (0.31, 2.55)	-0.74 (-8.04, 6.60)	
Baseline FVC percent predicted											0.0894
<=70%	118	114	96.6	96	88	91.7	0.1180	0.95 (0.89, 1.02)	0.39 (0.11, 1.32)	-4.94 (-12.49, 1.49)	
>70%	104	97	93.3	124	119	96.0	0.3634	1.03 (0.97, 1.10)	1.72 (0.53, 5.58)	2.70 (-3.42, 9.61)	
Baseline HRCT pattern											0.3877
UIP-like	158	150	94.9	154	143	92.9	0.4425	0.98 (0.92, 1.04)	0.69 (0.27, 1.77)	-2.08 (-7.83, 3.48)	
Other fibrotic patterns	64	61	95.3	66	64	97.0	0.6233	1.02 (0.95, 1.09)	1.57 (0.25, 9.74)	1.66 (-6.32, 10.16)	
Underlying ILD diagnosis											0.5295
iNSIP	40	39	97.5	55	50	90.9	0.1923	0.93 (0.85, 1.03)	0.26 (0.03, 2.29)	-6.59 (-17.28, 5.00)	
Unclassifiable IIP	36	34	94.4	40	38	95.0	0.9138	1.01 (0.90, 1.12)	1.12 (0.15, 8.37)	0.56 (-11.63, 13.65)	
HP	39	38	97.4	30	28	93.3	0.4074	0.96 (0.86, 1.07)	0.37 (0.03, 4.27)	-4.10 (-18.91, 7.56)	
Autoimmune ILD	71	64	90.1	70	66	94.3	0.3589	1.05 (0.95, 1.15)	1.80 (0.50, 6.46)	4.14 (-5.36, 13.90)	
Other ILD	36	36	100.0	25	25	100.0	0.8581	0.99 (0.93, 1.06)	NC (NC, NC)	0.00 (NC, NC)	
Region											0.8514
Europe	40	40	100.0	53	51	96.2	0.2142	0.96 (0.91, 1.01)	0.00 (NC, NC)	-3.77 (-12.75, 5.40)	
Asia	106	102	96.2	107	102	95.3	0.7443	0.99 (0.94, 1.05)	0.80 (0.21, 3.06)	-0.90 (-7.14, 5.24)	
Canada and USA	30	29	96.7	17	16	94.1	0.6774	0.97 (0.85, 1.12)	0.55 (0.03, 9.43)	-2.55 (-23.83, 11.64)	
Rest of the World	46	40	87.0	43	38	88.4	0.8393	1.02 (0.87, 1.19)	1.14 (0.32, 4.05)	1.42 (-13.18, 15.64)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.2.1.1: 3 Proportion of patients with serious adverse events over the whole trial - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	113	50.9	220	94	42.7	0.0851	0.84 (0.69, 1.03)	0.72 (0.49, 1.05)	-8.17 (-17.27, 1.12)	
Age											0.3089
<65 years	83	39	47.0	88	30	34.1	0.0858	0.73 (0.50, 1.05)	0.58 (0.32, 1.08)	-12.90 (-26.86, 1.77)	
>=65 years	139	74	53.2	132	64	48.5	0.4341	0.91 (0.72, 1.15)	0.83 (0.51, 1.33)	-4.75 (-16.39, 7.07)	
Sex											0.7443
Male	116	64	55.2	111	50	45.0	0.1271	0.82 (0.63, 1.06)	0.67 (0.39, 1.12)	-10.13 (-22.63, 2.84)	
Female	106	49	46.2	109	44	40.4	0.3859	0.87 (0.64, 1.19)	0.79 (0.46, 1.35)	-5.86 (-18.73, 7.28)	
Baseline FVC percent predicted											0.2769
<=70%	118	71	60.2	96	45	46.9	0.0522	0.78 (0.60, 1.01)	0.58 (0.34, 1.01)	-13.29 (-26.09, 0.10)	
>70%	104	42	40.4	124	49	39.5	0.8939	0.98 (0.71, 1.35)	0.96 (0.57, 1.64)	-0.87 (-13.48, 11.66)	
Baseline HRCT pattern											0.0296
UIP-like	158	75	47.5	154	71	46.1	0.8092	0.97 (0.77, 1.23)	0.95 (0.61, 1.48)	-1.36 (-12.28, 9.60)	
Other fibrotic patterns	64	38	59.4	66	23	34.8	0.0051	0.59 (0.40, 0.86)	0.37 (0.18, 0.74)	-24.53 (-39.77, -7.37)	
Underlying ILD diagnosis											0.5920
iNSIP	40	21	52.5	55	22	40.0	0.2269	0.76 (0.49, 1.18)	0.60 (0.27, 1.37)	-12.50 (-31.30, 7.47)	
Unclassifiable IIP	36	19	52.8	40	21	52.5	0.9807	0.99 (0.65, 1.52)	0.99 (0.40, 2.44)	-0.28 (-21.66, 21.19)	
HP	39	19	48.7	30	10	33.3	0.1993	0.68 (0.38, 1.25)	0.53 (0.20, 1.41)	-15.38 (-36.03, 7.86)	
Autoimmune ILD	71	29	40.8	70	29	41.4	0.9439	1.01 (0.68, 1.51)	1.02 (0.52, 2.00)	0.58 (-15.28, 16.42)	
Other ILD	36	25	69.4	25	12	48.0	0.0918	0.69 (0.44, 1.10)	0.41 (0.14, 1.17)	-21.44 (-43.36, 3.21)	
Region											0.3338
Europe	40	20	50.0	53	27	50.9	0.9282	1.02 (0.68, 1.53)	1.04 (0.46, 2.36)	0.94 (-18.80, 20.60)	
Asia	106	59	55.7	107	52	48.6	0.3023	0.87 (0.67, 1.13)	0.75 (0.44, 1.29)	-7.06 (-20.04, 6.26)	
Canada and USA	30	14	46.7	17	4	23.5	0.1169	0.50 (0.20, 1.29)	0.35 (0.09, 1.33)	-23.14 (-45.29, 5.73)	
Rest of the World	46	20	43.5	43	11	25.6	0.0766	0.59 (0.32, 1.08)	0.45 (0.18, 1.10)	-17.90 (-35.71, 1.87)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.2.1.1: 4 Proportion of patients with serious adverse events (excluding disease-related events) over the whole trial - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	108	48.6	220	91	41.4	0.1238	0.85 (0.69, 1.05)	0.74 (0.51, 1.08)	-7.29 (-16.37, 1.98)	
Age											0.3456
<65 years	83	37	44.6	88	29	33.0	0.1186	0.74 (0.50, 1.08)	0.61 (0.33, 1.14)	-11.62 (-25.56, 2.92)	
>=65 years	139	71	51.1	132	62	47.0	0.4988	0.92 (0.72, 1.17)	0.85 (0.53, 1.37)	-4.11 (-15.76, 7.70)	
Sex											0.8713
Male	116	61	52.6	111	49	44.1	0.2033	0.84 (0.64, 1.10)	0.71 (0.42, 1.20)	-8.44 (-20.99, 4.50)	
Female	106	47	44.3	109	42	38.5	0.3874	0.87 (0.63, 1.20)	0.79 (0.46, 1.36)	-5.81 (-18.61, 7.26)	
Baseline FVC percent predicted											0.2248
<=70%	118	67	56.8	96	42	43.8	0.0579	0.77 (0.58, 1.02)	0.59 (0.34, 1.02)	-13.03 (-25.83, 0.41)	
>70%	104	41	39.4	124	49	39.5	0.9886	1.00 (0.73, 1.38)	1.00 (0.59, 1.71)	0.09 (-12.52, 12.57)	
Baseline HRCT pattern											0.0355
UIP-like	158	72	45.6	154	69	44.8	0.8921	0.98 (0.77, 1.26)	0.97 (0.62, 1.51)	-0.76 (-11.66, 10.17)	
Other fibrotic patterns	64	36	56.3	66	22	33.3	0.0086	0.59 (0.40, 0.89)	0.39 (0.19, 0.79)	-22.92 (-38.24, -5.82)	
Underlying ILD diagnosis											0.5438
iNSIP	40	19	47.5	55	21	38.2	0.3638	0.80 (0.50, 1.28)	0.68 (0.30, 1.56)	-9.32 (-28.32, 10.34)	
Unclassifiable IIP	36	18	50.0	40	20	50.0	1.0000	1.00 (0.64, 1.57)	1.00 (0.41, 2.46)	0.00 (-21.45, 21.45)	
HP	39	19	48.7	30	9	30.0	0.1165	0.62 (0.33, 1.16)	0.45 (0.17, 1.23)	-18.72 (-38.85, 4.52)	
Autoimmune ILD	71	28	39.4	70	29	41.4	0.8096	1.05 (0.70, 1.57)	1.09 (0.55, 2.13)	1.99 (-13.88, 17.73)	
Other ILD	36	24	66.7	25	12	48.0	0.1449	0.72 (0.45, 1.15)	0.46 (0.16, 1.31)	-18.67 (-40.91, 6.01)	
Region											0.4099
Europe	40	19	47.5	53	25	47.2	0.9748	0.99 (0.64, 1.53)	0.99 (0.43, 2.25)	-0.33 (-20.04, 19.31)	
Asia	106	56	52.8	107	51	47.7	0.4508	0.90 (0.69, 1.18)	0.81 (0.47, 1.39)	-5.17 (-18.22, 8.14)	
Canada and USA	30	14	46.7	17	4	23.5	0.1169	0.50 (0.20, 1.29)	0.35 (0.09, 1.33)	-23.14 (-45.29, 5.73)	
Rest of the World	46	19	41.3	43	11	25.6	0.1169	0.62 (0.33, 1.15)	0.49 (0.20, 1.20)	-15.72 (-33.60, 3.88)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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I.1.2.2.1.2 Adverse events by intensity over the whole trial

Table I.1.2.2.1.2: 1 Proportion of patients with any adverse events with CTCAE grade >=3 over the whole trial - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	102	45.9	220	82	37.3	0.0644	0.81 (0.65, 1.01)	0.70 (0.48, 1.02)	-8.67 (-17.65, 0.51)	
Age											0.7635
<65 years	83	34	41.0	88	28	31.8	0.2137	0.78 (0.52, 1.16)	0.67 (0.36, 1.26)	-9.15 (-23.04, 5.19)	
>=65 years	139	68	48.9	132	54	40.9	0.1852	0.84 (0.64, 1.09)	0.72 (0.45, 1.17)	-8.01 (-19.50, 3.80)	
Sex											0.4722
Male	116	57	49.1	111	41	36.9	0.0636	0.75 (0.55, 1.02)	0.61 (0.36, 1.03)	-12.20 (-24.50, 0.67)	
Female	106	45	42.5	109	41	37.6	0.4691	0.89 (0.64, 1.23)	0.82 (0.47, 1.41)	-4.84 (-17.61, 8.14)	
Baseline FVC percent predicted											0.2577
<=70%	118	67	56.8	96	41	42.7	0.0406	0.75 (0.57, 1.00)	0.57 (0.33, 0.98)	-14.07 (-26.82, -0.62)	
>70%	104	35	33.7	124	41	33.1	0.9251	0.98 (0.68, 1.42)	0.97 (0.56, 1.69)	-0.59 (-12.81, 11.46)	
Baseline HRCT pattern											0.3644
UIP-like	158	71	44.9	154	60	39.0	0.2850	0.87 (0.67, 1.13)	0.78 (0.50, 1.23)	-5.98 (-16.68, 4.93)	
Other fibrotic patterns	64	31	48.4	66	22	33.3	0.0798	0.69 (0.45, 1.05)	0.53 (0.26, 1.08)	-15.10 (-30.82, 1.74)	
Underlying ILD diagnosis											0.6168
iNSIP	40	19	47.5	55	19	34.5	0.2032	0.73 (0.45, 1.19)	0.58 (0.25, 1.34)	-12.95 (-31.67, 6.70)	
Unclassifiable IIP	36	17	47.2	40	15	37.5	0.3914	0.79 (0.47, 1.35)	0.67 (0.27, 1.67)	-9.72 (-30.34, 11.99)	
HP	39	16	41.0	30	7	23.3	0.1222	0.57 (0.27, 1.20)	0.44 (0.15, 1.26)	-17.69 (-37.06, 4.76)	
Autoimmune ILD	71	28	39.4	70	29	41.4	0.8096	1.05 (0.70, 1.57)	1.09 (0.55, 2.13)	1.99 (-13.88, 17.73)	
Other ILD	36	22	61.1	25	12	48.0	0.3106	0.79 (0.48, 1.27)	0.59 (0.21, 1.65)	-13.11 (-35.95, 11.51)	
Region											0.5944
Europe	40	17	42.5	53	22	41.5	0.9236	0.98 (0.60, 1.58)	0.96 (0.42, 2.21)	-0.99 (-20.59, 18.38)	
Asia	106	55	51.9	107	46	43.0	0.1936	0.83 (0.62, 1.10)	0.70 (0.41, 1.20)	-8.90 (-21.81, 4.45)	
Canada and USA	30	12	40.0	17	4	23.5	0.2522	0.59 (0.22, 1.54)	0.46 (0.12, 1.76)	-16.47 (-39.01, 11.83)	
Rest of the World	46	18	39.1	43	10	23.3	0.1070	0.59 (0.31, 1.14)	0.47 (0.19, 1.19)	-15.87 (-33.48, 3.42)	

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.2.1.2: 2 Proportion of patients with any adverse events (excluding disease-related events) with CTCAE grade >=3 over the whole trial - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	94	42.3	220	79	35.9	0.1659	0.85 (0.67, 1.07)	0.76 (0.52, 1.12)	-6.43 (-15.37, 2.65)	
Age											0.6625
<65 years	83	31	37.3	88	26	29.5	0.2793	0.79 (0.52, 1.21)	0.70 (0.37, 1.33)	-7.80 (-21.52, 6.24)	
>=65 years	139	63	45.3	132	53	40.2	0.3897	0.89 (0.67, 1.17)	0.81 (0.50, 1.31)	-5.17 (-16.67, 6.55)	
Sex											0.6044
Male	116	51	44.0	111	39	35.1	0.1740	0.80 (0.58, 1.11)	0.69 (0.40, 1.18)	-8.83 (-21.10, 3.86)	
Female	106	43	40.6	109	40	36.7	0.5602	0.90 (0.65, 1.27)	0.85 (0.49, 1.47)	-3.87 (-16.60, 9.02)	
Baseline FVC percent predicted											0.1064
<=70%	118	63	53.4	96	38	39.6	0.0442	0.74 (0.55, 1.00)	0.57 (0.33, 0.99)	-13.81 (-26.50, -0.37)	
>70%	104	31	29.8	124	41	33.1	0.5982	1.11 (0.75, 1.63)	1.16 (0.66, 2.04)	3.26 (-8.86, 15.02)	
Baseline HRCT pattern											0.3376
UIP-like	158	64	40.5	154	57	37.0	0.5266	0.91 (0.69, 1.21)	0.86 (0.55, 1.36)	-3.49 (-14.12, 7.26)	
Other fibrotic patterns	64	30	46.9	66	22	33.3	0.1151	0.71 (0.46, 1.09)	0.57 (0.28, 1.15)	-13.54 (-29.32, 3.22)	
Underlying ILD diagnosis											0.5823
iNSIP	40	17	42.5	55	18	32.7	0.3296	0.77 (0.46, 1.30)	0.66 (0.28, 1.53)	-9.77 (-28.57, 9.44)	
Unclassifiable IIP	36	16	44.4	40	14	35.0	0.4003	0.79 (0.45, 1.38)	0.67 (0.27, 1.70)	-9.44 (-29.96, 12.05)	
HP	39	15	38.5	30	7	23.3	0.1813	0.61 (0.28, 1.30)	0.49 (0.17, 1.41)	-15.13 (-34.56, 7.09)	
Autoimmune ILD	71	26	36.6	70	29	41.4	0.5583	1.13 (0.75, 1.71)	1.22 (0.62, 2.41)	4.81 (-11.06, 20.36)	
Other ILD	36	20	55.6	25	11	44.0	0.3746	0.79 (0.47, 1.35)	0.63 (0.22, 1.76)	-11.56 (-34.42, 13.22)	
Region											0.6314
Europe	40	15	37.5	53	21	39.6	0.8352	1.06 (0.63, 1.78)	1.09 (0.47, 2.54)	2.12 (-17.47, 21.01)	
Asia	106	51	48.1	107	44	41.1	0.3047	0.85 (0.63, 1.15)	0.75 (0.44, 1.29)	-6.99 (-19.91, 6.27)	
Canada and USA	30	12	40.0	17	4	23.5	0.2522	0.59 (0.22, 1.54)	0.46 (0.12, 1.76)	-16.47 (-39.01, 11.83)	
Rest of the World	46	16	34.8	43	10	23.3	0.2321	0.67 (0.34, 1.31)	0.57 (0.22, 1.44)	-11.53 (-29.16, 7.35)	

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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I.1.2.2.1.3 Adverse events leading to treatment discontinuation over the whole trial

Table I.1.2.2.1.3: 1 Proportion of patients with any adverse events leading to treatment discontinuation over the whole trial - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	28	12.6	220	22	10.0	0.3859	0.79 (0.47, 1.34)	0.77 (0.43, 1.39)	-2.61 (-8.62, 3.38)	
Age											0.3927
<65 years	83	10	12.0	88	6	6.8	0.2405	0.57 (0.22, 1.49)	0.53 (0.19, 1.54)	-5.23 (-14.69, 3.81)	
>=65 years	139	18	12.9	132	16	12.1	0.8370	0.94 (0.50, 1.76)	0.93 (0.45, 1.90)	-0.83 (-8.82, 7.27)	
Sex											0.4621
Male	116	16	13.8	111	10	9.0	0.2579	0.65 (0.31, 1.38)	0.62 (0.27, 1.43)	-4.78 (-13.25, 3.72)	
Female	106	12	11.3	109	12	11.0	0.9422	0.97 (0.46, 2.07)	0.97 (0.41, 2.26)	-0.31 (-9.05, 8.34)	
Baseline FVC percent predicted											0.0913
<=70%	118	18	15.3	96	7	7.3	0.0713	0.48 (0.21, 1.10)	0.44 (0.17, 1.09)	-7.96 (-16.40, 0.87)	
>70%	104	10	9.6	124	15	12.1	0.5503	1.26 (0.59, 2.68)	1.29 (0.55, 3.02)	2.48 (-6.07, 10.62)	
Baseline HRCT pattern											0.7756
UIP-like	158	21	13.3	154	17	11.0	0.5431	0.83 (0.46, 1.51)	0.81 (0.41, 1.60)	-2.25 (-9.63, 5.15)	
Other fibrotic patterns	64	7	10.9	66	5	7.6	0.5080	0.69 (0.23, 2.07)	0.67 (0.20, 2.22)	-3.36 (-14.21, 7.17)	
Underlying ILD diagnosis											0.6531
iNSIP	40	3	7.5	55	7	12.7	0.4124	1.70 (0.47, 6.16)	1.80 (0.44, 7.43)	5.23 (-8.71, 17.54)	
Unclassifiable IIP	36	2	5.6	40	2	5.0	0.9138	0.90 (0.13, 6.06)	0.89 (0.12, 6.70)	-0.56 (-13.65, 11.63)	
HP	39	6	15.4	30	2	6.7	0.2622	0.43 (0.09, 2.00)	0.39 (0.07, 2.10)	-8.72 (-23.85, 8.05)	
Autoimmune ILD	71	10	14.1	70	6	8.6	0.3021	0.61 (0.23, 1.58)	0.57 (0.20, 1.67)	-5.51 (-16.46, 5.36)	
Other ILD	36	7	19.4	25	5	20.0	0.9572	1.03 (0.37, 2.88)	1.04 (0.29, 3.73)	0.56 (-18.60, 22.00)	
Region											0.9184
Europe	40	5	12.5	53	7	13.2	0.9197	1.06 (0.36, 3.09)	1.07 (0.31, 3.64)	0.71 (-14.45, 14.30)	
Asia	106	8	7.5	107	7	6.5	0.7744	0.87 (0.33, 2.31)	0.86 (0.30, 2.46)	-1.01 (-8.44, 6.33)	
Canada and USA	30	6	20.0	17	2	11.8	0.4704	0.59 (0.13, 2.60)	0.53 (0.09, 2.99)	-8.24 (-27.51, 16.66)	
Rest of the World	46	9	19.6	43	6	14.0	0.4797	0.71 (0.28, 1.84)	0.67 (0.22, 2.06)	-5.61 (-21.10, 10.41)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.2.1.3: 2 Proportion of patients with any adverse events leading to treatment discontinuation (excluding disease-related events) over the whole trial - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	24	10.8	220	22	10.0	0.7802	0.93 (0.53, 1.60)	0.92 (0.50, 1.69)	-0.81 (-6.61, 4.99)	
Age											0.5178
<65 years	83	8	9.6	88	6	6.8	0.5014	0.71 (0.26, 1.95)	0.69 (0.23, 2.07)	-2.82 (-11.84, 5.82)	
>=65 years	139	16	11.5	132	16	12.1	0.8763	1.05 (0.55, 2.02)	1.06 (0.51, 2.22)	0.61 (-7.20, 8.54)	
Sex											0.6211
Male	116	13	11.2	111	10	9.0	0.5833	0.80 (0.37, 1.76)	0.78 (0.33, 1.87)	-2.20 (-10.30, 5.96)	
Female	106	11	10.4	109	12	11.0	0.8809	1.06 (0.49, 2.30)	1.07 (0.45, 2.54)	0.63 (-7.96, 9.16)	
Baseline FVC percent predicted											0.1326
<=70%	118	15	12.7	96	7	7.3	0.1941	0.57 (0.24, 1.35)	0.54 (0.21, 1.38)	-5.42 (-13.53, 3.10)	
>70%	104	9	8.7	124	15	12.1	0.3988	1.40 (0.64, 3.06)	1.45 (0.61, 3.47)	3.44 (-4.93, 11.44)	
Baseline HRCT pattern											0.5429
UIP-like	158	17	10.8	154	17	11.0	0.9369	1.03 (0.54, 1.94)	1.03 (0.50, 2.10)	0.28 (-6.78, 7.39)	
Other fibrotic patterns	64	7	10.9	66	5	7.6	0.5080	0.69 (0.23, 2.07)	0.67 (0.20, 2.22)	-3.36 (-14.21, 7.17)	
Underlying ILD diagnosis											0.3782
iNSIP	40	1	2.5	55	7	12.7	0.0764	5.09 (0.65, 39.76)	5.69 (0.67, 48.22)	10.23 (-1.98, 21.70)	
Unclassifiable IIP	36	2	5.6	40	2	5.0	0.9138	0.90 (0.13, 6.06)	0.89 (0.12, 6.70)	-0.56 (-13.65, 11.63)	
HP	39	6	15.4	30	2	6.7	0.2622	0.43 (0.09, 2.00)	0.39 (0.07, 2.10)	-8.72 (-23.85, 8.05)	
Autoimmune ILD	71	9	12.7	70	6	8.6	0.4293	0.68 (0.25, 1.80)	0.65 (0.22, 1.92)	-4.10 (-14.83, 6.55)	
Other ILD	36	6	16.7	25	5	20.0	0.7391	1.20 (0.41, 3.50)	1.25 (0.34, 4.65)	3.33 (-15.53, 24.39)	
Region											0.9265
Europe	40	4	10.0	53	7	13.2	0.6353	1.32 (0.41, 4.20)	1.37 (0.37, 5.04)	3.21 (-11.45, 16.32)	
Asia	106	8	7.5	107	7	6.5	0.7744	0.87 (0.33, 2.31)	0.86 (0.30, 2.46)	-1.01 (-8.44, 6.33)	
Canada and USA	30	4	13.3	17	2	11.8	0.8769	0.88 (0.18, 4.33)	0.87 (0.14, 5.31)	-1.57 (-19.98, 22.39)	
Rest of the World	46	8	17.4	43	6	14.0	0.6562	0.80 (0.30, 2.12)	0.77 (0.24, 2.44)	-3.44 (-18.68, 12.25)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.2.1.3: 3 Descriptive statistics of patients with any adverse events leading to treatment discontinuation over the whole trial by SOC and PT - 18mg - TS (non-AF background)

Primary System Organ Class Preferred Term	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %
Overall	222	28	12.6	220	22	10.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		4	1.8		7	3.2
Squamous cell carcinoma of skin		0	0.0		3	1.4
Brain neoplasm malignant		1	0.5		0	0.0
Colon cancer		1	0.5		0	0.0
Colorectal cancer		0	0.0		1	0.5
Non-small cell lung cancer		0	0.0		1	0.5
Papillary thyroid cancer		1	0.5		0	0.0
Small cell lung cancer		0	0.0		1	0.5
Squamous cell carcinoma of lung		1	0.5		0	0.0
Squamous cell carcinoma of the cervix		0	0.0		1	0.5
Infections and infestations		7	3.2		3	1.4
Pneumonia		3	1.4		1	0.5
Bronchopulmonary aspergillosis		1	0.5		0	0.0
COVID-19		1	0.5		0	0.0
Infection		1	0.5		0	0.0
Influenza		0	0.0		1	0.5
Meningitis viral		1	0.5		0	0.0
Pneumocystis jirovecii pneumonia		0	0.0		1	0.5
Pulmonary tuberculosis		1	0.5		0	0.0
General disorders and administration site conditions		6	2.7		1	0.5
Condition aggravated		6	2.7		0	0.0
Peripheral swelling		0	0.0		1	0.5
Psychiatric disorders		3	1.4		4	1.8
Depression		2	0.9		2	0.9
Suicidal ideation		0	0.0		2	0.9
Anxiety		0	0.0		1	0.5
Insomnia		0	0.0		1	0.5
Negative thoughts		1	0.5		0	0.0
Respiratory, thoracic and mediastinal disorders		6	2.7		0	0.0
Dyspnoea		3	1.4		0	0.0
Cough		1	0.5		0	0.0
Interstitial lung disease		1	0.5		0	0.0
Pneumothorax		1	0.5		0	0.0
Gastrointestinal disorders		1	0.5		3	1.4

Study: 1305-0023. MedDRA version: 27.1
N is the number of patients, n the number of patients with at least one event.
Percentages are calculated using total number of patients per treatment as the denominator.

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Table I.1.2.2.1.3: 3 Descriptive statistics of patients with any adverse events leading to treatment discontinuation over the whole trial by SOC and PT - 18mg - TS (non-AF background)

Primary System Organ Class Preferred Term	Placebo N	 n	 %	Nera 18mg N	 n	 %
Diarrhoea		0	0.0		3	1.4
Abdominal pain upper		1	0.5		0	0.0
Investigations		1	0.5		2	0.9
Alanine aminotransferase increased		1	0.5		0	0.0
Aspartate aminotransferase increased		1	0.5		0	0.0
Blood creatine phosphokinase increased		1	0.5		0	0.0
Interferon gamma release assay positive		0	0.0		1	0.5
Weight decreased		0	0.0		1	0.5
Cardiac disorders		1	0.5		1	0.5
Angina unstable		0	0.0		1	0.5
Cardiac failure		1	0.5		0	0.0
Metabolism and nutrition disorders		1	0.5		1	0.5
Decreased appetite		1	0.5		1	0.5
Musculoskeletal and connective tissue disorders		1	0.5		1	0.5
Muscular weakness		1	0.5		0	0.0
Pain in extremity		0	0.0		1	0.5
Nervous system disorders		2	0.9		0	0.0
Dizziness		2	0.9		0	0.0
Vascular disorders		0	0.0		1	0.5
Hypertension		0	0.0		1	0.5

Study: 1305-0023. MedDRA version: 27.1
N is the number of patients, n the number of patients with at least one event.
Percentages are calculated using total number of patients per treatment as the denominator.

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I.1.2.2.1.4 Adverse events on SOC level over the whole trial

Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Cardiac disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	20	9.0	220	35	15.9	0.0280	1.77 (1.05, 2.96)	1.91 (1.07, 3.43)	6.90 (0.72, 13.14)	
Age											0.4257
<65 years	83	6	7.2	88	8	9.1	0.6571	1.26 (0.46, 3.47)	1.28 (0.43, 3.87)	1.86 (-6.98, 10.60)	
>=65 years	139	14	10.1	132	27	20.5	0.0171	2.03 (1.11, 3.70)	2.30 (1.15, 4.60)	10.38 (1.81, 19.02)	
Sex											0.4591
Male	116	11	9.5	111	22	19.8	0.0272	2.09 (1.06, 4.11)	2.36 (1.08, 5.13)	10.34 (1.10, 19.66)	
Female	106	9	8.5	109	13	11.9	0.4059	1.40 (0.63, 3.15)	1.46 (0.60, 3.57)	3.44 (-4.95, 11.84)	
Baseline FVC percent predicted											0.2263
<=70%	118	9	7.6	96	18	18.8	0.0148	2.46 (1.16, 5.22)	2.79 (1.19, 6.55)	11.12 (2.08, 20.76)	
>70%	104	11	10.6	124	17	13.7	0.4729	1.30 (0.64, 2.64)	1.34 (0.60, 3.01)	3.13 (-5.76, 11.62)	
Baseline HRCT pattern											0.2609
UIP-like	158	13	8.2	154	27	17.5	0.0140	2.13 (1.14, 3.97)	2.37 (1.17, 4.79)	9.30 (1.86, 16.87)	
Other fibrotic patterns	64	7	10.9	66	8	12.1	0.8327	1.11 (0.43, 2.88)	1.12 (0.38, 3.30)	1.18 (-10.37, 12.63)	
Underlying ILD diagnosis											0.8339
iNSIP	40	3	7.5	55	5	9.1	0.7828	1.21 (0.31, 4.78)	1.23 (0.28, 5.49)	1.59 (-11.80, 13.17)	
Unclassifiable IIP	36	5	13.9	40	7	17.5	0.6664	1.26 (0.44, 3.62)	1.32 (0.38, 4.58)	3.61 (-13.56, 20.04)	
HP	39	4	10.3	30	5	16.7	0.4332	1.63 (0.48, 5.54)	1.75 (0.43, 7.18)	6.41 (-9.85, 24.41)	
Autoimmune ILD	71	6	8.5	70	14	20.0	0.0494	2.37 (0.96, 5.81)	2.71 (0.98, 7.52)	11.55 (-0.13, 23.27)	
Other ILD	36	2	5.6	25	4	16.0	0.1779	2.88 (0.57, 14.54)	3.24 (0.54, 19.25)	10.44 (-5.39, 29.53)	
Region											0.5403
Europe	40	8	20.0	53	11	20.8	0.9288	1.04 (0.46, 2.34)	1.05 (0.38, 2.91)	0.75 (-16.40, 16.62)	
Asia	106	8	7.5	107	18	16.8	0.0387	2.23 (1.01, 4.90)	2.48 (1.03, 5.98)	9.28 (0.39, 18.27)	
Canada and USA	30	3	10.0	17	3	17.6	0.4503	1.76 (0.40, 7.80)	1.93 (0.34, 10.83)	7.65 (-11.72, 31.93)	
Rest of the World	46	1	2.2	43	3	7.0	0.2745	3.21 (0.35, 29.69)	3.38 (0.34, 33.76)	4.80 (-5.44, 16.57)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Ear and labyrinth disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	2	0.9	220	10	4.5	0.0184	5.05 (1.12, 22.76)	5.24 (1.13, 24.19)	3.64 (0.54, 7.32)	
Age											
<65 years	83	2	2.4	88	4	4.5					
>=65 years	139	0	0.0	132	6	4.5					
Sex											
Male	116	2	1.7	111	3	2.7					
Female	106	0	0.0	109	7	6.4					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	3	3.1					
>70%	104	2	1.9	124	7	5.6					
Baseline HRCT pattern											
UIP-like	158	2	1.3	154	6	3.9					
Other fibrotic patterns	64	0	0.0	66	4	6.1					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	2	3.6					
Unclassifiable IIP	36	0	0.0	40	4	10.0					
HP	39	1	2.6	30	0	0.0					
Autoimmune ILD	71	1	1.4	70	1	1.4					
Other ILD	36	0	0.0	25	3	12.0					
Region											
Europe	40	0	0.0	53	5	9.4					
Asia	106	1	0.9	107	2	1.9					
Canada and USA	30	0	0.0	17	1	5.9					
Rest of the World	46	1	2.2	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Eye disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	12	5.4	220	13	5.9	0.8187	1.09 (0.51, 2.34)	1.10 (0.49, 2.46)	0.50 (-4.01, 5.06)	
Age											
<65 years	83	4	4.8	88	5	5.7					
>=65 years	139	8	5.8	132	8	6.1					
Sex											
Male	116	7	6.0	111	5	4.5					
Female	106	5	4.7	109	8	7.3					
Baseline FVC percent predicted											
<=70%	118	5	4.2	96	5	5.2					
>70%	104	7	6.7	124	8	6.5					
Baseline HRCT pattern											
UIP-like	158	10	6.3	154	8	5.2					
Other fibrotic patterns	64	2	3.1	66	5	7.6					
Underlying ILD diagnosis											
iNSIP	40	4	10.0	55	2	3.6					
Unclassifiable IIP	36	3	8.3	40	4	10.0					
HP	39	1	2.6	30	1	3.3					
Autoimmune ILD	71	2	2.8	70	4	5.7					
Other ILD	36	2	5.6	25	2	8.0					
Region											
Europe	40	4	10.0	53	5	9.4					
Asia	106	6	5.7	107	6	5.6					
Canada and USA	30	1	3.3	17	1	5.9					
Rest of the World	46	1	2.2	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Gastrointestinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	88	39.6	220	103	46.8	0.1277	1.18 (0.95, 1.46)	1.34 (0.92, 1.96)	7.18 (-2.04, 16.23)	
Age											
<65 years	83	35	42.2	88	32	36.4					
>=65 years	139	53	38.1	132	71	53.8					
Sex											
Male	116	44	37.9	111	50	45.0					
Female	106	44	41.5	109	53	48.6					
Baseline FVC percent predicted											
<=70%	118	48	40.7	96	44	45.8					
>70%	104	40	38.5	124	59	47.6					
Baseline HRCT pattern											
UIP-like	158	61	38.6	154	76	49.4					
Other fibrotic patterns	64	27	42.2	66	27	40.9					
Underlying ILD diagnosis											
iNSIP	40	13	32.5	55	20	36.4					
Unclassifiable IIP	36	16	44.4	40	21	52.5					
HP	39	17	43.6	30	13	43.3					
Autoimmune ILD	71	28	39.4	70	34	48.6					
Other ILD	36	14	38.9	25	15	60.0					
Region											
Europe	40	13	32.5	53	24	45.3					
Asia	106	46	43.4	107	51	47.7					
Canada and USA	30	16	53.3	17	9	52.9					
Rest of the World	46	13	28.3	43	19	44.2					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	92	41.4	220	66	30.0	0.0121	0.72 (0.56, 0.93)	0.61 (0.41, 0.90)	-11.44 (-20.12, -2.51)	
Age											0.8420
<65 years	83	35	42.2	88	26	29.5	0.0850	0.70 (0.47, 1.06)	0.58 (0.31, 1.08)	-12.62 (-26.33, 1.71)	
>=65 years	139	57	41.0	132	40	30.3	0.0662	0.74 (0.53, 1.02)	0.63 (0.38, 1.03)	-10.70 (-21.69, 0.71)	
Sex											0.5326
Male	116	50	43.1	111	32	28.8	0.0252	0.67 (0.47, 0.96)	0.53 (0.31, 0.93)	-14.27 (-26.13, -1.78)	
Female	106	42	39.6	109	34	31.2	0.1961	0.79 (0.55, 1.13)	0.69 (0.39, 1.21)	-8.43 (-20.82, 4.30)	
Baseline FVC percent predicted											0.1670
<=70%	118	52	44.1	96	37	38.5	0.4146	0.87 (0.63, 1.21)	0.80 (0.46, 1.38)	-5.53 (-18.34, 7.68)	
>70%	104	40	38.5	124	29	23.4	0.0136	0.61 (0.41, 0.91)	0.49 (0.28, 0.87)	-15.07 (-26.72, -3.07)	
Baseline HRCT pattern											0.5095
UIP-like	158	62	39.2	154	41	26.6	0.0178	0.68 (0.49, 0.94)	0.56 (0.35, 0.91)	-12.62 (-22.66, -2.18)	
Other fibrotic patterns	64	30	46.9	66	25	37.9	0.2993	0.81 (0.54, 1.21)	0.69 (0.34, 1.39)	-9.00 (-25.13, 7.81)	
Underlying ILD diagnosis											0.2875
iNSIP	40	12	30.0	55	17	30.9	0.9243	1.03 (0.56, 1.91)	1.04 (0.43, 2.53)	0.91 (-17.83, 18.64)	
Unclassifiable IIP	36	17	47.2	40	11	27.5	0.0751	0.58 (0.32, 1.07)	0.42 (0.16, 1.10)	-19.72 (-39.18, 1.89)	
HP	39	22	56.4	30	8	26.7	0.0135	0.47 (0.25, 0.91)	0.28 (0.10, 0.78)	-29.74 (-48.71, -6.20)	
Autoimmune ILD	71	28	39.4	70	20	28.6	0.1734	0.72 (0.45, 1.16)	0.61 (0.30, 1.24)	-10.87 (-25.72, 4.72)	
Other ILD	36	13	36.1	25	10	40.0	0.7579	1.11 (0.58, 2.12)	1.18 (0.41, 3.37)	3.89 (-19.38, 27.49)	
Region											0.8120
Europe	40	15	37.5	53	18	34.0	0.7241	0.91 (0.52, 1.57)	0.86 (0.36, 2.02)	-3.54 (-22.68, 15.36)	
Asia	106	47	44.3	107	31	29.0	0.0199	0.65 (0.45, 0.94)	0.51 (0.29, 0.90)	-15.37 (-27.62, -2.43)	
Canada and USA	30	14	46.7	17	6	35.3	0.4486	0.76 (0.36, 1.60)	0.62 (0.18, 2.12)	-11.37 (-36.25, 17.23)	
Rest of the World	46	16	34.8	43	11	25.6	0.3454	0.74 (0.39, 1.40)	0.64 (0.26, 1.61)	-9.20 (-27.15, 9.81)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	164	73.9	220	148	67.3	0.1278	0.91 (0.81, 1.03)	0.73 (0.48, 1.10)	-6.60 (-14.97, 1.89)	
Age											
<65 years	83	62	74.7	88	56	63.6					
>=65 years	139	102	73.4	132	92	69.7					
Sex											
Male	116	88	75.9	111	72	64.9					
Female	106	76	71.7	109	76	69.7					
Baseline FVC percent predicted											
<=70%	118	90	76.3	96	59	61.5					
>70%	104	74	71.2	124	89	71.8					
Baseline HRCT pattern											
UIP-like	158	115	72.8	154	102	66.2					
Other fibrotic patterns	64	49	76.6	66	46	69.7					
Underlying ILD diagnosis											
iNSIP	40	29	72.5	55	33	60.0					
Unclassifiable IIP	36	26	72.2	40	25	62.5					
HP	39	28	71.8	30	20	66.7					
Autoimmune ILD	71	47	66.2	70	50	71.4					
Other ILD	36	34	94.4	25	20	80.0					
Region											
Europe	40	30	75.0	53	38	71.7					
Asia	106	82	77.4	107	72	67.3					
Canada and USA	30	25	83.3	17	13	76.5					
Rest of the World	46	27	58.7	43	25	58.1					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Injury, poisoning and procedural complications

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	30	13.5	220	27	12.3	0.6972	0.91 (0.56, 1.48)	0.90 (0.51, 1.56)	-1.24 (-7.56, 5.08)	
Age											
<65 years	83	7	8.4	88	9	10.2					
>=65 years	139	23	16.5	132	18	13.6					
Sex											
Male	116	14	12.1	111	8	7.2					
Female	106	16	15.1	109	19	17.4					
Baseline FVC percent predicted											
<=70%	118	8	6.8	96	12	12.5					
>70%	104	22	21.2	124	15	12.1					
Baseline HRCT pattern											
UIP-like	158	24	15.2	154	18	11.7					
Other fibrotic patterns	64	6	9.4	66	9	13.6					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	4	7.3					
Unclassifiable IIP	36	9	25.0	40	6	15.0					
HP	39	6	15.4	30	2	6.7					
Autoimmune ILD	71	8	11.3	70	11	15.7					
Other ILD	36	5	13.9	25	4	16.0					
Region											
Europe	40	8	20.0	53	8	15.1					
Asia	106	12	11.3	107	15	14.0					
Canada and USA	30	7	23.3	17	0	0.0					
Rest of the World	46	3	6.5	43	4	9.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Investigations

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	54	24.3	220	63	28.6	0.3042	1.18 (0.86, 1.61)	1.25 (0.82, 1.91)	4.31 (-3.91, 12.47)	
Age											
<65 years	83	19	22.9	88	18	20.5					
>=65 years	139	35	25.2	132	45	34.1					
Sex											
Male	116	28	24.1	111	35	31.5					
Female	106	26	24.5	109	28	25.7					
Baseline FVC percent predicted											
<=70%	118	33	28.0	96	26	27.1					
>70%	104	21	20.2	124	37	29.8					
Baseline HRCT pattern											
UIP-like	158	37	23.4	154	50	32.5					
Other fibrotic patterns	64	17	26.6	66	13	19.7					
Underlying ILD diagnosis											
iNSIP	40	8	20.0	55	16	29.1					
Unclassifiable IIP	36	7	19.4	40	16	40.0					
HP	39	12	30.8	30	5	16.7					
Autoimmune ILD	71	20	28.2	70	18	25.7					
Other ILD	36	7	19.4	25	8	32.0					
Region											
Europe	40	7	17.5	53	9	17.0					
Asia	106	31	29.2	107	40	37.4					
Canada and USA	30	10	33.3	17	7	41.2					
Rest of the World	46	6	13.0	43	7	16.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Metabolism and nutrition disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	46	20.7	220	35	15.9	0.1911	0.77 (0.52, 1.14)	0.72 (0.45, 1.18)	-4.81 (-12.00, 2.43)	
Age											
<65 years	83	14	16.9	88	9	10.2					
>=65 years	139	32	23.0	132	26	19.7					
Sex											
Male	116	23	19.8	111	19	17.1					
Female	106	23	21.7	109	16	14.7					
Baseline FVC percent predicted											
<=70%	118	28	23.7	96	14	14.6					
>70%	104	18	17.3	124	21	16.9					
Baseline HRCT pattern											
UIP-like	158	35	22.2	154	29	18.8					
Other fibrotic patterns	64	11	17.2	66	6	9.1					
Underlying ILD diagnosis											
iNSIP	40	9	22.5	55	5	9.1					
Unclassifiable IIP	36	7	19.4	40	6	15.0					
HP	39	6	15.4	30	3	10.0					
Autoimmune ILD	71	18	25.4	70	14	20.0					
Other ILD	36	6	16.7	25	7	28.0					
Region											
Europe	40	8	20.0	53	6	11.3					
Asia	106	29	27.4	107	21	19.6					
Canada and USA	30	5	16.7	17	2	11.8					
Rest of the World	46	4	8.7	43	6	14.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Musculoskeletal and connective tissue disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	61	27.5	220	61	27.7	0.9532	1.01 (0.75, 1.36)	1.01 (0.67, 1.54)	0.25 (-8.05, 8.55)	
Age											
<65 years	83	23	27.7	88	24	27.3					
>=65 years	139	38	27.3	132	37	28.0					
Sex											
Male	116	29	25.0	111	25	22.5					
Female	106	32	30.2	109	36	33.0					
Baseline FVC percent predicted											
<=70%	118	29	24.6	96	33	34.4					
>70%	104	32	30.8	124	28	22.6					
Baseline HRCT pattern											
UIP-like	158	47	29.7	154	42	27.3					
Other fibrotic patterns	64	14	21.9	66	19	28.8					
Underlying ILD diagnosis											
iNSIP	40	10	25.0	55	9	16.4					
Unclassifiable IIP	36	10	27.8	40	11	27.5					
HP	39	10	25.6	30	8	26.7					
Autoimmune ILD	71	20	28.2	70	23	32.9					
Other ILD	36	11	30.6	25	10	40.0					
Region											
Europe	40	12	30.0	53	22	41.5					
Asia	106	35	33.0	107	26	24.3					
Canada and USA	30	6	20.0	17	6	35.3					
Rest of the World	46	8	17.4	43	7	16.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	10	4.5	220	12	5.5	0.6461	1.21 (0.53, 2.74)	1.22 (0.52, 2.89)	0.95 (-3.32, 5.29)	
Age											
<65 years	83	4	4.8	88	4	4.5					
>=65 years	139	6	4.3	132	8	6.1					
Sex											
Male	116	8	6.9	111	5	4.5					
Female	106	2	1.9	109	7	6.4					
Baseline FVC percent predicted											
<=70%	118	3	2.5	96	4	4.2					
>70%	104	7	6.7	124	8	6.5					
Baseline HRCT pattern											
UIP-like	158	6	3.8	154	10	6.5					
Other fibrotic patterns	64	4	6.3	66	2	3.0					
Underlying ILD diagnosis											
iNSIP	40	4	10.0	55	3	5.5					
Unclassifiable IIP	36	2	5.6	40	2	5.0					
HP	39	2	5.1	30	1	3.3					
Autoimmune ILD	71	1	1.4	70	3	4.3					
Other ILD	36	1	2.8	25	3	12.0					
Region											
Europe	40	1	2.5	53	2	3.8					
Asia	106	4	3.8	107	5	4.7					
Canada and USA	30	4	13.3	17	1	5.9					
Rest of the World	46	1	2.2	43	4	9.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Nervous system disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	43	19.4	220	52	23.6	0.2749	1.22 (0.85, 1.75)	1.29 (0.82, 2.03)	4.27 (-3.40, 11.89)	
Age											
<65 years	83	15	18.1	88	13	14.8					
>=65 years	139	28	20.1	132	39	29.5					
Sex											
Male	116	23	19.8	111	27	24.3					
Female	106	20	18.9	109	25	22.9					
Baseline FVC percent predicted											
<=70%	118	21	17.8	96	22	22.9					
>70%	104	22	21.2	124	30	24.2					
Baseline HRCT pattern											
UIP-like	158	29	18.4	154	39	25.3					
Other fibrotic patterns	64	14	21.9	66	13	19.7					
Underlying ILD diagnosis											
iNSIP	40	3	7.5	55	8	14.5					
Unclassifiable IIP	36	8	22.2	40	6	15.0					
HP	39	14	35.9	30	12	40.0					
Autoimmune ILD	71	11	15.5	70	18	25.7					
Other ILD	36	7	19.4	25	8	32.0					
Region											
Europe	40	11	27.5	53	18	34.0					
Asia	106	16	15.1	107	20	18.7					
Canada and USA	30	6	20.0	17	5	29.4					
Rest of the World	46	10	21.7	43	9	20.9					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Psychiatric disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	51	23.0	220	54	24.5	0.6977	1.07 (0.76, 1.49)	1.09 (0.70, 1.69)	1.57 (-6.35, 9.48)	
Age											
<65 years	83	17	20.5	88	18	20.5					
>=65 years	139	34	24.5	132	36	27.3					
Sex											
Male	116	30	25.9	111	25	22.5					
Female	106	21	19.8	109	29	26.6					
Baseline FVC percent predicted											
<=70%	118	32	27.1	96	24	25.0					
>70%	104	19	18.3	124	30	24.2					
Baseline HRCT pattern											
UIP-like	158	36	22.8	154	36	23.4					
Other fibrotic patterns	64	15	23.4	66	18	27.3					
Underlying ILD diagnosis											
iNSIP	40	11	27.5	55	10	18.2					
Unclassifiable IIP	36	7	19.4	40	11	27.5					
HP	39	12	30.8	30	6	20.0					
Autoimmune ILD	71	15	21.1	70	18	25.7					
Other ILD	36	6	16.7	25	9	36.0					
Region											
Europe	40	13	32.5	53	14	26.4					
Asia	106	24	22.6	107	24	22.4					
Canada and USA	30	7	23.3	17	7	41.2					
Rest of the World	46	7	15.2	43	9	20.9					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Renal and urinary disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	18	8.1	220	11	5.0	0.1870	0.62 (0.30, 1.28)	0.60 (0.27, 1.29)	-3.11 (-7.97, 1.63)	
Age											
<65 years	83	3	3.6	88	2	2.3					
>=65 years	139	15	10.8	132	9	6.8					
Sex											
Male	116	12	10.3	111	5	4.5					
Female	106	6	5.7	109	6	5.5					
Baseline FVC percent predicted											
<=70%	118	12	10.2	96	4	4.2					
>70%	104	6	5.8	124	7	5.6					
Baseline HRCT pattern											
UIP-like	158	15	9.5	154	6	3.9					
Other fibrotic patterns	64	3	4.7	66	5	7.6					
Underlying ILD diagnosis											
iNSIP	40	8	20.0	55	2	3.6					
Unclassifiable IIP	36	0	0.0	40	1	2.5					
HP	39	2	5.1	30	2	6.7					
Autoimmune ILD	71	6	8.5	70	3	4.3					
Other ILD	36	2	5.6	25	3	12.0					
Region											
Europe	40	6	15.0	53	2	3.8					
Asia	106	12	11.3	107	6	5.6					
Canada and USA	30	0	0.0	17	2	11.8					
Rest of the World	46	0	0.0	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Reproductive system and breast disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	4	1.8	220	10	4.5	0.0996	2.52 (0.80, 7.92)	2.60 (0.80, 8.40)	2.74 (-0.68, 6.52)	
Age											
<65 years	83	2	2.4	88	9	10.2					
>=65 years	139	2	1.4	132	1	0.8					
Sex											
Male	116	3	2.6	111	6	5.4					
Female	106	1	0.9	109	4	3.7					
Baseline FVC percent predicted											
<=70%	118	2	1.7	96	6	6.3					
>70%	104	2	1.9	124	4	3.2					
Baseline HRCT pattern											
UIP-like	158	2	1.3	154	4	2.6					
Other fibrotic patterns	64	2	3.1	66	6	9.1					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	2	3.6					
Unclassifiable IIP	36	1	2.8	40	1	2.5					
HP	39	0	0.0	30	2	6.7					
Autoimmune ILD	71	1	1.4	70	3	4.3					
Other ILD	36	0	0.0	25	2	8.0					
Region											
Europe	40	0	0.0	53	2	3.8					
Asia	106	3	2.8	107	6	5.6					
Canada and USA	30	0	0.0	17	1	5.9					
Rest of the World	46	1	2.2	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	91	41.0	220	91	41.4	0.9366	1.01 (0.81, 1.26)	1.02 (0.70, 1.48)	0.37 (-8.73, 9.47)	
Age											
<65 years	83	32	38.6	88	29	33.0					
>=65 years	139	59	42.4	132	62	47.0					
Sex											
Male	116	46	39.7	111	49	44.1					
Female	106	45	42.5	109	42	38.5					
Baseline FVC percent predicted											
<=70%	118	54	45.8	96	47	49.0					
>70%	104	37	35.6	124	44	35.5					
Baseline HRCT pattern											
UIP-like	158	60	38.0	154	63	40.9					
Other fibrotic patterns	64	31	48.4	66	28	42.4					
Underlying ILD diagnosis											
iNSIP	40	12	30.0	55	20	36.4					
Unclassifiable IIP	36	12	33.3	40	15	37.5					
HP	39	26	66.7	30	15	50.0					
Autoimmune ILD	71	25	35.2	70	26	37.1					
Other ILD	36	16	44.4	25	15	60.0					
Region											
Europe	40	19	47.5	53	28	52.8					
Asia	106	44	41.5	107	42	39.3					
Canada and USA	30	11	36.7	17	12	70.6					
Rest of the World	46	17	37.0	43	9	20.9					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Skin and subcutaneous tissue disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	27	12.2	220	25	11.4	0.7945	0.93 (0.56, 1.56)	0.93 (0.52, 1.65)	-0.80 (-6.89, 5.30)	
Age											
<65 years	83	8	9.6	88	9	10.2					
>=65 years	139	19	13.7	132	16	12.1					
Sex											
Male	116	13	11.2	111	9	8.1					
Female	106	14	13.2	109	16	14.7					
Baseline FVC percent predicted											
<=70%	118	10	8.5	96	13	13.5					
>70%	104	17	16.3	124	12	9.7					
Baseline HRCT pattern											
UIP-like	158	19	12.0	154	19	12.3					
Other fibrotic patterns	64	8	12.5	66	6	9.1					
Underlying ILD diagnosis											
iNSIP	40	3	7.5	55	5	9.1					
Unclassifiable IIP	36	6	16.7	40	3	7.5					
HP	39	6	15.4	30	3	10.0					
Autoimmune ILD	71	6	8.5	70	10	14.3					
Other ILD	36	6	16.7	25	4	16.0					
Region											
Europe	40	7	17.5	53	6	11.3					
Asia	106	12	11.3	107	13	12.1					
Canada and USA	30	7	23.3	17	1	5.9					
Rest of the World	46	1	2.2	43	5	11.6					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Vascular disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	23	10.4	220	20	9.1	0.6525	0.88 (0.50, 1.55)	0.87 (0.46, 1.63)	-1.27 (-6.92, 4.37)	
Age											
<65 years	83	9	10.8	88	6	6.8					
>=65 years	139	14	10.1	132	14	10.6					
Sex											
Male	116	16	13.8	111	8	7.2					
Female	106	7	6.6	109	12	11.0					
Baseline FVC percent predicted											
<=70%	118	17	14.4	96	6	6.3					
>70%	104	6	5.8	124	14	11.3					
Baseline HRCT pattern											
UIP-like	158	15	9.5	154	13	8.4					
Other fibrotic patterns	64	8	12.5	66	7	10.6					
Underlying ILD diagnosis											
iNSIP	40	8	20.0	55	4	7.3					
Unclassifiable IIP	36	1	2.8	40	4	10.0					
HP	39	5	12.8	30	2	6.7					
Autoimmune ILD	71	4	5.6	70	7	10.0					
Other ILD	36	5	13.9	25	3	12.0					
Region											
Europe	40	6	15.0	53	7	13.2					
Asia	106	10	9.4	107	7	6.5					
Canada and USA	30	2	6.7	17	1	5.9					
Rest of the World	46	5	10.9	43	5	11.6					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Cardiac disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	10	4.5	220	15	6.8	0.2924	1.51 (0.70, 3.30)	1.55 (0.68, 3.53)	2.31 (-2.14, 6.92)	
Age											
<65 years	83	3	3.6	88	4	4.5					
>=65 years	139	7	5.0	132	11	8.3					
Sex											
Male	116	4	3.4	111	9	8.1					
Female	106	6	5.7	109	6	5.5					
Baseline FVC percent predicted											
<=70%	118	7	5.9	96	7	7.3					
>70%	104	3	2.9	124	8	6.5					
Baseline HRCT pattern											
UIP-like	158	5	3.2	154	12	7.8					
Other fibrotic patterns	64	5	7.8	66	3	4.5					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	2	3.6					
Unclassifiable IIP	36	2	5.6	40	3	7.5					
HP	39	2	5.1	30	3	10.0					
Autoimmune ILD	71	4	5.6	70	6	8.6					
Other ILD	36	2	5.6	25	1	4.0					
Region											
Europe	40	5	12.5	53	5	9.4					
Asia	106	4	3.8	107	6	5.6					
Canada and USA	30	1	3.3	17	1	5.9					
Rest of the World	46	0	0.0	43	3	7.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo						
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)		Odds ratio (95% CI)		Risk diff.	(95% CI)	Interaction p-value**
Overall	222	35	15.8	220	15	6.8	0.0030	0.43 (0.24,	0.77)	0.39 (0.21,	0.74)	-8.95	(-14.93, -3.06)	
Age														0.9861
<65 years	83	13	15.7	88	6	6.8	0.0659	0.44 (0.17,	1.09)	0.39 (0.14,	1.09)	-8.84	(-18.85, 0.76)	
>=65 years	139	22	15.8	132	9	6.8	0.0199	0.43 (0.21,	0.90)	0.39 (0.17,	0.88)	-9.01	(-16.68, -1.39)	
Sex														0.4303
Male	116	21	18.1	111	7	6.3	0.0069	0.35 (0.15,	0.79)	0.30 (0.12,	0.75)	-11.80	(-20.41, -3.25)	
Female	106	14	13.2	109	8	7.3	0.1558	0.56 (0.24,	1.27)	0.52 (0.21,	1.30)	-5.87	(-14.40, 2.42)	
Baseline FVC percent predicted														0.9914
<=70%	118	28	23.7	96	11	11.5	0.0207	0.48 (0.25,	0.92)	0.42 (0.19,	0.89)	-12.27	(-22.04, -1.86)	
>70%	104	7	6.7	124	4	3.2	0.2186	0.48 (0.14,	1.59)	0.46 (0.13,	1.62)	-3.50	(-10.31, 2.38)	
Baseline HRCT pattern														0.2221
UIP-like	158	29	18.4	154	10	6.5	0.0015	0.35 (0.18,	0.70)	0.31 (0.14,	0.66)	-11.86	(-19.23, -4.57)	
Other fibrotic patterns	64	6	9.4	66	5	7.6	0.7125	0.81 (0.26,	2.52)	0.79 (0.23,	2.74)	-1.80	(-12.32, 8.47)	
Underlying ILD diagnosis														0.2020
iNSIP	40	4	10.0	55	5	9.1	0.8812	0.91 (0.26,	3.17)	0.90 (0.23,	3.59)	-0.91	(-14.94, 11.19)	
Unclassifiable IIP	36	4	11.1	40	3	7.5	0.5867	0.68 (0.16,	2.81)	0.65 (0.13,	3.12)	-3.61	(-18.64, 10.45)	
HP	39	9	23.1	30	1	3.3	0.0209	0.14 (0.02,	1.08)	0.11 (0.01,	0.97)	-19.74	(-35.25, -2.81)	
Autoimmune ILD	71	10	14.1	70	1	1.4	0.0051	0.10 (0.01,	0.77)	0.09 (0.01,	0.71)	-12.66	(-22.66, -3.83)	
Other ILD	36	8	22.2	25	5	20.0	0.8349	0.90 (0.33,	2.43)	0.88 (0.25,	3.07)	-2.22	(-21.61, 19.60)	
Region														0.4956
Europe	40	5	12.5	53	5	9.4	0.6365	0.75 (0.23,	2.43)	0.73 (0.20,	2.71)	-3.07	(-17.69, 9.84)	
Asia	106	20	18.9	107	9	8.4	0.0261	0.45 (0.21,	0.93)	0.39 (0.17,	0.91)	-10.46	(-19.81, -1.18)	
Canada and USA	30	3	10.0	17	1	5.9	0.6269	0.59 (0.07,	5.22)	0.56 (0.05,	5.88)	-4.12	(-20.47, 17.97)	
Rest of the World	46	7	15.2	43	0	0.0	0.0126	0.07 (0.00,	1.21)	0.00 (NC,	NC)	-15.22	(-28.22, -4.01)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	47	21.2	220	37	16.8	0.2435	0.79 (0.54, 1.17)	0.75 (0.47, 1.21)	-4.35 (-11.64, 2.99)	
Age											
<65 years	83	15	18.1	88	8	9.1					
>=65 years	139	32	23.0	132	29	22.0					
Sex											
Male	116	26	22.4	111	21	18.9					
Female	106	21	19.8	109	16	14.7					
Baseline FVC percent predicted											
<=70%	118	32	27.1	96	21	21.9					
>70%	104	15	14.4	124	16	12.9					
Baseline HRCT pattern											
UIP-like	158	32	20.3	154	28	18.2					
Other fibrotic patterns	64	15	23.4	66	9	13.6					
Underlying ILD diagnosis											
iNSIP	40	6	15.0	55	10	18.2					
Unclassifiable IIP	36	8	22.2	40	6	15.0					
HP	39	6	15.4	30	3	10.0					
Autoimmune ILD	71	15	21.1	70	10	14.3					
Other ILD	36	12	33.3	25	8	32.0					
Region											
Europe	40	5	12.5	53	12	22.6					
Asia	106	30	28.3	107	19	17.8					
Canada and USA	30	5	16.7	17	2	11.8					
Rest of the World	46	7	15.2	43	4	9.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	8	3.6	220	10	4.5	0.6164	1.26 (0.51, 3.14)	1.27 (0.49, 3.29)	0.94 (-2.99, 4.97)	
Age											
<65 years	83	3	3.6	88	3	3.4					
>=65 years	139	5	3.6	132	7	5.3					
Sex											
Male	116	7	6.0	111	5	4.5					
Female	106	1	0.9	109	5	4.6					
Baseline FVC percent predicted											
<=70%	118	3	2.5	96	2	2.1					
>70%	104	5	4.8	124	8	6.5					
Baseline HRCT pattern											
UIP-like	158	5	3.2	154	8	5.2					
Other fibrotic patterns	64	3	4.7	66	2	3.0					
Underlying ILD diagnosis											
iNSIP	40	3	7.5	55	2	3.6					
Unclassifiable IIP	36	2	5.6	40	2	5.0					
HP	39	2	5.1	30	1	3.3					
Autoimmune ILD	71	0	0.0	70	3	4.3					
Other ILD	36	1	2.8	25	2	8.0					
Region											
Europe	40	0	0.0	53	1	1.9					
Asia	106	3	2.8	107	5	4.7					
Canada and USA	30	4	13.3	17	1	5.9					
Rest of the World	46	1	2.2	43	3	7.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Nervous system disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	5	2.3	220	11	5.0	0.1220	2.22 (0.78, 6.28)	2.28 (0.78, 6.69)	2.75 (-0.89, 6.69)	
Age											
<65 years	83	1	1.2	88	2	2.3					
>=65 years	139	4	2.9	132	9	6.8					
Sex											
Male	116	1	0.9	111	8	7.2					
Female	106	4	3.8	109	3	2.8					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	4	4.2					
>70%	104	5	4.8	124	7	5.6					
Baseline HRCT pattern											
UIP-like	158	3	1.9	154	8	5.2					
Other fibrotic patterns	64	2	3.1	66	3	4.5					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	5	9.1					
Unclassifiable IIP	36	0	0.0	40	2	5.0					
HP	39	1	2.6	30	0	0.0					
Autoimmune ILD	71	1	1.4	70	1	1.4					
Other ILD	36	1	2.8	25	3	12.0					
Region											
Europe	40	0	0.0	53	2	3.8					
Asia	106	2	1.9	107	8	7.5					
Canada and USA	30	0	0.0	17	1	5.9					
Rest of the World	46	3	6.5	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	36	16.2	220	23	10.5	0.0749	0.64 (0.40, 1.05)	0.60 (0.34, 1.06)	-5.76 (-12.15, 0.62)	
Age											
<65 years	83	12	14.5	88	6	6.8					
>=65 years	139	24	17.3	132	17	12.9					
Sex											
Male	116	20	17.2	111	14	12.6					
Female	106	16	15.1	109	9	8.3					
Baseline FVC percent predicted											
<=70%	118	28	23.7	96	14	14.6					
>70%	104	8	7.7	124	9	7.3					
Baseline HRCT pattern											
UIP-like	158	20	12.7	154	16	10.4					
Other fibrotic patterns	64	16	25.0	66	7	10.6					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	6	10.9					
Unclassifiable IIP	36	5	13.9	40	6	15.0					
HP	39	11	28.2	30	2	6.7					
Autoimmune ILD	71	9	12.7	70	5	7.1					
Other ILD	36	9	25.0	25	4	16.0					
Region											
Europe	40	10	25.0	53	5	9.4					
Asia	106	16	15.1	107	16	15.0					
Canada and USA	30	4	13.3	17	0	0.0					
Rest of the World	46	6	13.0	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Cardiac disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	6	2.7	220	13	5.9	0.0966	2.19 (0.85, 5.65)	2.26 (0.84, 6.06)	3.21 (-0.70, 7.40)	
Age											
<65 years	83	1	1.2	88	4	4.5					
>=65 years	139	5	3.6	132	9	6.8					
Sex											
Male	116	3	2.6	111	8	7.2					
Female	106	3	2.8	109	5	4.6					
Baseline FVC percent predicted											
<=70%	118	5	4.2	96	6	6.3					
>70%	104	1	1.0	124	7	5.6					
Baseline HRCT pattern											
UIP-like	158	4	2.5	154	10	6.5					
Other fibrotic patterns	64	2	3.1	66	3	4.5					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	2	3.6					
Unclassifiable IIP	36	2	5.6	40	3	7.5					
HP	39	1	2.6	30	3	10.0					
Autoimmune ILD	71	2	2.8	70	4	5.7					
Other ILD	36	1	2.8	25	1	4.0					
Region											
Europe	40	3	7.5	53	5	9.4					
Asia	106	3	2.8	107	4	3.7					
Canada and USA	30	0	0.0	17	1	5.9					
Rest of the World	46	0	0.0	43	3	7.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	33	14.9	220	15	6.8	0.0066	0.46 (0.26, 0.82)	0.42 (0.22, 0.80)	-8.05 (-13.95, -2.24)	
Age											0.9424
<65 years	83	12	14.5	88	6	6.8	0.1038	0.47 (0.19, 1.20)	0.43 (0.15, 1.21)	-7.64 (-17.48, 1.78)	
>=65 years	139	21	15.1	132	9	6.8	0.0297	0.45 (0.21, 0.95)	0.41 (0.18, 0.93)	-8.29 (-15.88, -0.75)	
Sex											0.7067
Male	116	20	17.2	111	8	7.2	0.0216	0.42 (0.19, 0.91)	0.37 (0.16, 0.89)	-10.03 (-18.67, -1.42)	
Female	106	13	12.3	109	7	6.4	0.1404	0.52 (0.22, 1.26)	0.49 (0.19, 1.28)	-5.84 (-14.11, 2.13)	
Baseline FVC percent predicted											0.5305
<=70%	118	27	22.9	96	10	10.4	0.0165	0.46 (0.23, 0.89)	0.39 (0.18, 0.86)	-12.46 (-22.04, -2.28)	
>70%	104	6	5.8	124	5	4.0	0.5421	0.70 (0.22, 2.22)	0.69 (0.20, 2.32)	-1.74 (-8.40, 4.20)	
Baseline HRCT pattern											0.3698
UIP-like	158	28	17.7	154	11	7.1	0.0047	0.40 (0.21, 0.78)	0.36 (0.17, 0.75)	-10.58 (-17.96, -3.25)	
Other fibrotic patterns	64	5	7.8	66	4	6.1	0.6940	0.78 (0.22, 2.76)	0.76 (0.19, 2.97)	-1.75 (-11.67, 7.84)	
Underlying ILD diagnosis											0.2150
iNSIP	40	3	7.5	55	5	9.1	0.7828	1.21 (0.31, 4.78)	1.23 (0.28, 5.49)	1.59 (-11.80, 13.17)	
Unclassifiable IIP	36	4	11.1	40	3	7.5	0.5867	0.68 (0.16, 2.81)	0.65 (0.13, 3.12)	-3.61 (-18.64, 10.45)	
HP	39	8	20.5	30	0	0.0	0.0136	0.08 (0.00, 1.26)	0.00 (NC, NC)	-20.51 (-35.53, -5.56)	
Autoimmune ILD	71	10	14.1	70	2	2.9	0.0169	0.20 (0.05, 0.89)	0.18 (0.04, 0.85)	-11.23 (-21.38, -1.86)	
Other ILD	36	8	22.2	25	5	20.0	0.8349	0.90 (0.33, 2.43)	0.88 (0.25, 3.07)	-2.22 (-21.61, 19.60)	
Region											0.7080
Europe	40	4	10.0	53	4	7.5	0.6762	0.75 (0.20, 2.84)	0.73 (0.17, 3.14)	-2.45 (-16.28, 9.50)	
Asia	106	20	18.9	107	9	8.4	0.0261	0.45 (0.21, 0.93)	0.39 (0.17, 0.91)	-10.46 (-19.81, -1.18)	
Canada and USA	30	3	10.0	17	1	5.9	0.6269	0.59 (0.07, 5.22)	0.56 (0.05, 5.88)	-4.12 (-20.47, 17.97)	
Rest of the World	46	6	13.0	43	1	2.3	0.0605	0.18 (0.02, 1.42)	0.16 (0.02, 1.38)	-10.72 (-23.48, 1.23)	

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	44	19.8	220	30	13.6	0.0817	0.69 (0.45, 1.05)	0.64 (0.38, 1.06)	-6.18 (-13.13, 0.81)	
Age											
<65 years	83	14	16.9	88	6	6.8					
>=65 years	139	30	21.6	132	24	18.2					
Sex											
Male	116	23	19.8	111	14	12.6					
Female	106	21	19.8	109	16	14.7					
Baseline FVC percent predicted											
<=70%	118	30	25.4	96	18	18.8					
>70%	104	14	13.5	124	12	9.7					
Baseline HRCT pattern											
UIP-like	158	31	19.6	154	21	13.6					
Other fibrotic patterns	64	13	20.3	66	9	13.6					
Underlying ILD diagnosis											
iNSIP	40	5	12.5	55	10	18.2					
Unclassifiable IIP	36	8	22.2	40	4	10.0					
HP	39	6	15.4	30	1	3.3					
Autoimmune ILD	71	13	18.3	70	9	12.9					
Other ILD	36	12	33.3	25	6	24.0					
Region											
Europe	40	4	10.0	53	11	20.8					
Asia	106	28	26.4	107	14	13.1					
Canada and USA	30	5	16.7	17	2	11.8					
Rest of the World	46	7	15.2	43	3	7.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	26	11.7	220	21	9.5	0.4601	0.82 (0.47, 1.40)	0.80 (0.43, 1.46)	-2.17 (-8.02, 3.68)	
Age											
<65 years	83	7	8.4	88	5	5.7					
>=65 years	139	19	13.7	132	16	12.1					
Sex											
Male	116	15	12.9	111	11	9.9					
Female	106	11	10.4	109	10	9.2					
Baseline FVC percent predicted											
<=70%	118	20	16.9	96	13	13.5					
>70%	104	6	5.8	124	8	6.5					
Baseline HRCT pattern											
UIP-like	158	16	10.1	154	15	9.7					
Other fibrotic patterns	64	10	15.6	66	6	9.1					
Underlying ILD diagnosis											
iNSIP	40	1	2.5	55	6	10.9					
Unclassifiable IIP	36	5	13.9	40	5	12.5					
HP	39	9	23.1	30	2	6.7					
Autoimmune ILD	71	6	8.5	70	5	7.1					
Other ILD	36	5	13.9	25	3	12.0					
Region											
Europe	40	6	15.0	53	5	9.4					
Asia	106	11	10.4	107	14	13.1					
Canada and USA	30	3	10.0	17	0	0.0					
Rest of the World	46	6	13.0	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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I.1.2.2.1.5 Adverse events on PT level over the whole trial

Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	39	17.6	220	60	27.3	0.0144	1.55 (1.09, 2.22)	1.76 (1.12, 2.77)	9.71 (1.92, 17.36)	
Age											0.0524
<65 years	83	16	19.3	88	16	18.2	0.8544	0.94 (0.51, 1.76)	0.93 (0.43, 2.01)	-1.10 (-12.92, 10.60)	
>=65 years	139	23	16.5	132	44	33.3	0.0014	2.01 (1.29, 3.14)	2.52 (1.42, 4.48)	16.79 (6.51, 26.71)	
Sex											0.4915
Male	116	22	19.0	111	29	26.1	0.1963	1.38 (0.84, 2.25)	1.51 (0.81, 2.83)	7.16 (-3.72, 17.92)	
Female	106	17	16.0	109	31	28.4	0.0290	1.77 (1.05, 3.01)	2.08 (1.07, 4.05)	12.40 (1.24, 23.17)	
Baseline FVC percent predicted											0.3223
<=70%	118	26	22.0	96	29	30.2	0.1735	1.37 (0.87, 2.16)	1.53 (0.83, 2.84)	8.17 (-3.54, 19.95)	
>70%	104	13	12.5	124	31	25.0	0.0172	2.00 (1.11, 3.62)	2.33 (1.15, 4.74)	12.50 (2.22, 22.21)	
Baseline HRCT pattern											0.4578
UIP-like	158	28	17.7	154	46	29.9	0.0117	1.69 (1.11, 2.55)	1.98 (1.16, 3.38)	12.15 (2.70, 21.38)	
Other fibrotic patterns	64	11	17.2	66	14	21.2	0.5605	1.23 (0.61, 2.51)	1.30 (0.54, 3.12)	4.02 (-9.68, 17.48)	
Underlying ILD diagnosis											0.5260
iNSIP	40	6	15.0	55	13	23.6	0.2988	1.58 (0.66, 3.79)	1.75 (0.60, 5.10)	8.64 (-8.21, 23.62)	
Unclassifiable IIP	36	5	13.9	40	11	27.5	0.1461	1.98 (0.76, 5.15)	2.35 (0.73, 7.59)	13.61 (-5.04, 30.82)	
HP	39	8	20.5	30	10	33.3	0.2293	1.63 (0.73, 3.61)	1.94 (0.65, 5.74)	12.82 (-7.78, 33.18)	
Autoimmune ILD	71	15	21.1	70	16	22.9	0.8041	1.08 (0.58, 2.02)	1.11 (0.50, 2.46)	1.73 (-11.91, 15.34)	
Other ILD	36	5	13.9	25	10	40.0	0.0199	2.88 (1.12, 7.41)	4.13 (1.20, 14.25)	26.11 (3.89, 46.89)	
Region											0.2703
Europe	40	5	12.5	53	16	30.2	0.0434	2.42 (0.97, 6.04)	3.03 (1.00, 9.14)	17.69 (0.39, 32.78)	
Asia	106	21	19.8	107	23	21.5	0.7615	1.09 (0.64, 1.84)	1.11 (0.57, 2.15)	1.68 (-9.22, 12.53)	
Canada and USA	30	7	23.3	17	7	41.2	0.1987	1.76 (0.75, 4.18)	2.30 (0.64, 8.31)	17.84 (-8.47, 43.41)	
Rest of the World	46	6	13.0	43	14	32.6	0.0275	2.50 (1.05, 5.91)	3.22 (1.10, 9.38)	19.51 (2.05, 35.97)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Gastrointestinal disorders
PT: Gastrooesophageal reflux disease

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	10	4.5	220	9	4.1	0.8303	0.91 (0.38, 2.19)	0.90 (0.36, 2.27)	-0.41 (-4.48, 3.64)	
Age											
<65 years	83	5	6.0	88	2	2.3					
>=65 years	139	5	3.6	132	7	5.3					
Sex											
Male	116	6	5.2	111	6	5.4					
Female	106	4	3.8	109	3	2.8					
Baseline FVC percent predicted											
<=70%	118	4	3.4	96	2	2.1					
>70%	104	6	5.8	124	7	5.6					
Baseline HRCT pattern											
UIP-like	158	7	4.4	154	6	3.9					
Other fibrotic patterns	64	3	4.7	66	3	4.5					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	0	0.0					
Unclassifiable IIP	36	2	5.6	40	2	5.0					
HP	39	0	0.0	30	1	3.3					
Autoimmune ILD	71	3	4.2	70	6	8.6					
Other ILD	36	3	8.3	25	0	0.0					
Region											
Europe	40	0	0.0	53	1	1.9					
Asia	106	8	7.5	107	5	4.7					
Canada and USA	30	1	3.3	17	1	5.9					
Rest of the World	46	1	2.2	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	9	4.1	220	17	7.7	0.1008	1.91 (0.87, 4.18)	1.98 (0.86, 4.55)	3.67 (-0.82, 8.38)	
Age											
<65 years	83	3	3.6	88	4	4.5					
>=65 years	139	6	4.3	132	13	9.8					
Sex											
Male	116	2	1.7	111	8	7.2					
Female	106	7	6.6	109	9	8.3					
Baseline FVC percent predicted											
<=70%	118	6	5.1	96	10	10.4					
>70%	104	3	2.9	124	7	5.6					
Baseline HRCT pattern											
UIP-like	158	4	2.5	154	13	8.4					
Other fibrotic patterns	64	5	7.8	66	4	6.1					
Underlying ILD diagnosis											
iNSIP	40	1	2.5	55	2	3.6					
Unclassifiable IIP	36	3	8.3	40	3	7.5					
HP	39	4	10.3	30	3	10.0					
Autoimmune ILD	71	0	0.0	70	6	8.6					
Other ILD	36	1	2.8	25	3	12.0					
Region											
Europe	40	3	7.5	53	4	7.5					
Asia	106	1	0.9	107	6	5.6					
Canada and USA	30	3	10.0	17	2	11.8					
Rest of the World	46	2	4.3	43	5	11.6					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	42	18.9	220	21	9.5	0.0048	0.50 (0.31, 0.82)	0.45 (0.26, 0.79)	-9.37 (-15.89, -2.86)	
Age											0.7194
<65 years	83	17	20.5	88	10	11.4	0.1022	0.55 (0.27, 1.14)	0.50 (0.21, 1.16)	-9.12 (-20.24, 1.93)	
>=65 years	139	25	18.0	132	11	8.3	0.0193	0.46 (0.24, 0.90)	0.41 (0.20, 0.88)	-9.65 (-17.73, -1.54)	
Sex											0.5291
Male	116	26	22.4	111	11	9.9	0.0108	0.44 (0.23, 0.85)	0.38 (0.18, 0.81)	-12.50 (-21.94, -2.88)	
Female	106	16	15.1	109	10	9.2	0.1832	0.61 (0.29, 1.28)	0.57 (0.25, 1.32)	-5.92 (-14.94, 2.95)	
Baseline FVC percent predicted											0.4739
<=70%	118	28	23.7	96	14	14.6	0.0939	0.61 (0.34, 1.10)	0.55 (0.27, 1.11)	-9.15 (-19.32, 1.66)	
>70%	104	14	13.5	124	7	5.6	0.0421	0.42 (0.18, 1.00)	0.38 (0.15, 0.99)	-7.82 (-16.20, -0.16)	
Baseline HRCT pattern											0.2483
UIP-like	158	32	20.3	154	13	8.4	0.0030	0.42 (0.23, 0.76)	0.36 (0.18, 0.72)	-11.81 (-19.56, -4.04)	
Other fibrotic patterns	64	10	15.6	66	8	12.1	0.5631	0.78 (0.33, 1.84)	0.74 (0.27, 2.03)	-3.50 (-15.79, 8.66)	
Underlying ILD diagnosis											0.3063
iNSIP	40	8	20.0	55	5	9.1	0.1266	0.45 (0.16, 1.29)	0.40 (0.12, 1.33)	-10.91 (-26.54, 3.24)	
Unclassifiable IIP	36	5	13.9	40	4	10.0	0.6003	0.72 (0.21, 2.48)	0.69 (0.17, 2.79)	-3.89 (-19.85, 11.32)	
HP	39	10	25.6	30	2	6.7	0.0393	0.26 (0.06, 1.10)	0.21 (0.04, 1.03)	-18.97 (-35.15, -0.61)	
Autoimmune ILD	71	12	16.9	70	4	5.7	0.0363	0.34 (0.11, 1.00)	0.30 (0.09, 0.97)	-11.19 (-22.11, -0.52)	
Other ILD	36	7	19.4	25	6	24.0	0.6692	1.23 (0.47, 3.24)	1.31 (0.38, 4.50)	4.56 (-15.42, 26.27)	
Region											0.9125
Europe	40	8	20.0	53	7	13.2	0.3779	0.66 (0.26, 1.67)	0.61 (0.20, 1.85)	-6.79 (-22.98, 8.23)	
Asia	106	20	18.9	107	9	8.4	0.0261	0.45 (0.21, 0.93)	0.39 (0.17, 0.91)	-10.46 (-19.81, -1.18)	
Canada and USA	30	4	13.3	17	1	5.9	0.4260	0.44 (0.05, 3.64)	0.41 (0.04, 3.96)	-7.45 (-24.50, 15.12)	
Rest of the World	46	10	21.7	43	4	9.3	0.1073	0.43 (0.14, 1.26)	0.37 (0.11, 1.28)	-12.44 (-27.37, 3.09)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions
PT: Fatigue

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	11	5.0	220	9	4.1	0.6621	0.83 (0.35, 1.95)	0.82 (0.33, 2.02)	-0.86 (-5.03, 3.25)	
Age											
<65 years	83	3	3.6	88	2	2.3					
>=65 years	139	8	5.8	132	7	5.3					
Sex											
Male	116	4	3.4	111	4	3.6					
Female	106	7	6.6	109	5	4.6					
Baseline FVC percent predicted											
<=70%	118	6	5.1	96	3	3.1					
>70%	104	5	4.8	124	6	4.8					
Baseline HRCT pattern											
UIP-like	158	7	4.4	154	6	3.9					
Other fibrotic patterns	64	4	6.3	66	3	4.5					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	2	3.6					
Unclassifiable IIP	36	2	5.6	40	1	2.5					
HP	39	3	7.7	30	2	6.7					
Autoimmune ILD	71	2	2.8	70	2	2.9					
Other ILD	36	2	5.6	25	2	8.0					
Region											
Europe	40	2	5.0	53	4	7.5					
Asia	106	2	1.9	107	2	1.9					
Canada and USA	30	7	23.3	17	2	11.8					
Rest of the World	46	0	0.0	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions
PT: Pyrexia

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	18	8.1	220	12	5.5	0.2674	0.67 (0.33, 1.36)	0.65 (0.31, 1.39)	-2.65 (-7.57, 2.17)	
Age											
<65 years	83	11	13.3	88	5	5.7					
>=65 years	139	7	5.0	132	7	5.3					
Sex											
Male	116	8	6.9	111	5	4.5					
Female	106	10	9.4	109	7	6.4					
Baseline FVC percent predicted											
<=70%	118	11	9.3	96	8	8.3					
>70%	104	7	6.7	124	4	3.2					
Baseline HRCT pattern											
UIP-like	158	10	6.3	154	8	5.2					
Other fibrotic patterns	64	8	12.5	66	4	6.1					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	3	5.5					
Unclassifiable IIP	36	2	5.6	40	2	5.0					
HP	39	2	5.1	30	0	0.0					
Autoimmune ILD	71	10	14.1	70	4	5.7					
Other ILD	36	4	11.1	25	3	12.0					
Region											
Europe	40	1	2.5	53	3	5.7					
Asia	106	14	13.2	107	7	6.5					
Canada and USA	30	1	3.3	17	0	0.0					
Rest of the World	46	2	4.3	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Bronchitis

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	18	8.1	220	18	8.2	0.9774	1.01 (0.54, 1.89)	1.01 (0.51, 2.00)	0.07 (-5.17, 5.34)	
Age											
<65 years	83	5	6.0	88	8	9.1					
>=65 years	139	13	9.4	132	10	7.6					
Sex											
Male	116	9	7.8	111	9	8.1					
Female	106	9	8.5	109	9	8.3					
Baseline FVC percent predicted											
<=70%	118	7	5.9	96	7	7.3					
>70%	104	11	10.6	124	11	8.9					
Baseline HRCT pattern											
UIP-like	158	9	5.7	154	12	7.8					
Other fibrotic patterns	64	9	14.1	66	6	9.1					
Underlying ILD diagnosis											
iNSIP	40	4	10.0	55	3	5.5					
Unclassifiable IIP	36	5	13.9	40	3	7.5					
HP	39	4	10.3	30	2	6.7					
Autoimmune ILD	71	2	2.8	70	4	5.7					
Other ILD	36	3	8.3	25	6	24.0					
Region											
Europe	40	11	27.5	53	10	18.9					
Asia	106	5	4.7	107	2	1.9					
Canada and USA	30	1	3.3	17	4	23.5					
Rest of the World	46	1	2.2	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: COVID-19

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	32	14.4	220	31	14.1	0.9225	0.98 (0.62, 1.54)	0.97 (0.57, 1.66)	-0.32 (-6.89, 6.26)	
Age											
<65 years	83	15	18.1	88	10	11.4					
>=65 years	139	17	12.2	132	21	15.9					
Sex											
Male	116	17	14.7	111	13	11.7					
Female	106	15	14.2	109	18	16.5					
Baseline FVC percent predicted											
<=70%	118	22	18.6	96	10	10.4					
>70%	104	10	9.6	124	21	16.9					
Baseline HRCT pattern											
UIP-like	158	19	12.0	154	20	13.0					
Other fibrotic patterns	64	13	20.3	66	11	16.7					
Underlying ILD diagnosis											
iNSIP	40	7	17.5	55	6	10.9					
Unclassifiable IIP	36	5	13.9	40	7	17.5					
HP	39	7	17.9	30	5	16.7					
Autoimmune ILD	71	7	9.9	70	8	11.4					
Other ILD	36	6	16.7	25	5	20.0					
Region											
Europe	40	7	17.5	53	7	13.2					
Asia	106	18	17.0	107	15	14.0					
Canada and USA	30	6	20.0	17	4	23.5					
Rest of the World	46	1	2.2	43	5	11.6					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Influenza

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	14	6.3	220	14	6.4	0.9803	1.01 (0.49, 2.07)	1.01 (0.47, 2.17)	0.06 (-4.68, 4.81)	
Age											
<65 years	83	9	10.8	88	4	4.5					
>=65 years	139	5	3.6	132	10	7.6					
Sex											
Male	116	4	3.4	111	6	5.4					
Female	106	10	9.4	109	8	7.3					
Baseline FVC percent predicted											
<=70%	118	8	6.8	96	3	3.1					
>70%	104	6	5.8	124	11	8.9					
Baseline HRCT pattern											
UIP-like	158	12	7.6	154	11	7.1					
Other fibrotic patterns	64	2	3.1	66	3	4.5					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	3	5.5					
Unclassifiable IIP	36	1	2.8	40	2	5.0					
HP	39	1	2.6	30	1	3.3					
Autoimmune ILD	71	9	12.7	70	5	7.1					
Other ILD	36	3	8.3	25	3	12.0					
Region											
Europe	40	3	7.5	53	3	5.7					
Asia	106	6	5.7	107	11	10.3					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	5	10.9	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Nasopharyngitis

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk ratio (95% CI) p-value*	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	24	10.8	220	27	12.3	0.6305 1.14 (0.68, 1.90)	1.15 (0.64, 2.07)	1.46 (-4.58, 7.53)	
Age										
<65 years	83	11	13.3	88	10	11.4				
>=65 years	139	13	9.4	132	17	12.9				
Sex										
Male	116	13	11.2	111	15	13.5				
Female	106	11	10.4	109	12	11.0				
Baseline FVC percent predicted										
<=70%	118	11	9.3	96	13	13.5				
>70%	104	13	12.5	124	14	11.3				
Baseline HRCT pattern										
UIP-like	158	19	12.0	154	16	10.4				
Other fibrotic patterns	64	5	7.8	66	11	16.7				
Underlying ILD diagnosis										
iNSIP	40	4	10.0	55	5	9.1				
Unclassifiable IIP	36	7	19.4	40	6	15.0				
HP	39	4	10.3	30	6	20.0				
Autoimmune ILD	71	7	9.9	70	8	11.4				
Other ILD	36	2	5.6	25	2	8.0				
Region										
Europe	40	5	12.5	53	7	13.2				
Asia	106	16	15.1	107	14	13.1				
Canada and USA	30	1	3.3	17	2	11.8				
Rest of the World	46	2	4.3	43	4	9.3				

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	33	14.9	220	35	15.9	0.7610	1.07 (0.69, 1.66)	1.08 (0.65, 1.82)	1.04 (-5.73, 7.82)	
Age											
<65 years	83	10	12.0	88	8	9.1					
>=65 years	139	23	16.5	132	27	20.5					
Sex											
Male	116	18	15.5	111	18	16.2					
Female	106	15	14.2	109	17	15.6					
Baseline FVC percent predicted											
<=70%	118	21	17.8	96	17	17.7					
>70%	104	12	11.5	124	18	14.5					
Baseline HRCT pattern											
UIP-like	158	21	13.3	154	25	16.2					
Other fibrotic patterns	64	12	18.8	66	10	15.2					
Underlying ILD diagnosis											
iNSIP	40	4	10.0	55	11	20.0					
Unclassifiable IIP	36	3	8.3	40	5	12.5					
HP	39	3	7.7	30	4	13.3					
Autoimmune ILD	71	13	18.3	70	12	17.1					
Other ILD	36	10	27.8	25	3	12.0					
Region											
Europe	40	3	7.5	53	9	17.0					
Asia	106	24	22.6	107	19	17.8					
Canada and USA	30	2	6.7	17	3	17.6					
Rest of the World	46	4	8.7	43	4	9.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Respiratory tract infection

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	11	5.0	220	17	7.7	0.2316	1.56 (0.75, 3.25)	1.61 (0.73, 3.51)	2.77 (-1.89, 7.59)	
Age											
<65 years	83	3	3.6	88	7	8.0					
>=65 years	139	8	5.8	132	10	7.6					
Sex											
Male	116	9	7.8	111	6	5.4					
Female	106	2	1.9	109	11	10.1					
Baseline FVC percent predicted											
<=70%	118	3	2.5	96	5	5.2					
>70%	104	8	7.7	124	12	9.7					
Baseline HRCT pattern											
UIP-like	158	9	5.7	154	14	9.1					
Other fibrotic patterns	64	2	3.1	66	3	4.5					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	6	10.9					
Unclassifiable IIP	36	3	8.3	40	3	7.5					
HP	39	1	2.6	30	1	3.3					
Autoimmune ILD	71	3	4.2	70	5	7.1					
Other ILD	36	4	11.1	25	2	8.0					
Region											
Europe	40	3	7.5	53	5	9.4					
Asia	106	4	3.8	107	6	5.6					
Canada and USA	30	3	10.0	17	1	5.9					
Rest of the World	46	1	2.2	43	5	11.6					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Upper respiratory tract infection

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	48	21.6	220	34	15.5	0.0954	0.71 (0.48, 1.06)	0.66 (0.41, 1.08)	-6.17 (-13.38, 1.10)	
Age											
<65 years	83	24	28.9	88	16	18.2					
>=65 years	139	24	17.3	132	18	13.6					
Sex											
Male	116	27	23.3	111	12	10.8					
Female	106	21	19.8	109	22	20.2					
Baseline FVC percent predicted											
<=70%	118	29	24.6	96	11	11.5					
>70%	104	19	18.3	124	23	18.5					
Baseline HRCT pattern											
UIP-like	158	36	22.8	154	25	16.2					
Other fibrotic patterns	64	12	18.8	66	9	13.6					
Underlying ILD diagnosis											
iNSIP	40	5	12.5	55	5	9.1					
Unclassifiable IIP	36	5	13.9	40	7	17.5					
HP	39	10	25.6	30	1	3.3					
Autoimmune ILD	71	16	22.5	70	16	22.9					
Other ILD	36	12	33.3	25	5	20.0					
Region											
Europe	40	8	20.0	53	2	3.8					
Asia	106	28	26.4	107	25	23.4					
Canada and USA	30	9	30.0	17	5	29.4					
Rest of the World	46	3	6.5	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Urinary tract infection

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	18	8.1	220	15	6.8	0.6059	0.84 (0.43, 1.63)	0.83 (0.41, 1.69)	-1.29 (-6.37, 3.76)	
Age											
<65 years	83	2	2.4	88	1	1.1					
>=65 years	139	16	11.5	132	14	10.6					
Sex											
Male	116	3	2.6	111	3	2.7					
Female	106	15	14.2	109	12	11.0					
Baseline FVC percent predicted											
<=70%	118	7	5.9	96	7	7.3					
>70%	104	11	10.6	124	8	6.5					
Baseline HRCT pattern											
UIP-like	158	12	7.6	154	9	5.8					
Other fibrotic patterns	64	6	9.4	66	6	9.1					
Underlying ILD diagnosis											
iNSIP	40	6	15.0	55	6	10.9					
Unclassifiable IIP	36	3	8.3	40	1	2.5					
HP	39	4	10.3	30	3	10.0					
Autoimmune ILD	71	3	4.2	70	4	5.7					
Other ILD	36	2	5.6	25	1	4.0					
Region											
Europe	40	2	5.0	53	7	13.2					
Asia	106	6	5.7	107	1	0.9					
Canada and USA	30	3	10.0	17	1	5.9					
Rest of the World	46	7	15.2	43	6	14.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Investigations
PT: C-reactive protein increased

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	6	2.7	220	11	5.0	0.2092	1.85 (0.70, 4.91)	1.89 (0.69, 5.22)	2.30 (-1.47, 6.30)	
Age											
<65 years	83	3	3.6	88	6	6.8					
>=65 years	139	3	2.2	132	5	3.8					
Sex											
Male	116	2	1.7	111	9	8.1					
Female	106	4	3.8	109	2	1.8					
Baseline FVC percent predicted											
<=70%	118	5	4.2	96	5	5.2					
>70%	104	1	1.0	124	6	4.8					
Baseline HRCT pattern											
UIP-like	158	4	2.5	154	8	5.2					
Other fibrotic patterns	64	2	3.1	66	3	4.5					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	3	5.5					
Unclassifiable IIP	36	1	2.8	40	1	2.5					
HP	39	1	2.6	30	1	3.3					
Autoimmune ILD	71	4	5.6	70	5	7.1					
Other ILD	36	0	0.0	25	1	4.0					
Region											
Europe	40	2	5.0	53	3	5.7					
Asia	106	4	3.8	107	7	6.5					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Investigations
PT: Weight decreased

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	16	7.2	220	33	15.0	0.0091	2.08 (1.18, 3.67)	2.27 (1.21, 4.26)	7.79 (1.93, 13.77)	
Age											0.8239
<65 years	83	4	4.8	88	8	9.1	0.2744	1.89 (0.59, 6.03)	1.98 (0.57, 6.82)	4.27 (-3.94, 12.64)	
>=65 years	139	12	8.6	132	25	18.9	0.0135	2.19 (1.15, 4.18)	2.47 (1.19, 5.16)	10.31 (2.09, 18.66)	
Sex											0.5041
Male	116	11	9.5	111	19	17.1	0.0895	1.81 (0.90, 3.62)	1.97 (0.89, 4.36)	7.63 (-1.28, 16.69)	
Female	106	5	4.7	109	14	12.8	0.0358	2.72 (1.02, 7.30)	2.98 (1.03, 8.58)	8.13 (0.41, 16.16)	
Baseline FVC percent predicted											0.0721
<=70%	118	13	11.0	96	15	15.6	0.3201	1.42 (0.71, 2.83)	1.50 (0.67, 3.32)	4.61 (-4.50, 14.27)	
>70%	104	3	2.9	124	18	14.5	0.0025	5.03 (1.52, 16.61)	5.72 (1.63, 20.00)	11.63 (4.29, 19.14)	
Baseline HRCT pattern											0.3756
UIP-like	158	11	7.0	154	26	16.9	0.0067	2.43 (1.24, 4.73)	2.71 (1.29, 5.71)	9.92 (2.73, 17.28)	
Other fibrotic patterns	64	5	7.8	66	7	10.6	0.5822	1.36 (0.45, 4.06)	1.40 (0.42, 4.66)	2.79 (-7.87, 13.46)	
Underlying ILD diagnosis											0.3532
iNSIP	40	2	5.0	55	5	9.1	0.4511	1.82 (0.37, 8.90)	1.90 (0.35, 10.33)	4.09 (-8.51, 15.18)	
Unclassifiable IIP	36	2	5.6	40	11	27.5	0.0112	4.95 (1.18, 20.85)	6.45 (1.32, 31.49)	21.94 (4.97, 37.80)	
HP	39	4	10.3	30	1	3.3	0.2715	0.33 (0.04, 2.76)	0.30 (0.03, 2.85)	-6.92 (-20.52, 7.78)	
Autoimmune ILD	71	4	5.6	70	10	14.3	0.0859	2.54 (0.83, 7.71)	2.79 (0.83, 9.37)	8.65 (-1.53, 19.27)	
Other ILD	36	4	11.1	25	6	24.0	0.1811	2.16 (0.68, 6.87)	2.53 (0.63, 10.11)	12.89 (-6.03, 33.44)	
Region											0.9020
Europe	40	1	2.5	53	4	7.5	0.2853	3.02 (0.35, 25.98)	3.18 (0.34, 29.65)	5.05 (-6.30, 15.56)	
Asia	106	11	10.4	107	21	19.6	0.0589	1.89 (0.96, 3.73)	2.11 (0.96, 4.63)	9.25 (-0.44, 18.88)	
Canada and USA	30	3	10.0	17	5	29.4	0.0889	2.94 (0.80, 10.81)	3.75 (0.77, 18.29)	19.41 (-3.04, 44.02)	
Rest of the World	46	1	2.2	43	3	7.0	0.2745	3.21 (0.35, 29.69)	3.38 (0.34, 33.76)	4.80 (-5.44, 16.57)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	16	7.2	220	16	7.3	0.9788	1.01 (0.52, 1.97)	1.01 (0.49, 2.07)	0.07 (-4.93, 5.08)	
Age											
<65 years	83	3	3.6	88	5	5.7					
>=65 years	139	13	9.4	132	11	8.3					
Sex											
Male	116	6	5.2	111	5	4.5					
Female	106	10	9.4	109	11	10.1					
Baseline FVC percent predicted											
<=70%	118	12	10.2	96	9	9.4					
>70%	104	4	3.8	124	7	5.6					
Baseline HRCT pattern											
UIP-like	158	12	7.6	154	11	7.1					
Other fibrotic patterns	64	4	6.3	66	5	7.6					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	4	7.3					
Unclassifiable IIP	36	4	11.1	40	2	5.0					
HP	39	3	7.7	30	1	3.3					
Autoimmune ILD	71	5	7.0	70	5	7.1					
Other ILD	36	2	5.6	25	4	16.0					
Region											
Europe	40	1	2.5	53	3	5.7					
Asia	106	11	10.4	107	8	7.5					
Canada and USA	30	4	13.3	17	1	5.9					
Rest of the World	46	0	0.0	43	4	9.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	14	6.3	220	17	7.7	0.5586	1.23 (0.62, 2.42)	1.24 (0.60, 2.59)	1.42 (-3.49, 6.40)	
Age											
<65 years	83	4	4.8	88	5	5.7					
>=65 years	139	10	7.2	132	12	9.1					
Sex											
Male	116	8	6.9	111	8	7.2					
Female	106	6	5.7	109	9	8.3					
Baseline FVC percent predicted											
<=70%	118	5	4.2	96	10	10.4					
>70%	104	9	8.7	124	7	5.6					
Baseline HRCT pattern											
UIP-like	158	10	6.3	154	10	6.5					
Other fibrotic patterns	64	4	6.3	66	7	10.6					
Underlying ILD diagnosis											
iNSIP	40	1	2.5	55	1	1.8					
Unclassifiable IIP	36	4	11.1	40	3	7.5					
HP	39	3	7.7	30	4	13.3					
Autoimmune ILD	71	2	2.8	70	6	8.6					
Other ILD	36	4	11.1	25	3	12.0					
Region											
Europe	40	5	12.5	53	11	20.8					
Asia	106	4	3.8	107	2	1.9					
Canada and USA	30	3	10.0	17	1	5.9					
Rest of the World	46	2	4.3	43	3	7.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Musculoskeletal and connective tissue disorders
PT: Back pain

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
								Risk	Odds	Risk		Interaction
Category	N	n	%	N	n	%	p-value*	ratio (95% CI)	ratio (95% CI)	diff. (95% CI)		p-value**
Overall	222	7	3.2	220	17	7.7	0.0339	2.45 (1.04, 5.79)	2.57 (1.04, 6.33)	4.57 (0.28, 9.17)		
Age												0.3610
<65 years	83	1	1.2	88	6	6.8	0.0641	5.66 (0.70, 46.01)	6.00 (0.71, 50.95)	5.61 (-0.83, 12.95)		
>=65 years	139	6	4.3	132	11	8.3	0.1729	1.93 (0.73, 5.07)	2.02 (0.72, 5.61)	4.02 (-1.98, 10.43)		
Sex												0.5071
Male	116	2	1.7	111	7	6.3	0.0770	3.66 (0.78, 17.23)	3.84 (0.78, 18.88)	4.58 (-0.82, 10.85)		
Female	106	5	4.7	109	10	9.2	0.1996	1.94 (0.69, 5.50)	2.04 (0.67, 6.18)	4.46 (-2.70, 11.86)		
Baseline FVC percent predicted												0.0499
<=70%	118	1	0.8	96	9	9.4	0.0033	>10 (1.43, 85.79)	>10 (1.51, 97.32)	8.53 (2.74, 16.05)		
>70%	104	6	5.8	124	8	6.5	0.8307	1.12 (0.40, 3.12)	1.13 (0.38, 3.36)	0.68 (-6.31, 7.23)		
Baseline HRCT pattern												0.6439
UIP-like	158	6	3.8	154	13	8.4	0.0864	2.22 (0.87, 5.70)	2.34 (0.86, 6.31)	4.64 (-0.82, 10.48)		
Other fibrotic patterns	64	1	1.6	66	4	6.1	0.1824	3.88 (0.45, 33.77)	4.06 (0.44, 37.39)	4.50 (-3.21, 13.11)		
Underlying ILD diagnosis												
iNSIP	40	1	2.5	55	6	10.9						
Unclassifiable IIP	36	1	2.8	40	4	10.0						
HP	39	2	5.1	30	2	6.7						
Autoimmune ILD	71	2	2.8	70	2	2.9						
Other ILD	36	1	2.8	25	3	12.0						
Region												0.8468
Europe	40	3	7.5	53	10	18.9	0.1175	2.52 (0.74, 8.55)	2.87 (0.73, 11.21)	11.37 (-3.51, 24.79)		
Asia	106	3	2.8	107	6	5.6	0.3137	1.98 (0.51, 7.72)	2.04 (0.50, 8.38)	2.78 (-3.20, 9.15)		
Canada and USA	30	1	3.3	17	0	0.0	0.7252	0.57 (0.02, 13.36)	0.00 (NC, NC)	-3.33 (-16.67, 15.30)		
Rest of the World	46	0	0.0	43	1	2.3	0.4457	3.20 (0.13, 76.60)	NC (NC, NC)	2.33 (-5.62, 12.06)		

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Nervous system disorders
PT: Headache

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	19	8.6	220	19	8.6	0.9767	1.01 (0.55, 1.85)	1.01 (0.52, 1.96)	0.08 (-5.29, 5.46)	
Age											
<65 years	83	10	12.0	88	5	5.7					
>=65 years	139	9	6.5	132	14	10.6					
Sex											
Male	116	9	7.8	111	9	8.1					
Female	106	10	9.4	109	10	9.2					
Baseline FVC percent predicted											
<=70%	118	11	9.3	96	11	11.5					
>70%	104	8	7.7	124	8	6.5					
Baseline HRCT pattern											
UIP-like	158	12	7.6	154	14	9.1					
Other fibrotic patterns	64	7	10.9	66	5	7.6					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	1	1.8					
Unclassifiable IIP	36	4	11.1	40	1	2.5					
HP	39	4	10.3	30	5	16.7					
Autoimmune ILD	71	6	8.5	70	8	11.4					
Other ILD	36	3	8.3	25	4	16.0					
Region											
Europe	40	6	15.0	53	8	15.1					
Asia	106	8	7.5	107	5	4.7					
Canada and USA	30	2	6.7	17	1	5.9					
Rest of the World	46	3	6.5	43	5	11.6					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Psychiatric disorders
PT: Anxiety

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	25	11.3	220	28	12.7	0.6352	1.13 (0.68, 1.87)	1.15 (0.65, 2.04)	1.47 (-4.67, 7.62)	
Age											
<65 years	83	11	13.3	88	13	14.8					
>=65 years	139	14	10.1	132	15	11.4					
Sex											
Male	116	18	15.5	111	12	10.8					
Female	106	7	6.6	109	16	14.7					
Baseline FVC percent predicted											
<=70%	118	14	11.9	96	13	13.5					
>70%	104	11	10.6	124	15	12.1					
Baseline HRCT pattern											
UIP-like	158	20	12.7	154	19	12.3					
Other fibrotic patterns	64	5	7.8	66	9	13.6					
Underlying ILD diagnosis											
iNSIP	40	6	15.0	55	4	7.3					
Unclassifiable IIP	36	4	11.1	40	4	10.0					
HP	39	4	10.3	30	3	10.0					
Autoimmune ILD	71	8	11.3	70	14	20.0					
Other ILD	36	3	8.3	25	3	12.0					
Region											
Europe	40	8	20.0	53	7	13.2					
Asia	106	11	10.4	107	10	9.3					
Canada and USA	30	4	13.3	17	5	29.4					
Rest of the World	46	2	4.3	43	6	14.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Psychiatric disorders
PT: Depression

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	28	12.6	220	26	11.8	0.7987	0.94 (0.57, 1.55)	0.93 (0.53, 1.64)	-0.79 (-6.98, 5.40)	
Age											
<65 years	83	7	8.4	88	10	11.4					
>=65 years	139	21	15.1	132	16	12.1					
Sex											
Male	116	18	15.5	111	10	9.0					
Female	106	10	9.4	109	16	14.7					
Baseline FVC percent predicted											
<=70%	118	19	16.1	96	14	14.6					
>70%	104	9	8.7	124	12	9.7					
Baseline HRCT pattern											
UIP-like	158	19	12.0	154	16	10.4					
Other fibrotic patterns	64	9	14.1	66	10	15.2					
Underlying ILD diagnosis											
iNSIP	40	4	10.0	55	2	3.6					
Unclassifiable IIP	36	5	13.9	40	5	12.5					
HP	39	6	15.4	30	4	13.3					
Autoimmune ILD	71	9	12.7	70	10	14.3					
Other ILD	36	4	11.1	25	5	20.0					
Region											
Europe	40	7	17.5	53	8	15.1					
Asia	106	13	12.3	107	12	11.2					
Canada and USA	30	3	10.0	17	4	23.5					
Rest of the World	46	5	10.9	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Psychiatric disorders
PT: Insomnia

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	7	3.2	220	11	5.0	0.3260	1.59 (0.63, 4.02)	1.62 (0.61, 4.25)	1.85 (-2.04, 5.91)	
Age											
<65 years	83	3	3.6	88	3	3.4					
>=65 years	139	4	2.9	132	8	6.1					
Sex											
Male	116	2	1.7	111	7	6.3					
Female	106	5	4.7	109	4	3.7					
Baseline FVC percent predicted											
<=70%	118	5	4.2	96	3	3.1					
>70%	104	2	1.9	124	8	6.5					
Baseline HRCT pattern											
UIP-like	158	5	3.2	154	7	4.5					
Other fibrotic patterns	64	2	3.1	66	4	6.1					
Underlying ILD diagnosis											
iNSIP	40	1	2.5	55	1	1.8					
Unclassifiable IIP	36	0	0.0	40	2	5.0					
HP	39	2	5.1	30	0	0.0					
Autoimmune ILD	71	3	4.2	70	4	5.7					
Other ILD	36	1	2.8	25	4	16.0					
Region											
Europe	40	0	0.0	53	2	3.8					
Asia	106	5	4.7	107	8	7.5					
Canada and USA	30	0	0.0	17	1	5.9					
Rest of the World	46	2	4.3	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	33	14.9	220	40	18.2	0.3477	1.22 (0.80, 1.86)	1.27 (0.77, 2.11)	3.32 (-3.64, 10.27)	
Age											
<65 years	83	11	13.3	88	17	19.3					
>=65 years	139	22	15.8	132	23	17.4					
Sex											
Male	116	15	12.9	111	22	19.8					
Female	106	18	17.0	109	18	16.5					
Baseline FVC percent predicted											
<=70%	118	17	14.4	96	21	21.9					
>70%	104	16	15.4	124	19	15.3					
Baseline HRCT pattern											
UIP-like	158	25	15.8	154	22	14.3					
Other fibrotic patterns	64	8	12.5	66	18	27.3					
Underlying ILD diagnosis											
iNSIP	40	5	12.5	55	8	14.5					
Unclassifiable IIP	36	5	13.9	40	6	15.0					
HP	39	9	23.1	30	8	26.7					
Autoimmune ILD	71	10	14.1	70	11	15.7					
Other ILD	36	4	11.1	25	7	28.0					
Region											
Europe	40	7	17.5	53	14	26.4					
Asia	106	15	14.2	107	14	13.1					
Canada and USA	30	3	10.0	17	8	47.1					
Rest of the World	46	8	17.4	43	4	9.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	17	7.7	220	23	10.5	0.3055	1.37 (0.75, 2.48)	1.41 (0.73, 2.71)	2.80 (-2.65, 8.32)	
Age											
<65 years	83	5	6.0	88	6	6.8					
>=65 years	139	12	8.6	132	17	12.9					
Sex											
Male	116	5	4.3	111	11	9.9					
Female	106	12	11.3	109	12	11.0					
Baseline FVC percent predicted											
<=70%	118	12	10.2	96	13	13.5					
>70%	104	5	4.8	124	10	8.1					
Baseline HRCT pattern											
UIP-like	158	8	5.1	154	16	10.4					
Other fibrotic patterns	64	9	14.1	66	7	10.6					
Underlying ILD diagnosis											
iNSIP	40	5	12.5	55	5	9.1					
Unclassifiable IIP	36	1	2.8	40	3	7.5					
HP	39	4	10.3	30	5	16.7					
Autoimmune ILD	71	5	7.0	70	5	7.1					
Other ILD	36	2	5.6	25	5	20.0					
Region											
Europe	40	4	10.0	53	10	18.9					
Asia	106	8	7.5	107	5	4.7					
Canada and USA	30	4	13.3	17	5	29.4					
Rest of the World	46	1	2.2	43	3	7.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Interstitial lung disease

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	11	5.0	220	7	3.2	0.3457	0.64 (0.25, 1.63)	0.63 (0.24, 1.66)	-1.77 (-5.82, 2.12)	
Age											
<65 years	83	5	6.0	88	1	1.1					
>=65 years	139	6	4.3	132	6	4.5					
Sex											
Male	116	7	6.0	111	1	0.9					
Female	106	4	3.8	109	6	5.5					
Baseline FVC percent predicted											
<=70%	118	7	5.9	96	2	2.1					
>70%	104	4	3.8	124	5	4.0					
Baseline HRCT pattern											
UIP-like	158	9	5.7	154	6	3.9					
Other fibrotic patterns	64	2	3.1	66	1	1.5					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	0	0.0					
Unclassifiable IIP	36	2	5.6	40	3	7.5					
HP	39	4	10.3	30	1	3.3					
Autoimmune ILD	71	1	1.4	70	3	4.3					
Other ILD	36	2	5.6	25	0	0.0					
Region											
Europe	40	2	5.0	53	1	1.9					
Asia	106	6	5.7	107	4	3.7					
Canada and USA	30	1	3.3	17	1	5.9					
Rest of the World	46	2	4.3	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Vascular disorders
PT: Hypertension

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	10	4.5	220	11	5.0	0.8066	1.11 (0.48, 2.56)	1.12 (0.46, 2.68)	0.50 (-3.71, 4.75)	
Age											
<65 years	83	4	4.8	88	3	3.4					
>=65 years	139	6	4.3	132	8	6.1					
Sex											
Male	116	6	5.2	111	2	1.8					
Female	106	4	3.8	109	9	8.3					
Baseline FVC percent predicted											
<=70%	118	8	6.8	96	5	5.2					
>70%	104	2	1.9	124	6	4.8					
Baseline HRCT pattern											
UIP-like	158	7	4.4	154	8	5.2					
Other fibrotic patterns	64	3	4.7	66	3	4.5					
Underlying ILD diagnosis											
iNSIP	40	3	7.5	55	1	1.8					
Unclassifiable IIP	36	0	0.0	40	3	7.5					
HP	39	3	7.7	30	1	3.3					
Autoimmune ILD	71	3	4.2	70	4	5.7					
Other ILD	36	1	2.8	25	2	8.0					
Region											
Europe	40	1	2.5	53	4	7.5					
Asia	106	4	3.8	107	3	2.8					
Canada and USA	30	1	3.3	17	1	5.9					
Rest of the World	46	4	8.7	43	3	7.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 2 Proportion of patients with frequent serious AEs by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup / Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk ratio p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	28	12.6	220	12	5.5	0.0087	0.43 (0.23, 0.83)	0.40 (0.20, 0.81)	-7.16 (-12.68, -1.80)	
Age											0.6259
<65 years	83	11	13.3	88	6	6.8	0.1599	0.51 (0.20, 1.33)	0.48 (0.17, 1.36)	-6.43 (-16.09, 2.80)	
>=65 years	139	17	12.2	132	6	4.5	0.0233	0.37 (0.15, 0.91)	0.34 (0.13, 0.90)	-7.68 (-14.61, -0.98)	
Sex											0.3199
Male	116	19	16.4	111	6	5.4	0.0083	0.33 (0.14, 0.80)	0.29 (0.11, 0.76)	-10.97 (-19.29, -2.82)	
Female	106	9	8.5	109	6	5.5	0.3902	0.65 (0.24, 1.76)	0.63 (0.22, 1.83)	-2.99 (-10.46, 4.19)	
Baseline FVC percent predicted											0.6042
<=70%	118	23	19.5	96	10	10.4	0.0675	0.53 (0.27, 1.07)	0.48 (0.22, 1.07)	-9.07 (-18.39, 0.78)	
>70%	104	5	4.8	124	2	1.6	0.1637	0.34 (0.07, 1.69)	0.32 (0.06, 1.71)	-3.19 (-9.27, 1.72)	
Baseline HRCT pattern											0.1240
UIP-like	158	23	14.6	154	7	4.5	0.0027	0.31 (0.14, 0.71)	0.28 (0.12, 0.67)	-10.01 (-16.76, -3.51)	
Other fibrotic patterns	64	5	7.8	66	5	7.6	0.9596	0.97 (0.29, 3.19)	0.97 (0.27, 3.51)	-0.24 (-10.40, 9.76)	
Underlying ILD diagnosis											0.3328
iNSIP	40	4	10.0	55	3	5.5	0.4024	0.55 (0.13, 2.30)	0.52 (0.11, 2.46)	-4.55 (-18.08, 6.63)	
Unclassifiable IIP	36	2	5.6	40	3	7.5	0.7328	1.35 (0.24, 7.63)	1.38 (0.22, 8.76)	1.94 (-11.57, 14.95)	
HP	39	7	17.9	30	1	3.3	0.0601	0.19 (0.02, 1.43)	0.16 (0.02, 1.36)	-14.62 (-29.59, 1.46)	
Autoimmune ILD	71	8	11.3	70	1	1.4	0.0169	0.13 (0.02, 0.99)	0.11 (0.01, 0.94)	-9.84 (-19.33, -1.56)	
Other ILD	36	7	19.4	25	4	16.0	0.7307	0.82 (0.27, 2.52)	0.79 (0.20, 3.05)	-3.44 (-21.75, 17.58)	
Region											0.6314
Europe	40	5	12.5	53	5	9.4	0.6365	0.75 (0.23, 2.43)	0.73 (0.20, 2.71)	-3.07 (-17.69, 9.84)	
Asia	106	16	15.1	107	7	6.5	0.0443	0.43 (0.19, 1.01)	0.39 (0.15, 1.00)	-8.55 (-17.24, -0.10)	
Canada and USA	30	3	10.0	17	0	0.0	0.2941	0.25 (0.01, 4.50)	0.00 (NC, NC)	-10.00 (-25.62, 9.56)	
Rest of the World	46	4	8.7	43	0	0.0	0.0775	0.12 (0.01, 2.14)	0.00 (NC, NC)	-8.70 (-20.32, 1.05)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 2 Proportion of patients with frequent serious AEs by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	23	10.4	220	22	10.0	0.9003	0.97 (0.55, 1.68)	0.96 (0.52, 1.78)	-0.36 (-6.11, 5.40)	
Age											
<65 years	83	5	6.0	88	5	5.7					
>=65 years	139	18	12.9	132	17	12.9					
Sex											
Male	116	12	10.3	111	10	9.0					
Female	106	11	10.4	109	12	11.0					
Baseline FVC percent predicted											
<=70%	118	15	12.7	96	15	15.6					
>70%	104	8	7.7	124	7	5.6					
Baseline HRCT pattern											
UIP-like	158	14	8.9	154	14	9.1					
Other fibrotic patterns	64	9	14.1	66	8	12.1					
Underlying ILD diagnosis											
iNSIP	40	4	10.0	55	9	16.4					
Unclassifiable IIP	36	2	5.6	40	3	7.5					
HP	39	2	5.1	30	1	3.3					
Autoimmune ILD	71	10	14.1	70	7	10.0					
Other ILD	36	5	13.9	25	2	8.0					
Region											
Europe	40	2	5.0	53	7	13.2					
Asia	106	16	15.1	107	12	11.2					
Canada and USA	30	2	6.7	17	1	5.9					
Rest of the World	46	3	6.5	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	27	12.2	220	12	5.5	0.0129	0.45 (0.23, 0.86)	0.42 (0.21, 0.85)	-6.71 (-12.17, -1.40)	
Age											0.6929
<65 years	83	11	13.3	88	6	6.8	0.1599	0.51 (0.20, 1.33)	0.48 (0.17, 1.36)	-6.43 (-16.09, 2.80)	
>=65 years	139	16	11.5	132	6	4.5	0.0359	0.39 (0.16, 0.98)	0.37 (0.14, 0.97)	-6.97 (-13.79, -0.36)	
Sex											0.5118
Male	116	19	16.4	111	7	6.3	0.0172	0.39 (0.17, 0.88)	0.34 (0.14, 0.85)	-10.07 (-18.50, -1.74)	
Female	106	8	7.5	109	5	4.6	0.3626	0.61 (0.21, 1.80)	0.59 (0.19, 1.86)	-2.96 (-10.10, 3.82)	
Baseline FVC percent predicted											0.9992
<=70%	118	22	18.6	96	9	9.4	0.0554	0.50 (0.24, 1.04)	0.45 (0.20, 1.03)	-9.27 (-18.36, 0.33)	
>70%	104	5	4.8	124	3	2.4	0.3290	0.50 (0.12, 2.06)	0.49 (0.11, 2.10)	-2.39 (-8.55, 2.84)	
Baseline HRCT pattern											0.2060
UIP-like	158	23	14.6	154	8	5.2	0.0057	0.36 (0.16, 0.77)	0.32 (0.14, 0.74)	-9.36 (-16.19, -2.73)	
Other fibrotic patterns	64	4	6.3	66	4	6.1	0.9642	0.97 (0.25, 3.71)	0.97 (0.23, 4.05)	-0.19 (-9.68, 9.13)	
Underlying ILD diagnosis											0.3708
iNSIP	40	3	7.5	55	3	5.5	0.6857	0.73 (0.15, 3.42)	0.71 (0.14, 3.72)	-2.05 (-14.92, 8.56)	
Unclassifiable IIP	36	2	5.6	40	3	7.5	0.7328	1.35 (0.24, 7.63)	1.38 (0.22, 8.76)	1.94 (-11.57, 14.95)	
HP	39	7	17.9	30	0	0.0	0.0235	0.09 (0.01, 1.45)	0.00 (NC, NC)	-17.95 (-32.67, -3.48)	
Autoimmune ILD	71	8	11.3	70	2	2.9	0.0517	0.25 (0.06, 1.15)	0.23 (0.05, 1.13)	-8.41 (-18.06, 0.44)	
Other ILD	36	7	19.4	25	4	16.0	0.7307	0.82 (0.27, 2.52)	0.79 (0.20, 3.05)	-3.44 (-21.75, 17.58)	
Region											0.8064
Europe	40	4	10.0	53	4	7.5	0.6762	0.75 (0.20, 2.84)	0.73 (0.17, 3.14)	-2.45 (-16.28, 9.50)	
Asia	106	16	15.1	107	7	6.5	0.0443	0.43 (0.19, 1.01)	0.39 (0.15, 1.00)	-8.55 (-17.24, -0.10)	
Canada and USA	30	3	10.0	17	0	0.0	0.2941	0.25 (0.01, 4.50)	0.00 (NC, NC)	-10.00 (-25.62, 9.56)	
Rest of the World	46	4	8.7	43	1	2.3	0.1922	0.27 (0.03, 2.30)	0.25 (0.03, 2.33)	-6.37 (-18.16, 4.69)	

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.1.2.2.1.5: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	22	9.9	220	20	9.1	0.7691	0.92 (0.52, 1.63)	0.91 (0.48, 1.72)	-0.82 (-6.41, 4.77)	
Age											
<65 years	83	4	4.8	88	5	5.7					
>=65 years	139	18	12.9	132	15	11.4					
Sex											
Male	116	11	9.5	111	8	7.2					
Female	106	11	10.4	109	12	11.0					
Baseline FVC percent predicted											
<=70%	118	13	11.0	96	15	15.6					
>70%	104	9	8.7	124	5	4.0					
Baseline HRCT pattern											
UIP-like	158	14	8.9	154	12	7.8					
Other fibrotic patterns	64	8	12.5	66	8	12.1					
Underlying ILD diagnosis											
iNSIP	40	3	7.5	55	9	16.4					
Unclassifiable IIP	36	2	5.6	40	2	5.0					
HP	39	2	5.1	30	1	3.3					
Autoimmune ILD	71	9	12.7	70	6	8.6					
Other ILD	36	6	16.7	25	2	8.0					
Region											
Europe	40	1	2.5	53	6	11.3					
Asia	106	16	15.1	107	11	10.3					
Canada and USA	30	2	6.7	17	1	5.9					
Rest of the World	46	3	6.5	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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I.1.2.3 Further analysis

I.1.2.3.1 Further safety analysis

Table I.1.2.3.1: 1 Proportion of patients with specific AEs over the whole trial - 18mg - TS (non-AF background)
PT: Abdominal pain

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	5	2.3	220	7	3.2	0.5477	1.41 (0.46, 4.38)	1.43 (0.45, 4.56)	0.93 (-2.41, 4.41)	
Age											0.7381
<65 years	83	1	1.2	88	1	1.1	0.9668	0.94 (0.06, 14.84)	0.94 (0.06, 15.32)	-0.07 (-5.46, 5.05)	
>=65 years	139	4	2.9	132	6	4.5	0.4667	1.58 (0.46, 5.47)	1.61 (0.44, 5.83)	1.67 (-3.27, 6.98)	
Sex											
Male	116	2	1.7	111	3	2.7					
Female	106	3	2.8	109	4	3.7					
Baseline FVC percent predicted											
<=70%	118	2	1.7	96	4	4.2					
>70%	104	3	2.9	124	3	2.4					
Baseline HRCT pattern											0.6188
UIP-like	158	5	3.2	154	6	3.9	0.7261	1.23 (0.38, 3.95)	1.24 (0.37, 4.15)	0.73 (-3.81, 5.43)	
Other fibrotic patterns	64	0	0.0	66	1	1.5	0.4896	2.91 (0.12, 70.15)	NC (NC, NC)	1.52 (-4.28, 8.10)	
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	1	1.8					
Unclassifiable IIP	36	2	5.6	40	2	5.0					
HP	39	1	2.6	30	0	0.0					
Autoimmune ILD	71	1	1.4	70	3	4.3					
Other ILD	36	1	2.8	25	1	4.0					
Region											
Europe	40	0	0.0	53	3	5.7					
Asia	106	0	0.0	107	2	1.9					
Canada and USA	30	2	6.7	17	0	0.0					
Rest of the World	46	3	6.5	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 1 Proportion of patients with specific AEs over the whole trial - 18mg - TS (non-AF background)
PT: Abdominal pain upper

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	6	2.7	220	6	2.7	0.9873	1.01 (0.33, 3.08)	1.01 (0.32, 3.18)	0.02 (-3.38, 3.45)	
Age											
<65 years	83	3	3.6	88	3	3.4					
>=65 years	139	3	2.2	132	3	2.3					
Sex											
Male	116	3	2.6	111	5	4.5					
Female	106	3	2.8	109	1	0.9					
Baseline FVC percent predicted											
<=70%	118	5	4.2	96	3	3.1					
>70%	104	1	1.0	124	3	2.4					
Baseline HRCT pattern											
UIP-like	158	3	1.9	154	4	2.6					
Other fibrotic patterns	64	3	4.7	66	2	3.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	3	5.5					
Unclassifiable IIP	36	2	5.6	40	2	5.0					
HP	39	2	5.1	30	0	0.0					
Autoimmune ILD	71	1	1.4	70	1	1.4					
Other ILD	36	1	2.8	25	0	0.0					
Region											
Europe	40	1	2.5	53	1	1.9					
Asia	106	4	3.8	107	5	4.7					
Canada and USA	30	1	3.3	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 1 Proportion of patients with specific AEs over the whole trial
- 18mg - TS (non-AF background)
PT: Decreased appetite

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	16	7.2	220	16	7.3	0.9788	1.01 (0.52, 1.97)	1.01 (0.49, 2.07)	0.07 (-4.93, 5.08)	
Age											0.4857
<65 years	83	3	3.6	88	5	5.7	0.5223	1.57 (0.39, 6.37)	1.61 (0.37, 6.94)	2.07 (-5.17, 9.40)	
>=65 years	139	13	9.4	132	11	8.3	0.7679	0.89 (0.41, 1.92)	0.88 (0.38, 2.04)	-1.02 (-8.02, 6.06)	
Sex											0.7758
Male	116	6	5.2	111	5	4.5	0.8148	0.87 (0.27, 2.77)	0.86 (0.26, 2.92)	-0.67 (-6.88, 5.59)	
Female	106	10	9.4	109	11	10.1	0.8710	1.07 (0.47, 2.41)	1.08 (0.44, 2.65)	0.66 (-7.65, 8.90)	
Baseline FVC percent predicted											0.5309
<=70%	118	12	10.2	96	9	9.4	0.8459	0.92 (0.41, 2.10)	0.91 (0.37, 2.27)	-0.79 (-8.85, 7.82)	
>70%	104	4	3.8	124	7	5.6	0.5278	1.47 (0.44, 4.88)	1.50 (0.43, 5.26)	1.80 (-4.53, 7.82)	
Baseline HRCT pattern											0.7391
UIP-like	158	12	7.6	154	11	7.1	0.8786	0.94 (0.43, 2.07)	0.94 (0.40, 2.19)	-0.45 (-6.52, 5.65)	
Other fibrotic patterns	64	4	6.3	66	5	7.6	0.7659	1.21 (0.34, 4.31)	1.23 (0.31, 4.80)	1.33 (-8.42, 11.06)	
Underlying ILD diagnosis											0.5106
iNSIP	40	2	5.0	55	4	7.3	0.6530	1.45 (0.28, 7.56)	1.49 (0.26, 8.56)	2.27 (-10.05, 12.90)	
Unclassifiable IIP	36	4	11.1	40	2	5.0	0.3239	0.45 (0.09, 2.31)	0.42 (0.07, 2.45)	-6.11 (-20.77, 7.20)	
HP	39	3	7.7	30	1	3.3	0.4424	0.43 (0.05, 3.96)	0.41 (0.04, 4.19)	-4.36 (-17.28, 9.90)	
Autoimmune ILD	71	5	7.0	70	5	7.1	0.9814	1.01 (0.31, 3.35)	1.02 (0.28, 3.67)	0.10 (-9.23, 9.50)	
Other ILD	36	2	5.6	25	4	16.0	0.1779	2.88 (0.57, 14.54)	3.24 (0.54, 19.25)	10.44 (-5.39, 29.53)	
Region											0.2697
Europe	40	1	2.5	53	3	5.7	0.4570	2.26 (0.24, 20.96)	2.34 (0.23, 23.38)	3.16 (-7.87, 13.09)	
Asia	106	11	10.4	107	8	7.5	0.4577	0.72 (0.30, 1.72)	0.70 (0.27, 1.81)	-2.90 (-11.02, 5.07)	
Canada and USA	30	4	13.3	17	1	5.9	0.4260	0.44 (0.05, 3.64)	0.41 (0.04, 3.96)	-7.45 (-24.50, 15.12)	
Rest of the World	46	0	0.0	43	4	9.3	0.0552	9.61 (0.53, >99)	NC (NC, NC)	9.30 (-0.24, 21.60)	

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 1 Proportion of patients with specific AEs over the whole trial
- 18mg - TS (non-AF background)
PT: Diarrhoea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	39	17.6	220	60	27.3	0.0144	1.55 (1.09, 2.22)	1.76 (1.12, 2.77)	9.71 (1.92, 17.36)	
Age											0.0524
<65 years	83	16	19.3	88	16	18.2	0.8544	0.94 (0.51, 1.76)	0.93 (0.43, 2.01)	-1.10 (-12.92, 10.60)	
>=65 years	139	23	16.5	132	44	33.3	0.0014	2.01 (1.29, 3.14)	2.52 (1.42, 4.48)	16.79 (6.51, 26.71)	
Sex											0.4915
Male	116	22	19.0	111	29	26.1	0.1963	1.38 (0.84, 2.25)	1.51 (0.81, 2.83)	7.16 (-3.72, 17.92)	
Female	106	17	16.0	109	31	28.4	0.0290	1.77 (1.05, 3.01)	2.08 (1.07, 4.05)	12.40 (1.24, 23.17)	
Baseline FVC percent predicted											0.3223
<=70%	118	26	22.0	96	29	30.2	0.1735	1.37 (0.87, 2.16)	1.53 (0.83, 2.84)	8.17 (-3.54, 19.95)	
>70%	104	13	12.5	124	31	25.0	0.0172	2.00 (1.11, 3.62)	2.33 (1.15, 4.74)	12.50 (2.22, 22.21)	
Baseline HRCT pattern											0.4578
UIP-like	158	28	17.7	154	46	29.9	0.0117	1.69 (1.11, 2.55)	1.98 (1.16, 3.38)	12.15 (2.70, 21.38)	
Other fibrotic patterns	64	11	17.2	66	14	21.2	0.5605	1.23 (0.61, 2.51)	1.30 (0.54, 3.12)	4.02 (-9.68, 17.48)	
Underlying ILD diagnosis											0.5260
iNSIP	40	6	15.0	55	13	23.6	0.2988	1.58 (0.66, 3.79)	1.75 (0.60, 5.10)	8.64 (-8.21, 23.62)	
Unclassifiable IIP	36	5	13.9	40	11	27.5	0.1461	1.98 (0.76, 5.15)	2.35 (0.73, 7.59)	13.61 (-5.04, 30.82)	
HP	39	8	20.5	30	10	33.3	0.2293	1.63 (0.73, 3.61)	1.94 (0.65, 5.74)	12.82 (-7.78, 33.18)	
Autoimmune ILD	71	15	21.1	70	16	22.9	0.8041	1.08 (0.58, 2.02)	1.11 (0.50, 2.46)	1.73 (-11.91, 15.34)	
Other ILD	36	5	13.9	25	10	40.0	0.0199	2.88 (1.12, 7.41)	4.13 (1.20, 14.25)	26.11 (3.89, 46.89)	
Region											0.2703
Europe	40	5	12.5	53	16	30.2	0.0434	2.42 (0.97, 6.04)	3.03 (1.00, 9.14)	17.69 (0.39, 32.78)	
Asia	106	21	19.8	107	23	21.5	0.7615	1.09 (0.64, 1.84)	1.11 (0.57, 2.15)	1.68 (-9.22, 12.53)	
Canada and USA	30	7	23.3	17	7	41.2	0.1987	1.76 (0.75, 4.18)	2.30 (0.64, 8.31)	17.84 (-8.47, 43.41)	
Rest of the World	46	6	13.0	43	14	32.6	0.0275	2.50 (1.05, 5.91)	3.22 (1.10, 9.38)	19.51 (2.05, 35.97)	

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 1 Proportion of patients with specific AEs over the whole trial
- 18mg - TS (non-AF background)
PT: Hepatic function abnormal

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	4	1.8	220	4	1.8	0.9897	1.01 (0.26, 3.98)	1.01 (0.25, 4.09)	0.02 (-2.94, 2.99)	
Age											
<65 years	83	1	1.2	88	2	2.3					
>=65 years	139	3	2.2	132	2	1.5					
Sex											
Male	116	3	2.6	111	4	3.6					
Female	106	1	0.9	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	3	2.5	96	1	1.0					
>70%	104	1	1.0	124	3	2.4					
Baseline HRCT pattern											
UIP-like	158	3	1.9	154	4	2.6					
Other fibrotic patterns	64	1	1.6	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	1	2.6	30	0	0.0					
Autoimmune ILD	71	2	2.8	70	2	2.9					
Other ILD	36	1	2.8	25	2	8.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	4	3.8	107	4	3.7					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 1 Proportion of patients with specific AEs over the whole trial - 18mg - TS (non-AF background)
PT: Nausea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	9	4.1	220	17	7.7	0.1008	1.91 (0.87, 4.18)	1.98 (0.86, 4.55)	3.67 (-0.82, 8.38)	
Age											0.5024
<65 years	83	3	3.6	88	4	4.5	0.7588	1.26 (0.29, 5.45)	1.27 (0.28, 5.85)	0.93 (-6.12, 7.91)	
>=65 years	139	6	4.3	132	13	9.8	0.0746	2.28 (0.89, 5.83)	2.42 (0.89, 6.57)	5.53 (-0.70, 12.22)	
Sex											0.1886
Male	116	2	1.7	111	8	7.2	0.0442	4.18 (0.91, 19.26)	4.43 (0.92, 21.33)	5.48 (-0.10, 11.98)	
Female	106	7	6.6	109	9	8.3	0.6443	1.25 (0.48, 3.24)	1.27 (0.46, 3.55)	1.65 (-5.82, 9.15)	
Baseline FVC percent predicted											0.9566
<=70%	118	6	5.1	96	10	10.4	0.1402	2.05 (0.77, 5.43)	2.17 (0.76, 6.21)	5.33 (-1.93, 13.51)	
>70%	104	3	2.9	124	7	5.6	0.3107	1.96 (0.52, 7.38)	2.01 (0.51, 7.99)	2.76 (-3.23, 8.63)	
Baseline HRCT pattern											0.0886
UIP-like	158	4	2.5	154	13	8.4	0.0215	3.33 (1.11, 10.00)	3.55 (1.13, 11.14)	5.91 (0.79, 11.59)	
Other fibrotic patterns	64	5	7.8	66	4	6.1	0.6940	0.78 (0.22, 2.76)	0.76 (0.19, 2.97)	-1.75 (-11.67, 7.84)	
Underlying ILD diagnosis											
iNSIP	40	1	2.5	55	2	3.6					
Unclassifiable IIP	36	3	8.3	40	3	7.5					
HP	39	4	10.3	30	3	10.0					
Autoimmune ILD	71	0	0.0	70	6	8.6					
Other ILD	36	1	2.8	25	3	12.0					
Region											
Europe	40	3	7.5	53	4	7.5					
Asia	106	1	0.9	107	6	5.6					
Canada and USA	30	3	10.0	17	2	11.8					
Rest of the World	46	2	4.3	43	5	11.6					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 1 Proportion of patients with specific AEs over the whole trial
- 18mg - TS (non-AF background)
PT: Vomiting

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	7	3.2	220	9	4.1	0.5977	1.30 (0.49, 3.42)	1.31 (0.48, 3.58)	0.94 (-2.81, 4.79)	
Age											0.0553
<65 years	83	4	4.8	88	1	1.1	0.1531	0.24 (0.03, 2.07)	0.23 (0.02, 2.07)	-3.68 (-10.67, 2.13)	
>=65 years	139	3	2.2	132	8	6.1	0.1037	2.81 (0.76, 10.36)	2.92 (0.76, 11.27)	3.90 (-1.07, 9.53)	
Sex											0.4685
Male	116	2	1.7	111	4	3.6	0.3776	2.09 (0.39, 11.18)	2.13 (0.38, 11.87)	1.88 (-2.99, 7.32)	
Female	106	5	4.7	109	5	4.6	0.9640	0.97 (0.29, 3.26)	0.97 (0.27, 3.46)	-0.13 (-6.54, 6.17)	
Baseline FVC percent predicted											
<=70%	118	2	1.7	96	5	5.2					
>70%	104	5	4.8	124	4	3.2					
Baseline HRCT pattern											0.2007
UIP-like	158	7	4.4	154	6	3.9	0.8133	0.88 (0.30, 2.56)	0.87 (0.29, 2.66)	-0.53 (-5.44, 4.36)	
Other fibrotic patterns	64	0	0.0	66	3	4.5	0.1355	6.79 (0.36, >99)	NC (NC, NC)	4.55 (-1.86, 12.53)	
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	1	1.8					
Unclassifiable IIP	36	3	8.3	40	3	7.5					
HP	39	0	0.0	30	1	3.3					
Autoimmune ILD	71	2	2.8	70	4	5.7					
Other ILD	36	0	0.0	25	0	0.0					
Region											0.6522
Europe	40	1	2.5	53	1	1.9	0.8401	0.75 (0.05, 11.70)	0.75 (0.05, 12.37)	-0.61 (-11.11, 7.70)	
Asia	106	3	2.8	107	7	6.5	0.2004	2.31 (0.61, 8.70)	2.40 (0.60, 9.56)	3.71 (-2.44, 10.33)	
Canada and USA	30	2	6.7	17	0	0.0	0.4568	0.34 (0.02, 6.78)	0.00 (NC, NC)	-6.67 (-21.32, 12.38)	
Rest of the World	46	1	2.2	43	1	2.3	0.9615	1.07 (0.07, 16.57)	1.07 (0.06, 17.68)	0.15 (-9.21, 10.05)	

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 1 Proportion of patients with specific AEs over the whole trial
- 18mg - TS (non-AF background)
SOC: Gastrointestinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	88	39.6	220	103	46.8	0.1277	1.18 (0.95, 1.46)	1.34 (0.92, 1.96)	7.18 (-2.04, 16.23)	
Age											0.0352
<65 years	83	35	42.2	88	32	36.4	0.4370	0.86 (0.59, 1.25)	0.78 (0.42, 1.45)	-5.81 (-20.00, 8.67)	
>=65 years	139	53	38.1	132	71	53.8	0.0097	1.41 (1.08, 1.84)	1.89 (1.16, 3.06)	15.66 (3.79, 26.93)	
Sex											0.9502
Male	116	44	37.9	111	50	45.0	0.2767	1.19 (0.87, 1.62)	1.34 (0.79, 2.28)	7.11 (-5.63, 19.56)	
Female	106	44	41.5	109	53	48.6	0.2946	1.17 (0.87, 1.58)	1.33 (0.78, 2.29)	7.11 (-6.10, 19.98)	
Baseline FVC percent predicted											0.6727
<=70%	118	48	40.7	96	44	45.8	0.4487	1.13 (0.83, 1.53)	1.23 (0.72, 2.13)	5.16 (-8.03, 18.19)	
>70%	104	40	38.5	124	59	47.6	0.1665	1.24 (0.91, 1.68)	1.45 (0.86, 2.47)	9.12 (-3.76, 21.50)	
Baseline HRCT pattern											0.2595
UIP-like	158	61	38.6	154	76	49.4	0.0559	1.28 (0.99, 1.65)	1.55 (0.99, 2.43)	10.74 (-0.26, 21.39)	
Other fibrotic patterns	64	27	42.2	66	27	40.9	0.8824	0.97 (0.64, 1.46)	0.95 (0.47, 1.91)	-1.28 (-17.73, 15.25)	
Underlying ILD diagnosis											0.8381
iNSIP	40	13	32.5	55	20	36.4	0.6962	1.12 (0.63, 1.97)	1.19 (0.50, 2.80)	3.86 (-15.38, 21.99)	
Unclassifiable IIP	36	16	44.4	40	21	52.5	0.4830	1.18 (0.74, 1.89)	1.38 (0.56, 3.41)	8.06 (-13.86, 28.89)	
HP	39	17	43.6	30	13	43.3	0.9830	0.99 (0.58, 1.71)	0.99 (0.38, 2.59)	-0.26 (-22.46, 22.31)	
Autoimmune ILD	71	28	39.4	70	34	48.6	0.2746	1.23 (0.85, 1.79)	1.45 (0.74, 2.83)	9.13 (-7.10, 24.72)	
Other ILD	36	14	38.9	25	15	60.0	0.1044	1.54 (0.92, 2.59)	2.36 (0.83, 6.69)	21.11 (-4.09, 42.89)	
Region											0.5934
Europe	40	13	32.5	53	24	45.3	0.2124	1.39 (0.82, 2.38)	1.72 (0.73, 4.04)	12.78 (-7.19, 30.95)	
Asia	106	46	43.4	107	51	47.7	0.5318	1.10 (0.82, 1.47)	1.19 (0.69, 2.04)	4.27 (-8.97, 17.29)	
Canada and USA	30	16	53.3	17	9	52.9	0.9793	0.99 (0.57, 1.74)	0.98 (0.30, 3.24)	-0.39 (-27.84, 26.66)	
Rest of the World	46	13	28.3	43	19	44.2	0.1177	1.56 (0.88, 2.76)	2.01 (0.83, 4.84)	15.93 (-3.91, 34.25)	

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 1 Proportion of patients with specific AEs over the whole trial - 18mg - TS (non-AF background)
SOC: Hepatobiliary disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	8	3.6	220	9	4.1	0.7900	1.14 (0.45, 2.89)	1.14 (0.43, 3.01)	0.49 (-3.37, 4.41)	
Age											0.4612
<65 years	83	2	2.4	88	4	4.5	0.4481	1.89 (0.35, 10.03)	1.93 (0.34, 10.82)	2.14 (-4.43, 8.93)	
>=65 years	139	6	4.3	132	5	3.8	0.8255	0.88 (0.27, 2.81)	0.87 (0.26, 2.93)	-0.53 (-5.77, 4.78)	
Sex											0.4395
Male	116	6	5.2	111	5	4.5	0.8148	0.87 (0.27, 2.77)	0.86 (0.26, 2.92)	-0.67 (-6.88, 5.59)	
Female	106	2	1.9	109	4	3.7	0.4275	1.94 (0.36, 10.40)	1.98 (0.36, 11.05)	1.78 (-3.45, 7.34)	
Baseline FVC percent predicted											0.7514
<=70%	118	4	3.4	96	3	3.1	0.9137	0.92 (0.21, 4.02)	0.92 (0.20, 4.21)	-0.26 (-5.67, 5.76)	
>70%	104	4	3.8	124	6	4.8	0.7155	1.26 (0.36, 4.34)	1.27 (0.35, 4.63)	0.99 (-5.21, 6.80)	
Baseline HRCT pattern											0.6295
UIP-like	158	7	4.4	154	7	4.5	0.9608	1.03 (0.37, 2.86)	1.03 (0.35, 3.00)	0.12 (-4.89, 5.19)	
Other fibrotic patterns	64	1	1.6	66	2	3.0	0.5774	1.94 (0.18, 20.87)	1.97 (0.17, 22.26)	1.47 (-5.65, 8.94)	
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	1	1.8					
Unclassifiable IIP	36	2	5.6	40	2	5.0					
HP	39	1	2.6	30	0	0.0					
Autoimmune ILD	71	3	4.2	70	3	4.3					
Other ILD	36	2	5.6	25	3	12.0					
Region											0.9837
Europe	40	1	2.5	53	2	3.8	0.7307	1.51 (0.14, 16.07)	1.53 (0.13, 17.48)	1.27 (-9.46, 10.49)	
Asia	106	7	6.6	107	7	6.5	0.9855	0.99 (0.36, 2.73)	0.99 (0.33, 2.93)	-0.06 (-7.28, 7.13)	
Canada and USA	30	0	0.0	17	0	0.0	0.7810	1.72 (0.04, 83.12)	NC (NC, NC)	0.00 (NC, NC)	
Rest of the World	46	0	0.0	43	0	0.0	0.9735	1.07 (0.02, 52.68)	NC (NC, NC)	0.00 (NC, NC)	

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial - 18mg - TS (non-AF background)
PT: Abdominal pain

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial - 18mg - TS (non-AF background)
PT: Abdominal pain upper

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial - 18mg - TS (non-AF background)
PT: Decreased appetite

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial - 18mg - TS (non-AF background)
PT: Diarrhoea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial - 18mg - TS (non-AF background)
PT: Hepatic function abnormal

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial - 18mg - TS (non-AF background)

PT: Nausea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial - 18mg - TS (non-AF background)

PT: Vomiting

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial - 18mg - TS (non-AF background)
SOC: Gastrointestinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	6	2.7	220	6	2.7	0.9873	1.01 (0.33, 3.08)	1.01 (0.32, 3.18)	0.02 (-3.38, 3.45)	
Age											
<65 years	83	2	2.4	88	1	1.1					
>=65 years	139	4	2.9	132	5	3.8					
Sex											
Male	116	4	3.4	111	2	1.8					
Female	106	2	1.9	109	4	3.7					
Baseline FVC percent predicted											
<=70%	118	3	2.5	96	2	2.1					
>70%	104	3	2.9	124	4	3.2					
Baseline HRCT pattern											
UIP-like	158	4	2.5	154	4	2.6					
Other fibrotic patterns	64	2	3.1	66	2	3.0					
Underlying ILD diagnosis											
iNSIP	40	1	2.5	55	1	1.8					
Unclassifiable IIP	36	0	0.0	40	2	5.0					
HP	39	1	2.6	30	0	0.0					
Autoimmune ILD	71	3	4.2	70	3	4.3					
Other ILD	36	1	2.8	25	0	0.0					
Region											
Europe	40	2	5.0	53	0	0.0					
Asia	106	3	2.8	107	5	4.7					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	1	2.2	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial - 18mg - TS (non-AF background)
SOC: Hepatobiliary disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	4	1.8	220	1	0.5	0.1805	0.25 (0.03, 2.24)	0.25 (0.03, 2.24)	-1.35 (-4.11, 1.00)	
Age											
<65 years	83	2	2.4	88	0	0.0					
>=65 years	139	2	1.4	132	1	0.8					
Sex											
Male	116	2	1.7	111	0	0.0					
Female	106	2	1.9	109	1	0.9					
Baseline FVC percent predicted											
<=70%	118	2	1.7	96	0	0.0					
>70%	104	2	1.9	124	1	0.8					
Baseline HRCT pattern											
UIP-like	158	3	1.9	154	1	0.6					
Other fibrotic patterns	64	1	1.6	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	2	5.6	40	1	2.5					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	2	5.6	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	4	3.8	107	1	0.9					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial - 18mg - TS (non-AF background)
PT: Abdominal pain

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial - 18mg - TS (non-AF background)
PT: Abdominal pain upper

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial - 18mg - TS (non-AF background)
PT: Decreased appetite

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial - 18mg - TS (non-AF background)
PT: Diarrhoea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial - 18mg - TS (non-AF background)
PT: Hepatic function abnormal

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	1	0.5	220	0	0.0	0.4825	0.34 (0.01, 8.21)	0.00 (NC, NC)	-0.45 (-2.51, 1.31)	
Age											
<65 years	83	1	1.2	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	1	0.9	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	1	0.8	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	1	1.6	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	1	2.8	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	1	0.9	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial - 18mg - TS (non-AF background)

PT: Nausea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial - 18mg - TS (non-AF background)

PT: Vomiting

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial - 18mg - TS (non-AF background)
SOC: Gastrointestinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	4	1.8	220	7	3.2	0.3517	1.77 (0.52, 5.95)	1.79 (0.52, 6.21)	1.38 (-1.81, 4.80)	
Age											
<65 years	83	1	1.2	88	1	1.1					
>=65 years	139	3	2.2	132	6	4.5					
Sex											
Male	116	3	2.6	111	3	2.7					
Female	106	1	0.9	109	4	3.7					
Baseline FVC percent predicted											
<=70%	118	2	1.7	96	2	2.1					
>70%	104	2	1.9	124	5	4.0					
Baseline HRCT pattern											
UIP-like	158	4	2.5	154	5	3.2					
Other fibrotic patterns	64	0	0.0	66	2	3.0					
Underlying ILD diagnosis											
iNSIP	40	1	2.5	55	1	1.8					
Unclassifiable IIP	36	0	0.0	40	2	5.0					
HP	39	1	2.6	30	0	0.0					
Autoimmune ILD	71	2	2.8	70	3	4.3					
Other ILD	36	0	0.0	25	1	4.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	3	2.8	107	5	4.7					
Canada and USA	30	0	0.0	17	1	5.9					
Rest of the World	46	1	2.2	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial - 18mg - TS (non-AF background)
SOC: Hepatobiliary disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	3	1.4	220	1	0.5	0.3195	0.34 (0.04, 3.21)	0.33 (0.03, 3.23)	-0.90 (-3.47, 1.36)	
Age											
<65 years	83	2	2.4	88	0	0.0					
>=65 years	139	1	0.7	132	1	0.8					
Sex											
Male	116	1	0.9	111	0	0.0					
Female	106	2	1.9	109	1	0.9					
Baseline FVC percent predicted											
<=70%	118	1	0.8	96	0	0.0					
>70%	104	2	1.9	124	1	0.8					
Baseline HRCT pattern											
UIP-like	158	2	1.3	154	1	0.6					
Other fibrotic patterns	64	1	1.6	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	2	5.6	40	1	2.5					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	1	2.8	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	3	2.8	107	1	0.9					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.1.2.3.1: 4 Proportion of patients with Diarrhoea with CTCAE grade <3 over the whole trial - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	39	17.6	220	60	27.3	0.0144	1.55 (1.09, 2.22)	1.76 (1.12, 2.77)	9.71 (1.92, 17.36)	
Age											0.0524
<65 years	83	16	19.3	88	16	18.2	0.8544	0.94 (0.51, 1.76)	0.93 (0.43, 2.01)	-1.10 (-12.92, 10.60)	
>=65 years	139	23	16.5	132	44	33.3	0.0014	2.01 (1.29, 3.14)	2.52 (1.42, 4.48)	16.79 (6.51, 26.71)	
Sex											0.4915
Male	116	22	19.0	111	29	26.1	0.1963	1.38 (0.84, 2.25)	1.51 (0.81, 2.83)	7.16 (-3.72, 17.92)	
Female	106	17	16.0	109	31	28.4	0.0290	1.77 (1.05, 3.01)	2.08 (1.07, 4.05)	12.40 (1.24, 23.17)	
Baseline FVC percent predicted											0.3223
<=70%	118	26	22.0	96	29	30.2	0.1735	1.37 (0.87, 2.16)	1.53 (0.83, 2.84)	8.17 (-3.54, 19.95)	
>70%	104	13	12.5	124	31	25.0	0.0172	2.00 (1.11, 3.62)	2.33 (1.15, 4.74)	12.50 (2.22, 22.21)	
Baseline HRCT pattern											0.4578
UIP-like	158	28	17.7	154	46	29.9	0.0117	1.69 (1.11, 2.55)	1.98 (1.16, 3.38)	12.15 (2.70, 21.38)	
Other fibrotic patterns	64	11	17.2	66	14	21.2	0.5605	1.23 (0.61, 2.51)	1.30 (0.54, 3.12)	4.02 (-9.68, 17.48)	
Underlying ILD diagnosis											0.5260
iNSIP	40	6	15.0	55	13	23.6	0.2988	1.58 (0.66, 3.79)	1.75 (0.60, 5.10)	8.64 (-8.21, 23.62)	
Unclassifiable IIP	36	5	13.9	40	11	27.5	0.1461	1.98 (0.76, 5.15)	2.35 (0.73, 7.59)	13.61 (-5.04, 30.82)	
HP	39	8	20.5	30	10	33.3	0.2293	1.63 (0.73, 3.61)	1.94 (0.65, 5.74)	12.82 (-7.78, 33.18)	
Autoimmune ILD	71	15	21.1	70	16	22.9	0.8041	1.08 (0.58, 2.02)	1.11 (0.50, 2.46)	1.73 (-11.91, 15.34)	
Other ILD	36	5	13.9	25	10	40.0	0.0199	2.88 (1.12, 7.41)	4.13 (1.20, 14.25)	26.11 (3.89, 46.89)	
Region											0.2703
Europe	40	5	12.5	53	16	30.2	0.0434	2.42 (0.97, 6.04)	3.03 (1.00, 9.14)	17.69 (0.39, 32.78)	
Asia	106	21	19.8	107	23	21.5	0.7615	1.09 (0.64, 1.84)	1.11 (0.57, 2.15)	1.68 (-9.22, 12.53)	
Canada and USA	30	7	23.3	17	7	41.2	0.1987	1.76 (0.75, 4.18)	2.30 (0.64, 8.31)	17.84 (-8.47, 43.41)	
Rest of the World	46	6	13.0	43	14	32.6	0.0275	2.50 (1.05, 5.91)	3.22 (1.10, 9.38)	19.51 (2.05, 35.97)	

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: Each patient is considered only once with the worst CTCAE grade.

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Table I.1.2.3.1: 5 Proportion of patients with Diarrhoea with CTCAE grade >=3 over the whole trial - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: Each patient is considered only once with the worst CTCAE grade.

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I.1.2.3.2 Time to event analyses: treatment policy approach to lung transplant

Table I.1.2.3.2: 1 Cox model for time to first confirmed acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n (e/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (e/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	222	50 (22/ 28)	22.5	16.79	220	26 (13/ 13)	11.8	8.40	0.57	(0.35, 0.92)	0.0221	
Age												0.2996
<65 years	83	12 (6/ 6)	14.5	10.18	88	9 (5/ 4)	10.2	7.08	0.83	(0.35, 1.98)	0.6736	
>=65 years	139	38 (16/ 22)	27.3	21.11	132	17 (8/ 9)	12.9	9.33	0.48	(0.27, 0.85)	0.0125	
Sex												0.4994
Male	116	30 (14/ 16)	25.9	19.89	111	13 (5/ 8)	11.7	8.43	0.49	(0.25, 0.95)	0.0350	
Female	106	20 (8/ 12)	18.9	13.60	109	13 (8/ 5)	11.9	8.38	0.68	(0.34, 1.38)	0.2863	
Baseline FVC percent predicted												0.1764
<=70%	118	39 (17/ 22)	33.1	25.63	96	15 (9/ 6)	15.6	11.31	0.46	(0.25, 0.83)	0.0099	
>70%	104	11 (5/ 6)	10.6	7.55	124	11 (4/ 7)	8.9	6.22	0.94	(0.40, 2.20)	0.8784	
Baseline HRCT pattern												0.6515
UIP-like	158	36 (17/ 19)	22.8	17.29	154	18 (7/ 11)	11.7	8.32	0.53	(0.30, 0.94)	0.0306	
Other fibrotic patterns	64	14 (5/ 9)	21.9	15.62	66	8 (6/ 2)	12.1	8.60	0.68	(0.28, 1.64)	0.3897	
Underlying ILD diagnosis												0.4820
iNSIP	40	8 (4/ 4)	20.0	13.90	55	8 (3/ 5)	14.5	10.48	0.84	(0.32, 2.26)	0.7368	
Unclassifiable IIP	36	6 (1/ 5)	16.7	11.96	40	5 (4/ 1)	12.5	9.03	0.91	(0.28, 3.01)	0.8812	
HP	39	12 (7/ 5)	30.8	27.03	30	3 (1/ 2)	10.0	7.20	0.33	(0.09, 1.20)	0.0927	
Autoimmune ILD	71	14 (6/ 8)	19.7	14.27	70	5 (1/ 4)	7.1	4.91	0.34	(0.12, 0.94)	0.0382	
Other ILD	36	10 (4/ 6)	27.8	21.00	25	5 (4/ 1)	20.0	14.64	0.90	(0.30, 2.63)	0.8405	
Region												0.2300
Europe	40	7 (2/ 5)	17.5	13.33	53	10 (5/ 5)	18.9	14.56	1.20	(0.45, 3.16)	0.7143	
Asia	106	20 (12/ 8)	18.9	13.17	107	13 (6/ 7)	12.1	8.41	0.70	(0.35, 1.41)	0.3210	
Canada and USA	30	9 (3/ 6)	30.0	23.31	17	0 (0/ 0)	0.0	0.00	0.00	(NC, NC)	0.9832	
Rest of the World	46	14 (5/ 9)	30.4	25.50	43	3 (2/ 1)	7.0	4.94	0.22	(0.06, 0.79)	0.0200	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed acute ILD exacerbations, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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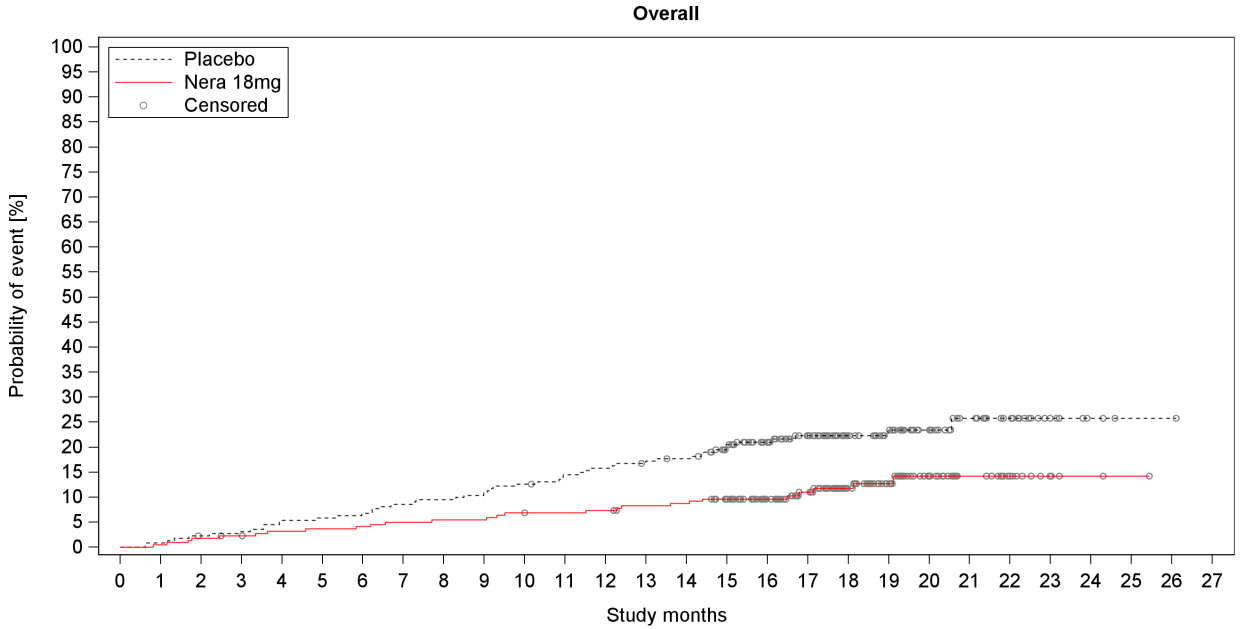

Number at risk (percentage relative to baseline)

Placebo	222	220	216	214	210	208	206	202	200	197	193	188	185	181	179	162	136	114	80	64	43	29	20	7	3	1	1	0
%	100.0	99.1	97.3	96.4	94.6	93.7	92.8	91.0	90.1	88.7	86.9	84.7	83.3	81.5	80.6	73.0	61.3	51.4	36.0	28.8	19.4	13.1	9.0	3.2	1.4	0.5	0.5	0.0
Nera 18mg	220	219	216	214	211	210	209	207	206	206	203	202	201	197	196	186	149	127	87	65	41	23	16	4	2	1	0	0
%	100.0	99.5	98.2	97.3	95.9	95.5	95.0	94.1	93.6	93.6	92.3	91.8	91.4	89.5	89.1	84.5	67.7	57.7	39.5	29.5	18.6	10.5	7.3	1.8	0.9	0.5	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	1	1	1	1	1	1	1	1	1	2	2	3	4	15	40	60	94	109	130	143	152	165	169	171	171	172
%	0.0	0.0	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.9	0.9	1.4	1.8	6.8	18.0	27.0	42.3	49.1	58.6	64.4	68.5	74.3	76.1	77.0	77.0	77.5
Nera 18mg	0	0	0	1	2	2	2	2	2	2	2	3	3	5	5	13	50	70	109	130	153	171	178	190	192	193	194	194
%	0.0	0.0	0.0	0.5	0.9	0.9	0.9	0.9	0.9	0.9	0.9	1.4	1.4	2.3	2.3	5.9	22.7	31.8	49.5	59.1	69.5	77.7	80.9	86.4	87.3	87.7	88.2	88.2

Study: 1305-0023

Figure I.1.2.3.2: 1 Time to first confirmed acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate - 18mg - FAS (non-AF background)

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Figure I.1.2.3.2: 1

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Table I.1.2.3.2: 2 Cox model for time to first confirmed or suspected acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n (e/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (e/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio (95% CI)	p-value	Interaction p-value
Overall	222	55 (33/ 22)	24.8	18.93	220	30 (18/ 12)	13.6	9.83	0.58 (0.37, 0.91)	0.0185	
Age											0.2222
<65 years	83	15 (12/ 3)	18.1	13.20	88	12 (9/ 3)	13.6	9.63	0.86 (0.40, 1.84)	0.6936	
>=65 years	139	40 (21/ 19)	28.8	22.60	132	18 (9/ 9)	13.6	9.96	0.48 (0.27, 0.83)	0.0096	
Sex											0.7379
Male	116	32 (21/ 11)	27.6	21.74	111	16 (9/ 7)	14.4	10.58	0.54 (0.30, 1.00)	0.0498	
Female	106	23 (12/ 11)	21.7	16.04	109	14 (9/ 5)	12.8	9.09	0.63 (0.33, 1.23)	0.1794	
Baseline FVC percent predicted											0.2622
<=70%	118	41 (23/ 18)	34.7	27.65	96	17 (12/ 5)	17.7	13.03	0.48 (0.27, 0.85)	0.0123	
>70%	104	14 (10/ 4)	13.5	9.83	124	13 (6/ 7)	10.5	7.43	0.84 (0.39, 1.81)	0.6494	
Baseline HRCT pattern											0.7473
UIP-like	158	38 (23/ 15)	24.1	18.51	154	20 (10/ 10)	13.0	9.32	0.55 (0.32, 0.96)	0.0341	
Other fibrotic patterns	64	17 (10/ 7)	26.6	19.93	66	10 (8/ 2)	15.2	11.01	0.65 (0.29, 1.43)	0.2846	
Underlying ILD diagnosis											0.7653
iNSIP	40	10 (8/ 2)	25.0	18.16	55	9 (4/ 5)	16.4	11.89	0.68 (0.27, 1.67)	0.3960	
Unclassifiable IIP	36	6 (2/ 4)	16.7	11.99	40	5 (4/ 1)	12.5	9.03	0.87 (0.26, 2.87)	0.8227	
HP	39	13 (9/ 4)	33.3	30.01	30	4 (2/ 2)	13.3	9.81	0.41 (0.13, 1.28)	0.1238	
Autoimmune ILD	71	16 (9/ 7)	22.5	16.78	70	7 (3/ 4)	10.0	7.05	0.43 (0.18, 1.05)	0.0635	
Other ILD	36	10 (5/ 5)	27.8	21.36	25	5 (5/ 0)	20.0	14.65	0.86 (0.29, 2.52)	0.7785	
Region											0.3233
Europe	40	8 (6/ 2)	20.0	15.86	53	12 (7/ 5)	22.6	18.01	1.18 (0.48, 2.88)	0.7237	
Asia	106	21 (14/ 7)	19.8	13.98	107	13 (7/ 6)	12.1	8.41	0.66 (0.33, 1.32)	0.2408	
Canada and USA	30	10 (4/ 6)	33.3	26.48	17	0 (0/ 0)	0.0	0.00	0.00 (NC, NC)	0.9818	
Rest of the World	46	16 (9/ 7)	34.8	30.63	43	5 (4/ 1)	11.6	8.51	0.32 (0.12, 0.90)	0.0299	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb). The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed or suspected acute ILD exacerbations, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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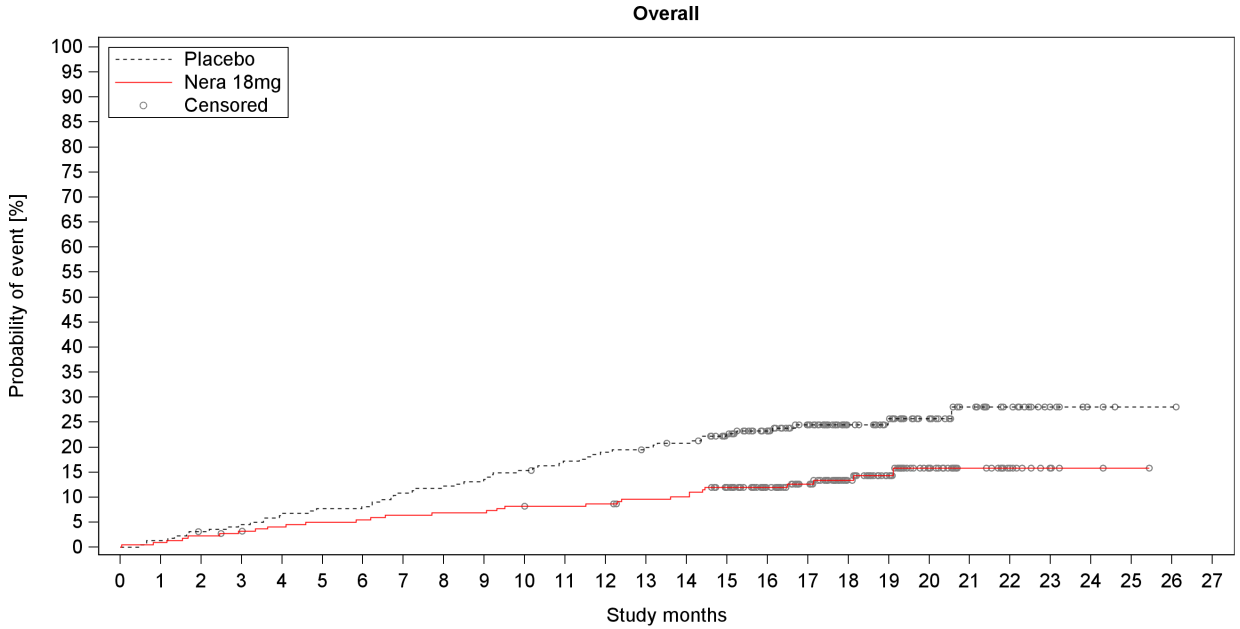

Number at risk (percentage relative to baseline)

Placebo	222	219	214	211	207	204	203	197	194	191	187	182	178	175	172	157	132	110	76	61	42	28	19	7	3	1	1	0
%	100.0	98.6	96.4	95.0	93.2	91.9	91.4	88.7	87.4	86.0	84.2	82.0	80.2	78.8	77.5	70.7	59.5	49.5	34.2	27.5	18.9	12.6	8.6	3.2	1.4	0.5	0.5	0.0
Nera 18mg	220	218	215	212	209	207	206	204	203	203	200	199	198	194	193	182	145	125	86	65	41	23	16	4	2	1	0	0
%	100.0	99.1	97.7	96.4	95.0	94.1	93.6	92.7	92.3	92.3	90.9	90.5	90.0	88.2	87.7	82.7	65.9	56.8	39.1	29.5	18.6	10.5	7.3	1.8	0.9	0.5	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	1	1	1	1	1	1	1	1	1	2	2	3	4	15	39	59	93	107	126	139	148	160	164	166	166	167
%	0.0	0.0	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.9	0.9	1.4	1.8	6.8	17.6	26.6	41.9	48.2	56.8	62.6	66.7	72.1	73.9	74.8	74.8	75.2
Nera 18mg	0	0	0	1	2	2	2	2	2	2	2	3	3	5	5	12	49	68	106	126	149	167	174	186	188	189	190	190
%	0.0	0.0	0.0	0.5	0.9	0.9	0.9	0.9	0.9	0.9	0.9	1.4	1.4	2.3	2.3	5.5	22.3	30.9	48.2	57.3	67.7	75.9	79.1	84.5	85.5	85.9	86.4	86.4

Study: 1305-0023

Figure I.1.2.3.2: 2 Time to first confirmed or suspected acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate - 18mg - FAS (non-AF background)

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Table I.1.2.3.2: 3 Cox model for time to death - treatment policy approach to lung transplant - over the whole trial - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	222	36	16.2	11.54	220	15	6.8	4.71	0.45	(0.24,	0.82)	0.0098	
Age													0.2601
<65 years	83	7	8.4	5.72	88	5	5.7	3.85	0.79	(0.25,	2.50)	0.6883	
>=65 years	139	29	20.9	15.30	132	10	7.6	5.30	0.36	(0.18,	0.75)	0.0061	
Sex													0.9958
Male	116	22	19.0	13.82	111	9	8.1	5.72	0.45	(0.20,	0.99)	0.0477	
Female	106	14	13.2	9.17	109	6	5.5	3.73	0.45	(0.17,	1.17)	0.1014	
Baseline FVC percent predicted													0.1559
<=70%	118	29	24.6	17.82	96	8	8.3	5.77	0.33	(0.15,	0.72)	0.0053	
>70%	104	7	6.7	4.69	124	7	5.6	3.89	0.84	(0.29,	2.41)	0.7482	
Baseline HRCT pattern													0.9912
UIP-like	158	26	16.5	11.87	154	11	7.1	4.95	0.45	(0.22,	0.91)	0.0274	
Other fibrotic patterns	64	10	15.6	10.76	66	4	6.1	4.15	0.45	(0.14,	1.43)	0.1732	
Underlying ILD diagnosis													0.5540
iNSIP	40	4	10.0	6.61	55	5	9.1	6.42	1.16	(0.31,	4.33)	0.8300	
Unclassifiable IIP	36	5	13.9	9.77	40	3	7.5	5.13	0.61	(0.15,	2.59)	0.5061	
HP	39	9	23.1	18.79	30	2	6.7	4.79	0.32	(0.07,	1.51)	0.1501	
Autoimmune ILD	71	10	14.1	9.75	70	4	5.7	3.90	0.35	(0.11,	1.12)	0.0768	
Other ILD	36	8	22.2	16.09	25	1	4.0	2.64	0.20	(0.03,	1.64)	0.1344	
Region													0.3044
Europe	40	6	15.0	10.96	53	6	11.3	8.43	0.84	(0.27,	2.60)	0.7577	
Asia	106	11	10.4	6.86	107	8	7.5	5.02	0.78	(0.31,	1.94)	0.5891	
Canada and USA	30	9	30.0	23.04	17	0	0.0	0.00	0.00	(NC,	NC)	0.9877	
Rest of the World	46	10	21.7	17.34	43	1	2.3	1.60	0.10	(0.01,	0.76)	0.0261	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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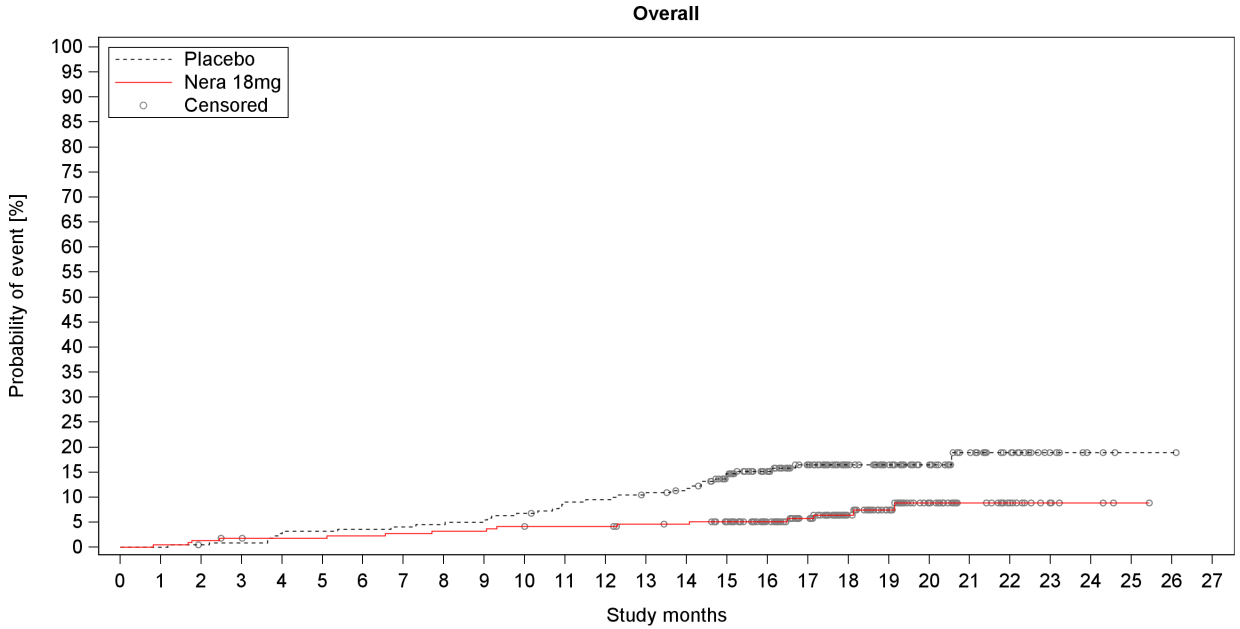

Number at risk (percentage relative to baseline)

Placebo	222	222	220	219	215	214	213	212	211	209	206	200	199	195	192	172	145	120	85	69	47	30	20	7	3	1	1	0
%	100.0	100.0	99.1	98.6	96.8	96.4	95.9	95.5	95.0	94.1	92.8	90.1	89.6	87.8	86.5	77.5	65.3	54.1	38.3	31.1	21.2	13.5	9.0	3.2	1.4	0.5	0.5	0.0
Nera 18mg	220	219	217	215	214	214	213	212	211	211	209	208	208	205	204	194	157	134	93	71	45	26	19	5	3	1	0	0
%	100.0	99.5	98.6	97.7	97.3	97.3	96.8	96.4	95.9	95.9	95.0	94.5	94.5	93.2	92.7	88.2	71.4	60.9	42.3	32.3	20.5	11.8	8.6	2.3	1.4	0.5	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	1	1	1	1	1	1	1	1	1	2	2	3	5	18	44	67	102	118	140	156	166	179	183	185	185	186
%	0.0	0.0	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.9	0.9	1.4	2.3	8.1	19.8	30.2	45.9	53.2	63.1	70.3	74.8	80.6	82.4	83.3	83.3	83.8
Nera 18mg	0	0	0	1	2	2	2	2	2	2	2	3	3	5	6	15	52	74	114	135	160	179	186	200	202	204	205	205
%	0.0	0.0	0.0	0.5	0.9	0.9	0.9	0.9	0.9	0.9	0.9	1.4	1.4	2.3	2.7	6.8	23.6	33.6	51.8	61.4	72.7	81.4	84.5	90.9	91.8	92.7	93.2	93.2

Study: 1305-0023

Figure I.1.2.3.2: 3 Time to death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate - 18mg - FAS (non-AF background)

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Table I.1.2.3.2: 4 Cox model for time to first confirmed acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	222	22	9.9	7.40	220	13	5.9	4.20	0.69	(0.35, 1.39)	0.3037	
Age												0.4652
<65 years	83	6	7.2	5.09	88	5	5.7	3.93	0.99	(0.30, 3.29)	0.9851	
>=65 years	139	16	11.5	8.91	132	8	6.1	4.39	0.57	(0.24, 1.35)	0.1999	
Sex												0.2472
Male	116	14	12.1	9.30	111	5	4.5	3.25	0.45	(0.16, 1.28)	0.1358	
Female	106	8	7.5	5.45	109	8	7.3	5.16	1.05	(0.39, 2.81)	0.9171	
Baseline FVC percent predicted												0.7566
<=70%	118	17	14.4	11.19	96	9	9.4	6.79	0.66	(0.29, 1.47)	0.3073	
>70%	104	5	4.8	3.44	124	4	3.2	2.27	0.85	(0.21, 3.38)	0.8122	
Baseline HRCT pattern												0.1523
UIP-like	158	17	10.8	8.17	154	7	4.5	3.24	0.48	(0.20, 1.17)	0.1075	
Other fibrotic patterns	64	5	7.8	5.59	66	6	9.1	6.45	1.50	(0.42, 5.36)	0.5314	
Underlying ILD diagnosis												
iNSIP	40	4	10.0		55	3	5.5					
Unclassifiable IIP	36	1	2.8		40	4	10.0					
HP	39	7	17.9		30	1	3.3					
Autoimmune ILD	71	6	8.5		70	1	1.4					
Other ILD	36	4	11.1		25	4	16.0					
Region												0.5741
Europe	40	2	5.0	3.81	53	5	9.4	7.30	2.10	(0.41, 10.89)	0.3761	
Asia	106	12	11.3	7.90	107	6	5.6	3.88	0.59	(0.22, 1.57)	0.2900	
Canada and USA	30	3	10.0	7.85	17	0	0.0	0.00	0.00	(NC, NC)	0.9881	
Rest of the World	46	5	10.9	9.11	43	2	4.7	3.30	0.49	(0.09, 2.68)	0.4096	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb). The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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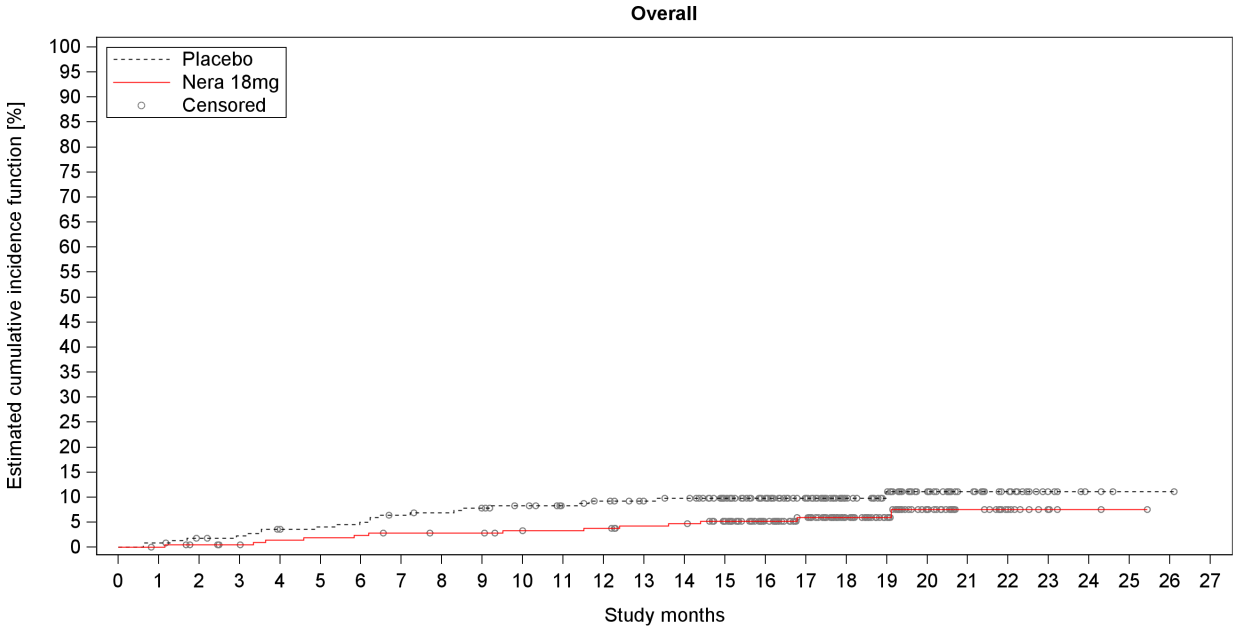

Number at risk (percentage relative to baseline)																											
Placebo	222	220	216	214	210	208	206	202	200	197	193	188	184	179	177	162	136	114	80	64	43	29	20	7	3	1	1	0
%	100.0	99.1	97.3	96.4	94.6	93.7	92.8	91.0	90.1	88.7	86.9	84.7	82.9	80.6	79.7	73.0	61.3	51.4	36.0	28.8	19.4	13.1	9.0	3.2	1.4	0.5	0.5	0.0
Nera 18mg	220	219	216	214	211	210	209	207	206	206	203	202	201	197	196	185	148	126	87	65	41	23	16	4	2	1	0	0
%	100.0	99.5	98.2	97.3	95.9	95.5	95.0	94.1	93.6	93.6	92.3	91.8	91.4	89.5	89.1	84.1	67.3	57.3	39.5	29.5	18.6	10.5	7.3	1.8	0.9	0.5	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																											
Placebo	0	0	2	3	4	5	5	6	7	8	11	16	18	23	24	39	65	87	121	136	157	171	180	193	197	199	199	200
%	0.0	0.0	0.9	1.4	1.8	2.3	2.3	2.7	3.2	3.6	5.0	7.2	8.1	10.4	10.8	17.6	29.3	39.2	54.5	61.3	70.7	77.0	81.1	86.9	88.7	89.6	89.6	90.1
Nera 18mg	0	1	3	5	6	6	6	7	8	8	10	11	11	14	14	24	61	82	121	143	166	184	191	203	205	206	207	207
%	0.0	0.5	1.4	2.3	2.7	2.7	2.7	3.2	3.6	3.6	4.5	5.0	5.0	6.4	6.4	10.9	27.7	37.3	55.0	65.0	75.5	83.6	86.8	92.3	93.2	93.6	94.1	94.1

Study: 1305-0023

Figure I.1.2.3.2: 4 Time to first confirmed acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial, estimated cumulative incidence function - 18mg - FAS (non-AF background)

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Table I.1.2.3.2: 5 Cox model for time to first confirmed or suspected acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	222	33	14.9	11.37	220	18	8.2	5.90	0.60	(0.33, 1.06)	0.0798	
Age												0.3506
<65 years	83	12	14.5	10.56	88	9	10.2	7.23	0.81	(0.34, 1.95)	0.6448	
>=65 years	139	21	15.1	11.89	132	9	6.8	4.98	0.47	(0.21, 1.02)	0.0576	
Sex												0.4170
Male	116	21	18.1	14.29	111	9	8.1	5.96	0.48	(0.22, 1.06)	0.0695	
Female	106	12	11.3	8.38	109	9	8.3	5.84	0.78	(0.33, 1.85)	0.5732	
Baseline FVC percent predicted												0.8411
<=70%	118	23	19.5	15.53	96	12	12.5	9.20	0.62	(0.31, 1.25)	0.1783	
>70%	104	10	9.6	7.04	124	6	4.8	3.44	0.54	(0.19, 1.53)	0.2490	
Baseline HRCT pattern												0.3261
UIP-like	158	23	14.6	11.22	154	10	6.5	4.67	0.48	(0.23, 1.01)	0.0520	
Other fibrotic patterns	64	10	15.6	11.75	66	8	12.1	8.81	0.88	(0.34, 2.28)	0.7856	
Underlying ILD diagnosis												0.1739
iNSIP	40	8	20.0	14.58	55	4	7.3	5.28	0.35	(0.10, 1.17)	0.0883	
Unclassifiable IIP	36	2	5.6	4.01	40	4	10.0	7.24	1.92	(0.35, 10.56)	0.4524	
HP	39	9	23.1	20.78	30	2	6.7	4.90	0.29	(0.06, 1.38)	0.1194	
Autoimmune ILD	71	9	12.7	9.44	70	3	4.3	3.02	0.38	(0.10, 1.40)	0.1453	
Other ILD	36	5	13.9	10.68	25	5	20.0	14.65	1.64	(0.47, 5.70)	0.4345	
Region												0.8806
Europe	40	6	15.0	11.90	53	7	13.2	10.53	0.89	(0.30, 2.64)	0.8300	
Asia	106	14	13.2	9.32	107	7	6.5	4.53	0.57	(0.23, 1.41)	0.2228	
Canada and USA	30	4	13.3	10.71	17	0	0.0	0.00	0.00	(NC, NC)	0.9857	
Rest of the World	46	9	19.6	17.23	43	4	9.3	6.82	0.47	(0.14, 1.55)	0.2139	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb). The subgroup model additionally includes the subgroup and treatment by subgroup interaction. Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined). N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk. NC=not calculable.

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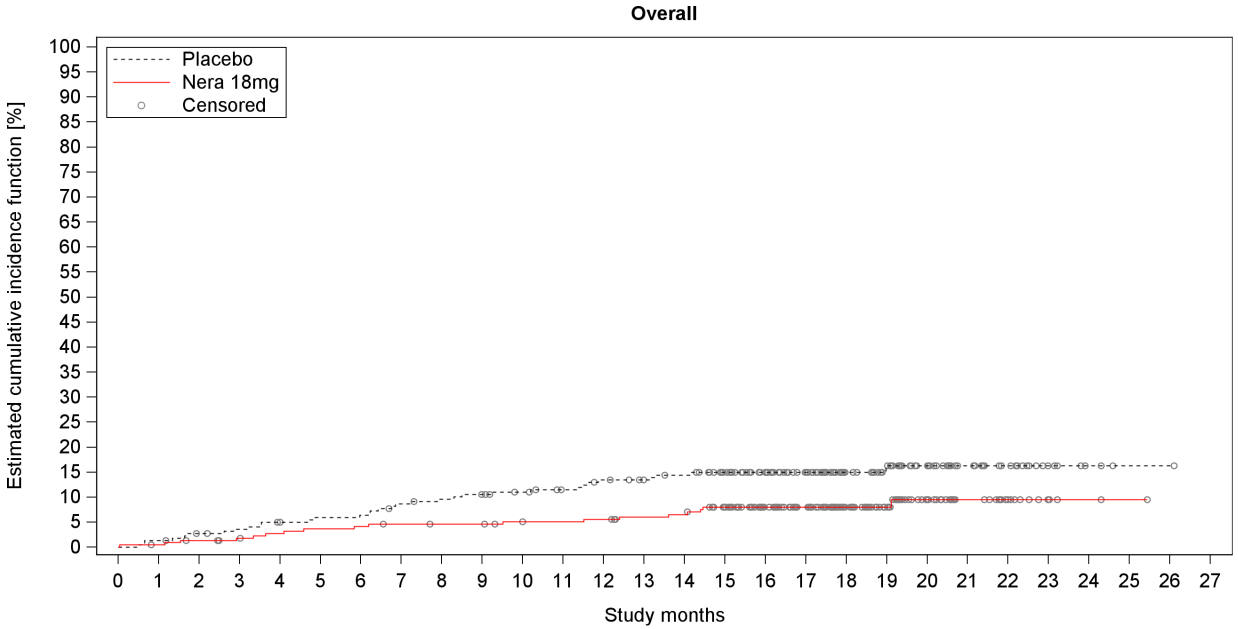

	Number at risk (percentage relative to baseline)																										
Placebo	222	219	214	211	207	204	203	197	194	191	187	182	177	173	170	157	132	110	76	61	42	28	19	7	3	1	1	0
%	100.0	98.6	96.4	95.0	93.2	91.9	91.4	88.7	87.4	86.0	84.2	82.0	79.7	77.9	76.6	70.7	59.5	49.5	34.2	27.5	18.9	12.6	8.6	3.2	1.4	0.5	0.5	0.0
Nera 18mg	220	218	215	212	209	207	206	204	203	203	200	199	198	194	193	181	144	124	86	65	41	23	16	4	2	1	0	0
%	100.0	99.1	97.7	96.4	95.0	94.1	93.6	92.7	92.3	92.3	90.9	90.5	90.0	88.2	87.7	82.3	65.5	56.4	39.1	29.5	18.6	10.5	7.3	1.8	0.9	0.5	0.0	0.0
	Number censored (percentage relative to number at risk at baseline)																										
Placebo	0	0	2	3	4	5	5	6	7	8	11	15	16	20	21	33	58	80	114	128	147	161	170	182	186	188	188	189
%	0.0	0.0	0.9	1.4	1.8	2.3	2.3	2.7	3.2	3.6	5.0	6.8	7.2	9.0	9.5	14.9	26.1	36.0	51.4	57.7	66.2	72.5	76.6	82.0	83.8	84.7	84.7	85.1
Nera 18mg	0	1	2	4	5	5	5	6	7	7	9	10	10	13	13	22	59	79	117	138	161	179	186	198	200	201	202	202
%	0.0	0.5	0.9	1.8	2.3	2.3	2.3	2.7	3.2	3.2	4.1	4.5	4.5	5.9	5.9	10.0	26.8	35.9	53.2	62.7	73.2	81.4	84.5	90.0	90.9	91.4	91.8	91.8

Study: 1305-0023

Figure I.1.2.3.2: 5 Time to first confirmed or suspected acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial, estimated cumulative incidence function - 18mg - FAS (non-AF background)

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BI Trial No.: x1305p3.hta

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I.2 Nerandomilast PPF HTA Analysis: DBL1 Analysis

I.2.1 Population with Nintedanib background

I.2.1.1 Efficacy Analysis

I.2.1.1.1 Time to event analyses

I.2.1.1.1.1 Analyses of composite endpoints

I.2.1.1.1.1.1 Time to first confirmed or suspected acute ILD exacerbation, respiratory hospitalisation or death

Table I.2.1.1.1.1.1: 1 Cox model for time to first confirmed or suspected acute ILD exacerbation, respiratory hospitalisation or death over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo e/	Placebo h/	Placebo d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg e/	Nera 18mg h/	Nera 18mg d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	50	17/	28/	5)	29.6	28.05	170	44	11/	32/	1)	25.9	25.40	0.83	(0.55,	1.25)	0.3677	
Age																			0.8926
<65 years	65	14	3/	9/	2)	21.5	19.23	64	12	5/	7/	0)	18.8	18.53	0.87	(0.39,	1.92)	0.7240	
>=65 years	104	36	14/	19/	3)	34.6	34.14	106	32	6/	25/	1)	30.2	29.49	0.81	(0.50,	1.31)	0.3975	
Sex																			0.4141
Male	114	40	14/	21/	5)	35.1	33.66	108	31	8/	22/	1)	28.7	28.66	0.76	(0.47,	1.22)	0.2552	
Female	55	10	3/	7/	0)	18.2	16.83	62	13	3/	10/	0)	21.0	19.97	1.13	(0.49,	2.59)	0.7726	
Baseline FVC percent predicted																			0.3968
<=70%	95	31	13/	17/	1)	32.6	32.29	97	26	9/	17/	0)	26.8	26.86	0.72	(0.43,	1.23)	0.2289	
>70%	74	19	4/	11/	4)	25.7	23.10	73	18	2/	15/	1)	24.7	23.54	1.04	(0.54,	1.99)	0.9094	
Baseline HRCT pattern																			0.4417
UIP-like	116	33	12/	19/	2)	28.4	26.85	121	35	9/	25/	1)	28.9	28.31	0.92	(0.57,	1.48)	0.7183	
Other fibrotic patterns	53	17	5/	9/	3)	32.1	30.70	49	9	2/	7/	0)	18.4	18.13	0.63	(0.28,	1.42)	0.2665	
Underlying ILD diagnosis																			0.7318
iNSIP	32	8	1/	7/	0)	25.0	24.80	27	9	4/	5/	0)	33.3	36.01	1.16	(0.44,	3.05)	0.7665	
Unclassifiable IIP	46	20	8/	9/	3)	43.5	41.47	32	7	2/	5/	0)	21.9	20.00	0.53	(0.22,	1.27)	0.1564	
HP	38	7	2/	4/	1)	18.4	16.75	43	10	0/	9/	1)	23.3	24.28	1.22	(0.46,	3.22)	0.6952	
Autoimmune ILD	29	7	3/	4/	0)	24.1	22.74	43	12	4/	8/	0)	27.9	26.98	0.80	(0.31,	2.10)	0.6544	
Other ILD	24	8	3/	4/	1)	33.3	31.75	25	6	1/	5/	0)	24.0	21.73	0.87	(0.30,	2.53)	0.7911	
Region																			0.9668
Europe	78	21	6/	13/	2)	26.9	25.38	67	15	3/	12/	0)	22.4	22.60	0.79	(0.41,	1.55)	0.4994	
Asia	45	15	6/	7/	2)	33.3	30.82	41	14	5/	9/	0)	34.1	33.02	0.83	(0.40,	1.72)	0.6098	
Canada and USA	30	9	4/	5/	0)	30.0	28.33	37	8	3/	5/	0)	21.6	19.73	0.70	(0.26,	1.89)	0.4843	
Rest of the World	16	5	1/	3/	1)	31.3	33.16	25	7	0/	6/	1)	28.0	29.23	1.04	(0.33,	3.31)	0.9481	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb). The subgroup model additionally includes the subgroup and treatment by subgroup interaction. Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined). N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk. e:Number of confirmed or suspected acute ILD exacerbations, h:Number of hospitalizations for respiratory cause, d:Number of deaths, NC:Not calculable If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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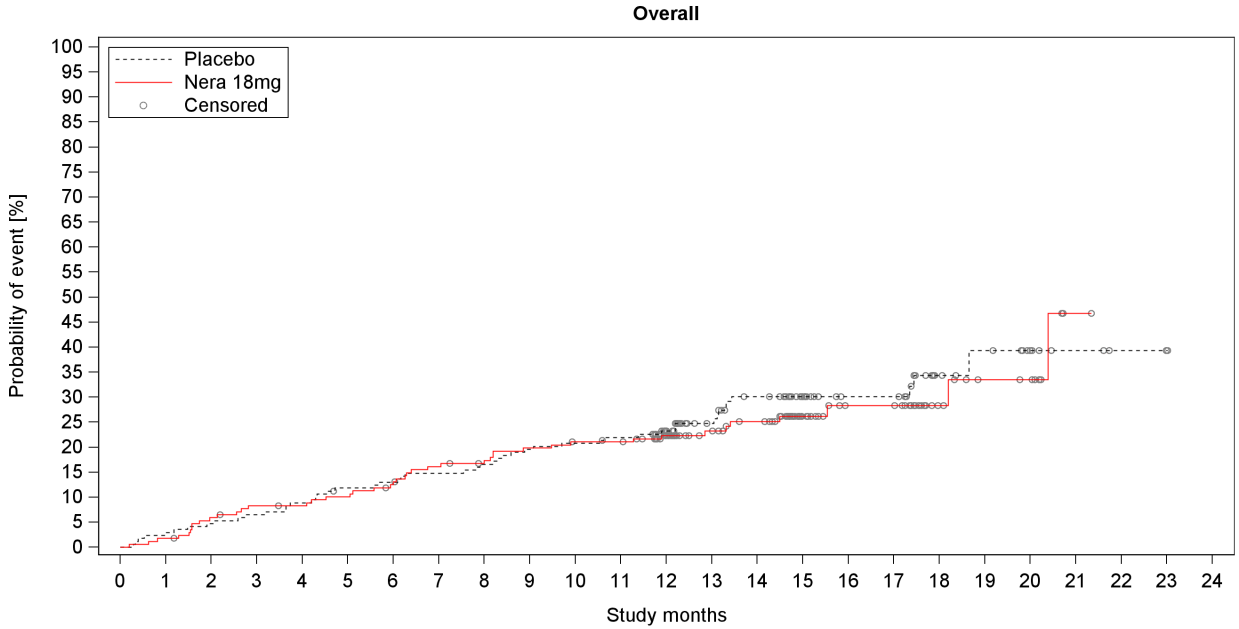

Number at risk (percentage relative to baseline)

Placebo	169	164	161	158	154	148	146	143	140	135	133	130	106	86	76	47	38	38	15	12	8	4	2	1	0
%	100.0	97.0	95.3	93.5	91.1	87.6	86.4	84.6	82.8	79.9	78.7	76.9	62.7	50.9	45.0	27.8	22.5	22.5	8.9	7.1	4.7	2.4	1.2	0.6	0.0
Nera 18mg	170	167	159	154	153	150	145	138	135	130	127	127	108	85	78	42	30	30	15	10	9	1	0	0	0
%	100.0	98.2	93.5	90.6	90.0	88.2	85.3	81.2	79.4	76.5	74.7	74.7	63.5	50.0	45.9	24.7	17.6	17.6	8.8	5.9	5.3	0.6	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	1	1	1	1	1	1	2	24	42	46	75	84	84	105	107	111	115	117	118	119
%	0.0	0.0	0.0	0.0	0.0	0.6	0.6	0.6	0.6	0.6	0.6	1.2	14.2	24.9	27.2	44.4	49.7	49.7	62.1	63.3	65.7	68.0	69.2	69.8	70.4
Nera 18mg	0	0	1	2	3	3	4	5	7	7	8	8	25	47	52	87	98	98	113	117	118	125	126	126	126
%	0.0	0.0	0.6	1.2	1.8	1.8	2.4	2.9	4.1	4.1	4.7	4.7	14.7	27.6	30.6	51.2	57.6	57.6	66.5	68.8	69.4	73.5	74.1	74.1	74.1

Study: 1305-0023

Figure I.2.1.1.1.1: 1 Time to first confirmed or suspected acute ILD exacerbation, respiratory hospitalisation or death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (NIN background)

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Figure I.2.1.1.1.1: 1

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I.2.1.1.1.1.2 Time to first confirmed acute ILD exacerbation or death

Table I.2.1.1.1.1.2: 1 Cox model for time to first confirmed acute ILD exacerbation or death over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n (e/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (e/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	31 (17/ 14)	18.3	15.96	170	18 (10/ 8)	10.6	9.32	0.52	(0.29, 0.93)	0.0266	
Age												0.8288
<65 years	65	7 (4/ 3)	10.8	9.00	64	3 (3/ 0)	4.7	4.24	0.45	(0.11, 1.74)	0.2449	
>=65 years	104	24 (13/ 11)	23.1	20.59	106	15 (7/ 8)	14.2	12.26	0.53	(0.27, 1.01)	0.0538	
Sex												0.5277
Male	114	26 (14/ 12)	22.8	20.11	108	13 (8/ 5)	12.0	10.88	0.48	(0.25, 0.94)	0.0319	
Female	55	5 (3/ 2)	9.1	7.70	62	5 (2/ 3)	8.1	6.79	0.76	(0.22, 2.63)	0.6603	
Baseline FVC percent predicted												0.2163
<=70%	95	19 (12/ 7)	20.0	17.93	97	8 (7/ 1)	8.2	7.30	0.37	(0.16, 0.86)	0.0199	
>70%	74	12 (5/ 7)	16.2	13.59	73	10 (3/ 7)	13.7	11.97	0.79	(0.34, 1.85)	0.5870	
Baseline HRCT pattern												0.0890
UIP-like	116	20 (12/ 8)	17.2	14.98	121	17 (10/ 7)	14.0	12.22	0.70	(0.36, 1.34)	0.2767	
Other fibrotic patterns	53	11 (5/ 6)	20.8	18.11	49	1 (0/ 1)	2.0	1.85	0.11	(0.01, 0.83)	0.0329	
Underlying ILD diagnosis												0.2663
iNSIP	32	3 (0/ 3)	9.4	8.05	27	6 (4/ 2)	22.2	22.04	2.30	(0.57, 9.31)	0.2443	
Unclassifiable IIP	46	13 (8/ 5)	28.3	25.95	32	4 (2/ 2)	12.5	10.52	0.40	(0.13, 1.23)	0.1086	
HP	38	5 (3/ 2)	13.2	11.12	43	3 (1/ 2)	7.0	6.31	0.39	(0.09, 1.65)	0.1986	
Autoimmune ILD	29	5 (3/ 2)	17.2	14.72	43	4 (2/ 2)	9.3	7.97	0.42	(0.11, 1.57)	0.1959	
Other ILD	24	5 (3/ 2)	20.8	17.85	25	1 (1/ 0)	4.0	3.31	0.25	(0.03, 2.13)	0.2022	
Region												0.7245
Europe	78	13 (7/ 6)	16.7	14.39	67	4 (2/ 2)	6.0	5.38	0.30	(0.10, 0.93)	0.0373	
Asia	45	10 (7/ 3)	22.2	18.82	41	7 (5/ 2)	17.1	14.42	0.58	(0.22, 1.54)	0.2755	
Canada and USA	30	5 (2/ 3)	16.7	14.43	37	4 (3/ 1)	10.8	9.46	0.74	(0.20, 2.78)	0.6558	
Rest of the World	16	3 (1/ 2)	18.8	18.58	25	3 (0/ 3)	12.0	10.70	0.66	(0.13, 3.36)	0.6211	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed acute ILD exacerbations, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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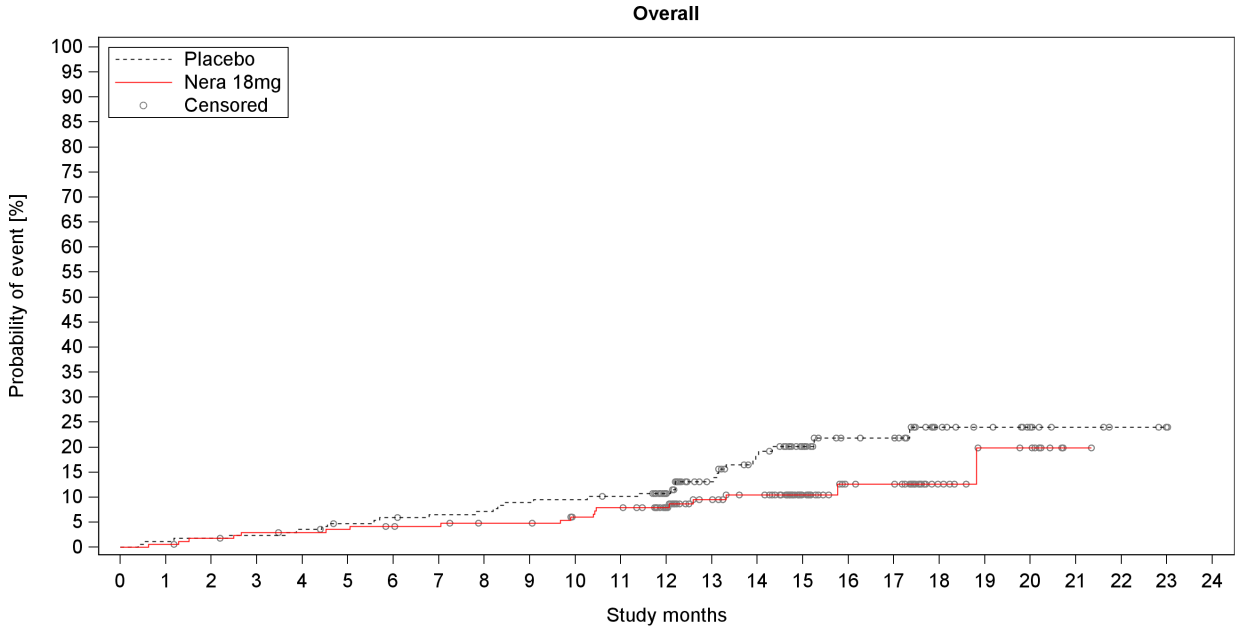

Number at risk (percentage relative to baseline)

Placebo	169	167	166	165	163	159	157	155	154	151	150	148	124	101	90	54	43	42	17	13	9	5	3	1	0
%	100.0	98.8	98.2	97.6	96.4	94.1	92.9	91.7	91.1	89.3	88.8	87.6	73.4	59.8	53.3	32.0	25.4	24.9	10.1	7.7	5.3	3.0	1.8	0.6	0.0
Nera 18mg	170	169	166	163	162	161	159	158	155	155	150	147	129	99	93	52	38	37	17	10	9	1	0	0	0
%	100.0	99.4	97.6	95.9	95.3	94.7	93.5	92.9	91.2	91.2	88.2	86.5	75.9	58.2	54.7	30.6	22.4	21.8	10.0	5.9	5.3	0.6	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	2	2	3	3	3	3	4	27	47	52	86	96	97	121	125	129	133	135	137	138
%	0.0	0.0	0.0	0.0	0.0	1.2	1.2	1.8	1.8	1.8	1.8	2.4	16.0	27.8	30.8	50.9	56.8	57.4	71.6	74.0	76.3	78.7	79.9	81.1	81.7
Nera 18mg	0	0	1	2	3	3	4	5	7	7	10	10	28	56	61	102	115	116	136	142	143	151	152	152	152
%	0.0	0.0	0.6	1.2	1.8	1.8	2.4	2.9	4.1	4.1	5.9	5.9	16.5	32.9	35.9	60.0	67.6	68.2	80.0	83.5	84.1	88.8	89.4	89.4	89.4

Study: 1305-0023

Figure I.2.1.1.1.2: 1 Time to first confirmed acute ILD exacerbation or death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (NIN background)

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Figure I.2.1.1.1.2: 1

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I.2.1.1.1.1.3 Time to first confirmed or suspected acute ILD exacerbation or death

Table I.2.1.1.1.1.3: 1 Cox model for time to first confirmed or suspected acute ILD exacerbation or death over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n (e/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (e/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	35 (22/ 13)	20.7	18.29	170	21 (13/ 8)	12.4	10.93	0.53	(0.31, 0.92)	0.0230	
Age												0.6552
<65 years	65	8 (5/ 3)	12.3	10.32	64	5 (5/ 0)	7.8	7.17	0.66	(0.22, 2.04)	0.4718	
>=65 years	104	27 (17/ 10)	26.0	23.72	106	16 (8/ 8)	15.1	13.08	0.49	(0.26, 0.92)	0.0268	
Sex												0.4162
Male	114	28 (17/ 11)	24.6	21.98	108	14 (9/ 5)	13.0	11.71	0.47	(0.25, 0.90)	0.0219	
Female	55	7 (5/ 2)	12.7	10.94	62	7 (4/ 3)	11.3	9.64	0.78	(0.27, 2.25)	0.6494	
Baseline FVC percent predicted												0.3185
<=70%	95	22 (16/ 6)	23.2	21.03	97	11 (10/ 1)	11.3	10.13	0.43	(0.21, 0.88)	0.0217	
>70%	74	13 (6/ 7)	17.6	14.98	73	10 (3/ 7)	13.7	11.97	0.75	(0.32, 1.73)	0.4979	
Baseline HRCT pattern												0.2064
UIP-like	116	22 (15/ 7)	19.0	16.72	121	18 (11/ 7)	14.9	12.98	0.66	(0.35, 1.24)	0.1944	
Other fibrotic patterns	53	13 (7/ 6)	24.5	21.75	49	3 (2/ 1)	6.1	5.61	0.27	(0.08, 0.93)	0.0388	
Underlying ILD diagnosis												0.2758
iNSIP	32	4 (2/ 2)	12.5	11.21	27	7 (5/ 2)	25.9	25.71	1.83	(0.53, 6.38)	0.3408	
Unclassifiable IIP	46	13 (8/ 5)	28.3	25.95	32	4 (2/ 2)	12.5	10.52	0.41	(0.13, 1.27)	0.1239	
HP	38	6 (4/ 2)	15.8	13.41	43	3 (1/ 2)	7.0	6.31	0.34	(0.08, 1.37)	0.1290	
Autoimmune ILD	29	6 (4/ 2)	20.7	18.08	43	6 (4/ 2)	14.0	12.21	0.50	(0.16, 1.58)	0.2390	
Other ILD	24	6 (4/ 2)	25.0	21.70	25	1 (1/ 0)	4.0	3.31	0.20	(0.02, 1.68)	0.1385	
Region												0.7957
Europe	78	15 (10/ 5)	19.2	16.79	67	5 (3/ 2)	7.5	6.77	0.34	(0.12, 0.94)	0.0382	
Asia	45	10 (7/ 3)	22.2	18.82	41	8 (6/ 2)	19.5	16.69	0.65	(0.25, 1.65)	0.3636	
Canada and USA	30	7 (4/ 3)	23.3	21.38	37	5 (4/ 1)	13.5	11.83	0.62	(0.19, 1.96)	0.4153	
Rest of the World	16	3 (1/ 2)	18.8	18.58	25	3 (0/ 3)	12.0	10.70	0.63	(0.12, 3.17)	0.5737	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed or suspected acute ILD exacerbations, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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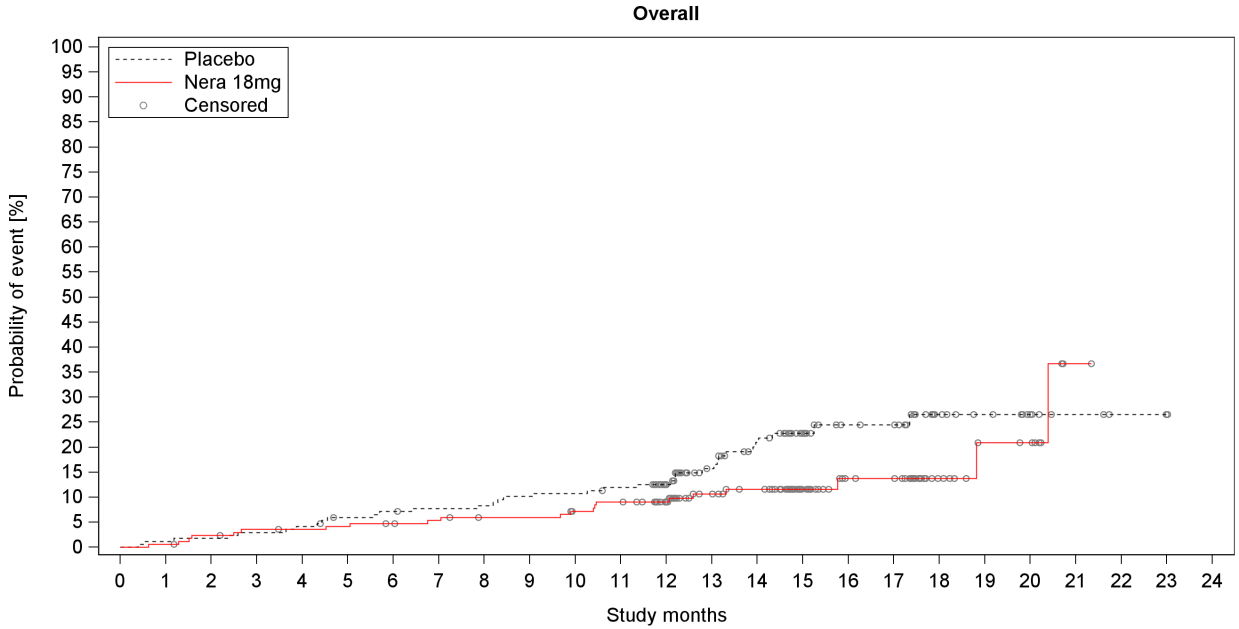

	Number at risk (percentage relative to baseline)																								
Placebo	169	167	166	164	162	157	155	153	152	149	148	145	122	98	87	52	42	41	16	12	8	4	2	1	0
%	100.0	98.8	98.2	97.0	95.9	92.9	91.7	90.5	89.9	88.2	87.6	85.8	72.2	58.0	51.5	30.8	24.9	24.3	9.5	7.1	4.7	2.4	1.2	0.6	0.0
Nera 18mg	170	169	165	162	161	160	158	156	153	153	149	146	129	99	93	52	38	37	17	10	9	1	0	0	0
%	100.0	99.4	97.1	95.3	94.7	94.1	92.9	91.8	90.0	90.0	87.6	85.9	75.9	58.2	54.7	30.6	22.4	21.8	10.0	5.9	5.3	0.6	0.0	0.0	0.0
	Number censored (percentage relative to number at risk at baseline)																								
Placebo	0	0	0	0	0	2	2	3	3	3	3	4	26	46	51	84	93	94	118	122	126	130	132	133	134
%	0.0	0.0	0.0	0.0	0.0	1.2	1.2	1.8	1.8	1.8	1.8	2.4	15.4	27.2	30.2	49.7	55.0	55.6	69.8	72.2	74.6	76.9	78.1	78.7	79.3
Nera 18mg	0	0	1	2	3	3	4	5	7	7	9	9	26	54	59	100	113	114	134	140	141	148	149	149	149
%	0.0	0.0	0.6	1.2	1.8	1.8	2.4	2.9	4.1	4.1	5.3	5.3	15.3	31.8	34.7	58.8	66.5	67.1	78.8	82.4	82.9	87.1	87.6	87.6	87.6

Study: 1305-0023

Figure I.2.1.1.1.3: 1 Time to first confirmed or suspected acute ILD exacerbation or death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (NIN background)

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Figure I.2.1.1.1.3: 1

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I.2.1.1.1.1.4 Time to first respiratory hospitalisation or death

Table I.2.1.1.1.1.4: 1 Cox model for time to first respiratory hospitalisation or death over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n (h/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (h/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio (95% CI)	p-value	Interaction p-value
Overall	169	45 (40/ 5)	26.6	24.63	170	40 (39/ 1)	23.5	22.79	0.84 (0.55, 1.29)	0.4281	
Age											0.7960
<65 years	65	13 (11/ 2)	20.0	17.77	64	10 (10/ 0)	15.6	15.19	0.76 (0.32, 1.79)	0.5331	
>=65 years	104	32 (29/ 3)	30.8	29.22	106	30 (29/ 1)	28.3	27.36	0.87 (0.53, 1.43)	0.5810	
Sex											0.5514
Male	114	36 (31/ 5)	31.6	29.40	108	29 (28/ 1)	26.9	26.52	0.79 (0.48, 1.30)	0.3522	
Female	55	9 (9/ 0)	16.4	14.94	62	11 (11/ 0)	17.7	16.63	1.08 (0.44, 2.61)	0.8716	
Baseline FVC percent predicted											0.3191
<=70%	95	27 (26/ 1)	28.4	27.31	97	22 (22/ 0)	22.7	22.22	0.71 (0.40, 1.25)	0.2316	
>70%	74	18 (14/ 4)	24.3	21.47	73	18 (17/ 1)	24.7	23.53	1.10 (0.57, 2.13)	0.7783	
Baseline HRCT pattern											0.2701
UIP-like	116	29 (27/ 2)	25.0	22.93	121	33 (32/ 1)	27.3	26.35	0.97 (0.59, 1.62)	0.9204	
Other fibrotic patterns	53	16 (13/ 3)	30.2	28.46	49	7 (7/ 0)	14.3	13.93	0.55 (0.22, 1.33)	0.1844	
Underlying ILD diagnosis											0.7413
iNSIP	32	7 (7/ 0)	21.9	20.71	27	7 (7/ 0)	25.9	26.79	0.97 (0.34, 2.80)	0.9584	
Unclassifiable IIP	46	19 (16/ 3)	41.3	38.31	32	7 (7/ 0)	21.9	19.99	0.57 (0.24, 1.35)	0.2010	
HP	38	6 (5/ 1)	15.8	14.23	43	10 (9/ 1)	23.3	24.28	1.40 (0.50, 3.89)	0.5188	
Autoimmune ILD	29	6 (6/ 0)	20.7	19.00	43	10 (10/ 0)	23.3	21.94	0.80 (0.28, 2.28)	0.6803	
Other ILD	24	7 (6/ 1)	29.2	27.39	25	6 (6/ 0)	24.0	21.73	1.06 (0.35, 3.21)	0.9138	
Region											0.9751
Europe	78	19 (17/ 2)	24.4	22.65	67	14 (14/ 0)	20.9	20.94	0.83 (0.42, 1.68)	0.6111	
Asia	45	15 (13/ 2)	33.3	30.79	41	13 (13/ 0)	31.7	30.17	0.76 (0.36, 1.61)	0.4797	
Canada and USA	30	6 (6/ 0)	20.0	17.14	37	6 (6/ 0)	16.2	14.42	0.77 (0.23, 2.53)	0.6643	
Rest of the World	16	5 (4/ 1)	31.3	33.14	25	7 (6/ 1)	28.0	29.23	1.05 (0.33, 3.34)	0.9402	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
h:Number of hospitalizations for respiratory cause, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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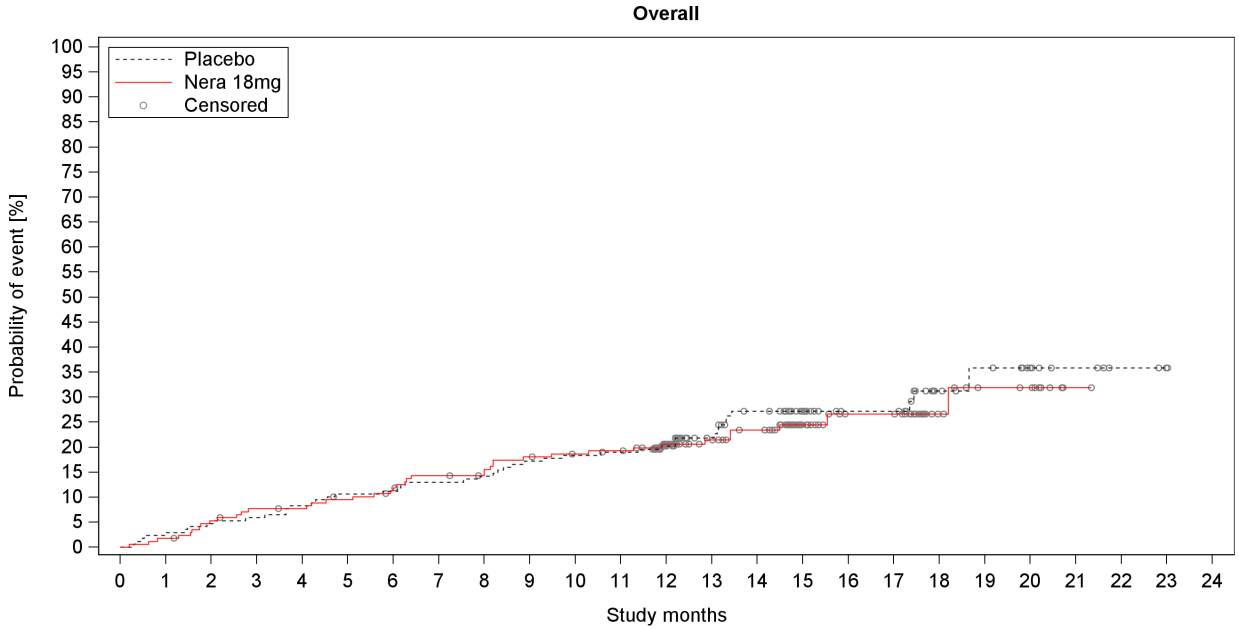

Number at risk (percentage relative to baseline)

Placebo	169	164	161	159	155	150	149	146	144	139	137	135	110	89	79	49	40	40	17	14	10	6	3	1	0
%	100.0	97.0	95.3	94.1	91.7	88.8	88.2	86.4	85.2	82.2	81.1	79.9	65.1	52.7	46.7	29.0	23.7	23.7	10.1	8.3	5.9	3.6	1.8	0.6	0.0
Nera 18mg	170	167	160	155	154	151	147	141	139	133	130	129	109	86	79	43	31	31	15	10	9	1	0	0	0
%	100.0	98.2	94.1	91.2	90.6	88.8	86.5	82.9	81.8	78.2	76.5	75.9	64.1	50.6	46.5	25.3	18.2	18.2	8.8	5.9	5.3	0.6	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	1	1	1	1	1	1	2	25	44	48	78	87	87	108	110	114	118	121	123	124
%	0.0	0.0	0.0	0.0	0.0	0.6	0.6	0.6	0.6	0.6	0.6	1.2	14.8	26.0	28.4	46.2	51.5	51.5	63.9	65.1	67.5	69.8	71.6	72.8	73.4
Nera 18mg	0	0	1	2	3	3	4	5	7	7	9	9	27	49	54	89	100	100	116	120	121	129	130	130	130
%	0.0	0.0	0.6	1.2	1.8	1.8	2.4	2.9	4.1	4.1	5.3	5.3	15.9	28.8	31.8	52.4	58.8	58.8	68.2	70.6	71.2	75.9	76.5	76.5	76.5

Study: 1305-0023

Figure I.2.1.1.1.4: 1 Time to first respiratory hospitalisation or death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (NIN background)

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Figure I.2.1.1.1.4: 1

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I.2.1.1.1.1.5 Time to first non-elective hospitalisation for any cause or death

Table I.2.1.1.1.1.5: 1 Cox model for time to first non-elective hospitalisation for any cause or death over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n (h/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (h/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	55 (50/ 5)	32.5	31.19	170	58 (57/ 1)	34.1	35.37	1.05	(0.72, 1.53)	0.7934	
Age												0.9382
<65 years	65	16 (14/ 2)	24.6	22.17	64	16 (16/ 0)	25.0	25.49	1.07	(0.53, 2.16)	0.8594	
>=65 years	104	39 (36/ 3)	37.5	37.44	106	42 (41/ 1)	39.6	41.49	1.03	(0.66, 1.60)	0.8900	
Sex												0.2763
Male	114	43 (38/ 5)	37.7	36.73	108	40 (39/ 1)	37.0	38.52	0.93	(0.60, 1.44)	0.7519	
Female	55	12 (12/ 0)	21.8	20.25	62	18 (18/ 0)	29.0	29.92	1.50	(0.72, 3.13)	0.2822	
Baseline FVC percent predicted												0.0397
<=70%	95	35 (34/ 1)	36.8	37.32	97	31 (31/ 0)	32.0	32.75	0.76	(0.46, 1.24)	0.2649	
>70%	74	20 (16/ 4)	27.0	24.23	73	27 (26/ 1)	37.0	38.94	1.69	(0.94, 3.02)	0.0795	
Baseline HRCT pattern												0.6920
UIP-like	116	37 (35/ 2)	31.9	30.53	121	45 (44/ 1)	37.2	38.75	1.10	(0.71, 1.71)	0.6661	
Other fibrotic patterns	53	18 (15/ 3)	34.0	32.65	49	13 (13/ 0)	26.5	27.16	0.93	(0.45, 1.90)	0.8415	
Underlying ILD diagnosis												0.3794
iNSIP	32	8 (8/ 0)	25.0	24.58	27	10 (10/ 0)	37.0	41.77	1.35	(0.53, 3.45)	0.5364	
Unclassifiable IIP	46	23 (20/ 3)	50.0	49.46	32	10 (10/ 0)	31.3	29.02	0.61	(0.29, 1.30)	0.2002	
HP	38	7 (6/ 1)	18.4	16.95	43	12 (11/ 1)	27.9	29.48	1.54	(0.60, 3.92)	0.3709	
Autoimmune ILD	29	9 (9/ 0)	31.0	29.41	43	15 (15/ 0)	34.9	36.35	0.98	(0.42, 2.28)	0.9610	
Other ILD	24	8 (7/ 1)	33.3	31.52	25	11 (11/ 0)	44.0	46.57	1.79	(0.71, 4.53)	0.2159	
Region												0.9723
Europe	78	23 (21/ 2)	29.5	28.25	67	20 (20/ 0)	29.9	31.47	1.07	(0.58, 1.96)	0.8345	
Asia	45	21 (19/ 2)	46.7	45.87	41	21 (21/ 0)	51.2	55.80	0.94	(0.51, 1.74)	0.8531	
Canada and USA	30	6 (6/ 0)	20.0	17.62	37	9 (9/ 0)	24.3	23.16	1.20	(0.41, 3.46)	0.7408	
Rest of the World	16	5 (4/ 1)	31.3	33.14	25	8 (7/ 1)	32.0	33.40	1.20	(0.39, 3.71)	0.7491	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
h:Number of non-elective hospitalizations for any cause, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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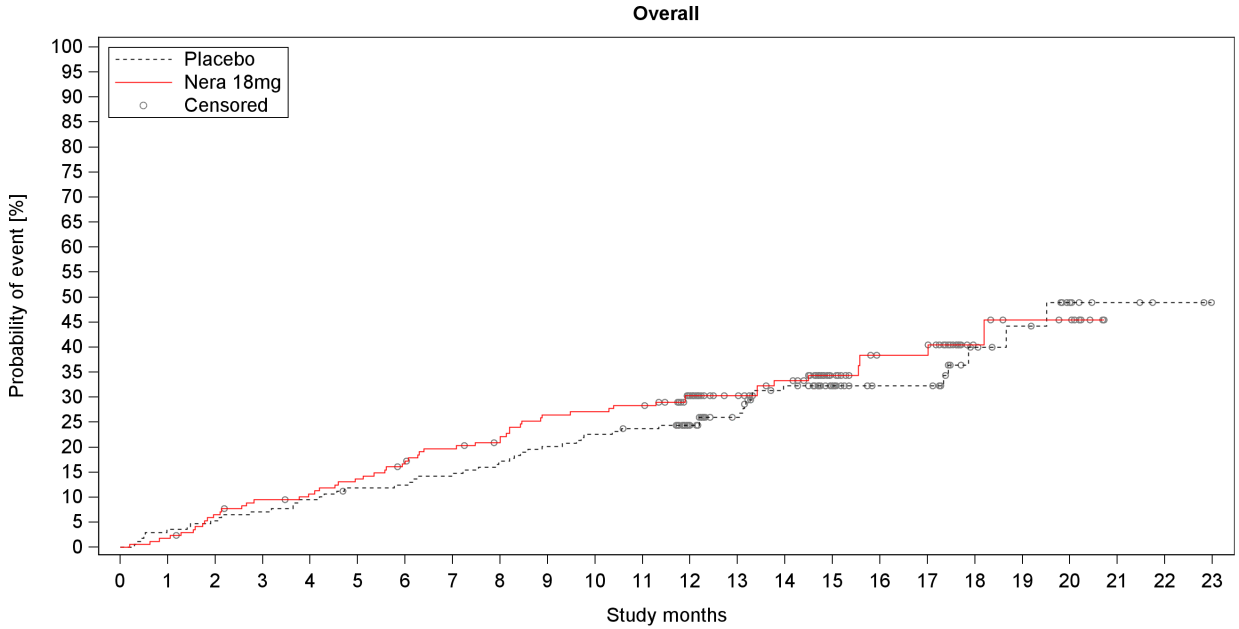

Number at risk (percentage relative to baseline)

Placebo	169	163	160	157	153	148	147	143	139	134	130	127	103	84	73	45	36	36	16	13	8	4	2	0
%	100.0	96.4	94.7	92.9	90.5	87.6	87.0	84.6	82.2	79.3	76.9	75.1	60.9	49.7	43.2	26.6	21.3	21.3	9.5	7.7	4.7	2.4	1.2	0.0
Nera 18mg	170	167	158	152	149	144	138	132	128	119	118	116	95	74	66	39	29	29	12	9	8	0	0	0
%	100.0	98.2	92.9	89.4	87.6	84.7	81.2	77.6	75.3	70.0	69.4	68.2	55.9	43.5	38.8	22.9	17.1	17.1	7.1	5.3	4.7	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	1	1	1	1	1	1	2	25	42	46	74	83	83	100	102	106	110	112	114
%	0.0	0.0	0.0	0.0	0.0	0.6	0.6	0.6	0.6	0.6	0.6	1.2	14.8	24.9	27.2	43.8	49.1	49.1	59.2	60.4	62.7	65.1	66.3	67.5
Nera 18mg	0	0	1	2	3	3	4	5	7	7	7	7	25	46	51	77	85	85	101	103	104	112	112	112
%	0.0	0.0	0.6	1.2	1.8	1.8	2.4	2.9	4.1	4.1	4.1	4.1	14.7	27.1	30.0	45.3	50.0	50.0	59.4	60.6	61.2	65.9	65.9	65.9

Study: 1305-0023

Figure I.2.1.1.1.5: 1 Time to first non-elective hospitalisation for any cause or death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (NIN background)

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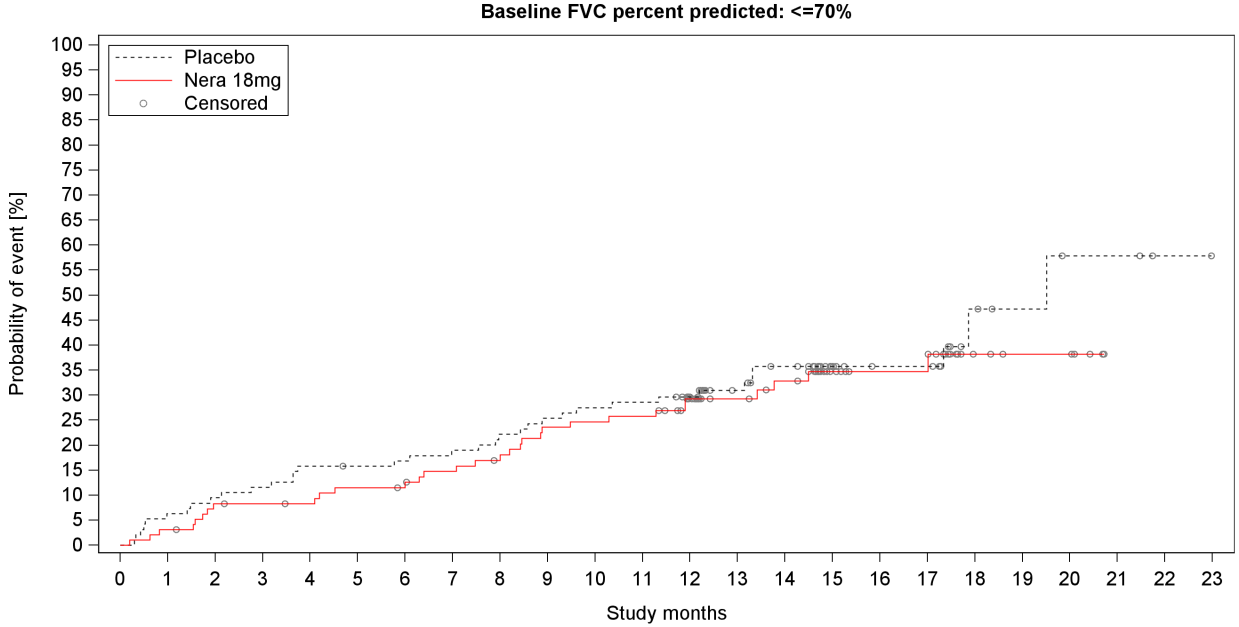

Number at risk (percentage relative to baseline)

Placebo	95	89	86	84	80	79	78	76	73	70	68	67	57	45	39	23	19	19	7	5	3	3	1	0
%	100.0	93.7	90.5	88.4	84.2	83.2	82.1	80.0	76.8	73.7	71.6	70.5	60.0	47.4	41.1	24.2	20.0	20.0	7.4	5.3	3.2	3.2	1.1	0.0
Nera 18mg	97	94	88	87	86	83	82	78	75	69	68	67	55	41	37	23	19	19	7	5	5	0	0	0
%	100.0	96.9	90.7	89.7	88.7	85.6	84.5	80.4	77.3	71.1	70.1	69.1	56.7	42.3	38.1	23.7	19.6	19.6	7.2	5.2	5.2	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	1	1	1	1	1	1	1	10	21	24	40	44	44	54	56	57	57	59	60
%	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	1.1	1.1	1.1	1.1	10.5	22.1	25.3	42.1	46.3	46.3	56.8	58.9	60.0	60.0	62.1	63.2
Nera 18mg	0	0	1	2	3	3	4	5	6	6	6	6	15	29	31	44	48	48	59	61	61	66	66	66
%	0.0	0.0	1.0	2.1	3.1	3.1	4.1	5.2	6.2	6.2	6.2	6.2	15.5	29.9	32.0	45.4	49.5	49.5	60.8	62.9	62.9	68.0	68.0	68.0

Study: 1305-0023

Figure I.2.1.1.1.5: 1 Time to first non-elective hospitalisation for any cause or death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (NIN background)

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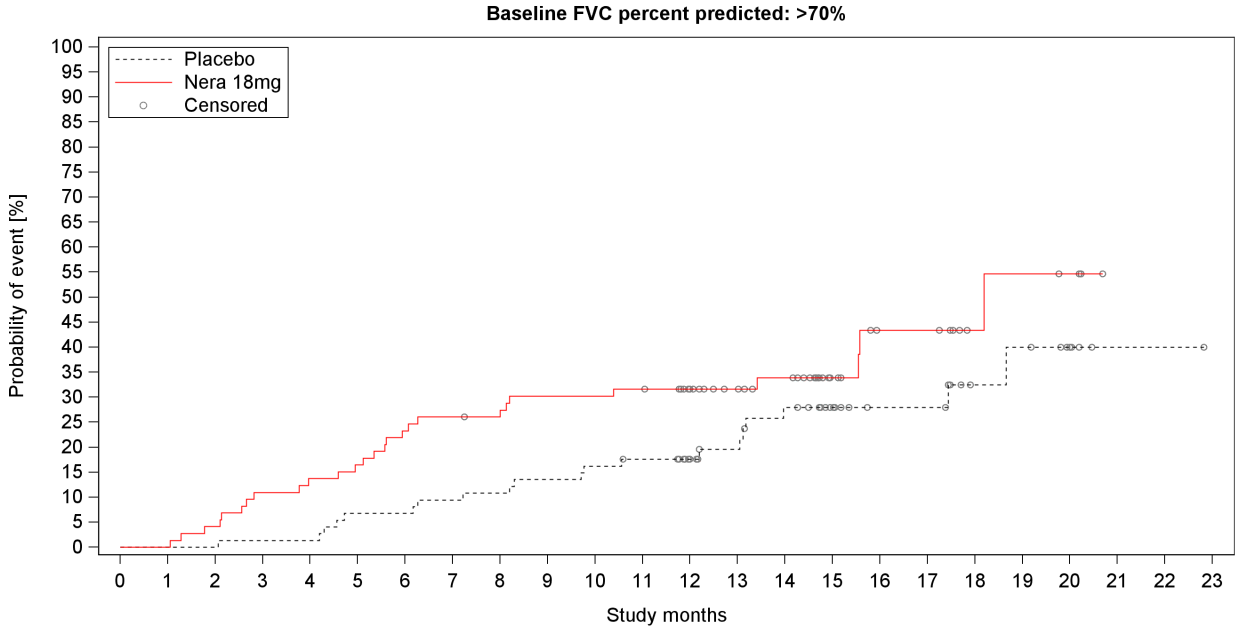

Number at risk (percentage relative to baseline)

Placebo	74	74	74	73	73	69	69	67	66	64	62	60	46	39	34	22	17	17	9	8	5	1	1	0
%	100.0	100.0	100.0	98.6	98.6	93.2	93.2	90.5	89.2	86.5	83.8	81.1	62.2	52.7	45.9	29.7	23.0	23.0	12.2	10.8	6.8	1.4	1.4	0.0
Nera 18mg	73	73	70	65	63	61	56	54	53	50	50	49	40	33	29	16	10	10	5	4	3	0	0	0
%	100.0	100.0	95.9	89.0	86.3	83.6	76.7	74.0	72.6	68.5	68.5	67.1	54.8	45.2	39.7	21.9	13.7	13.7	6.8	5.5	4.1	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	0	0	0	0	0	0	1	15	21	22	34	39	39	46	46	49	53	53	54
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.4	20.3	28.4	29.7	45.9	52.7	52.7	62.2	62.2	66.2	71.6	71.6	73.0
Nera 18mg	0	0	0	0	0	0	0	0	1	1	1	1	10	17	20	33	37	37	42	42	43	46	46	46
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.4	1.4	1.4	1.4	13.7	23.3	27.4	45.2	50.7	50.7	57.5	57.5	58.9	63.0	63.0	63.0

Study: 1305-0023

Figure I.2.1.1.1.5: 1 Time to first non-elective hospitalisation for any cause or death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (NIN background)

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I.2.1.1.1.2 Analyses of single endpoints

I.2.1.1.1.2.1 Time to death

Table I.2.1.1.1.2.1: 1 Cox model for time to death over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	20	11.8	9.99	170	12	7.1	6.09	0.51	(0.25,	1.05)	0.0669	
Age													0.8034
<65 years	65	3	4.6	3.75	64	1	1.6	1.39	0.38	(0.04,	3.74)	0.4104	
>=65 years	104	17	16.3	14.14	106	11	10.4	8.78	0.52	(0.24,	1.12)	0.0961	
Sex													0.3451
Male	114	17	14.9	12.74	108	8	7.4	6.50	0.42	(0.18,	0.99)	0.0468	
Female	55	3	5.5	4.49	62	4	6.5	5.41	0.97	(0.22,	4.40)	0.9719	
Baseline FVC percent predicted													0.2368
<=70%	95	12	12.6	10.91	97	5	5.2	4.47	0.35	(0.12,	1.02)	0.0539	
>70%	74	8	10.8	8.87	73	7	9.6	8.24	0.87	(0.31,	2.45)	0.7878	
Baseline HRCT pattern													0.2471
UIP-like	116	14	12.1	10.19	121	11	9.1	7.70	0.64	(0.29,	1.42)	0.2746	
Other fibrotic patterns	53	6	11.3	9.55	49	1	2.0	1.85	0.17	(0.02,	1.40)	0.0991	
Underlying ILD diagnosis													0.6395
iNSIP	32	3	9.4	8.05	27	5	18.5	17.53	1.51	(0.35,	6.47)	0.5784	
Unclassifiable IIP	46	8	17.4	15.06	32	2	6.3	5.06	0.35	(0.07,	1.66)	0.1860	
HP	38	2	5.3	4.34	43	2	4.7	4.18	0.51	(0.07,	3.78)	0.5108	
Autoimmune ILD	29	4	13.8	11.38	43	3	7.0	5.90	0.35	(0.08,	1.59)	0.1740	
Other ILD	24	3	12.5	10.45	25	0	0.0	0.00	0.00	(NC,	NC)	0.9909	
Region													0.8244
Europe	78	7	9.0	7.59	67	3	4.5	4.03	0.36	(0.09,	1.43)	0.1463	
Asia	45	7	15.6	12.54	41	5	12.2	9.91	0.69	(0.21,	2.23)	0.5359	
Canada and USA	30	3	10.0	8.31	37	1	2.7	2.27	0.27	(0.03,	2.61)	0.2578	
Rest of the World	16	3	18.8	18.53	25	3	12.0	10.70	0.69	(0.13,	3.58)	0.6570	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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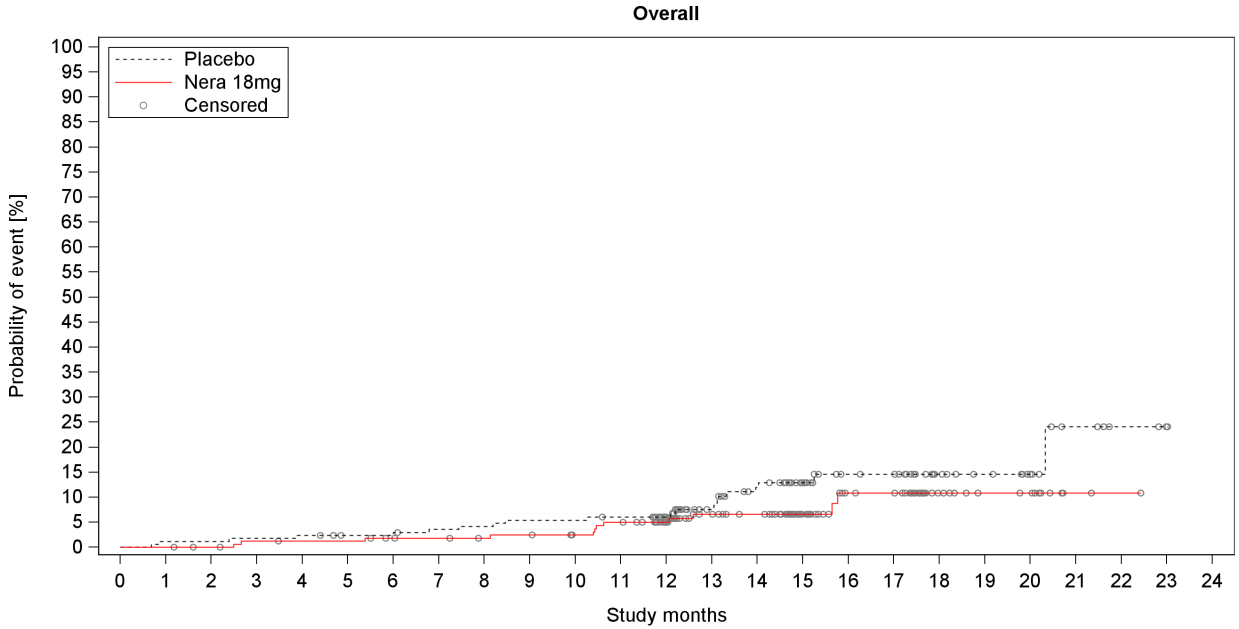

Number at risk (percentage relative to baseline)

Placebo	169	167	167	166	165	162	162	159	158	156	156	154	130	105	95	59	46	44	20	16	12	6	3	1	0
%	100.0	98.8	98.8	98.2	97.6	95.9	95.9	94.1	93.5	92.3	92.3	91.1	76.9	62.1	56.2	34.9	27.2	26.0	11.8	9.5	7.1	3.6	1.8	0.6	0.0
Nera 18mg	170	170	168	165	164	164	161	160	158	157	154	150	132	102	97	55	39	38	17	11	10	2	1	0	0
%	100.0	100.0	98.8	97.1	96.5	96.5	94.7	94.1	92.9	92.4	90.6	88.2	77.6	60.0	57.1	32.4	22.9	22.4	10.0	6.5	5.9	1.2	0.6	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	3	3	4	4	4	4	5	29	52	57	92	104	106	130	134	138	143	146	148	149
%	0.0	0.0	0.0	0.0	0.0	1.8	1.8	2.4	2.4	2.4	2.4	3.0	17.2	30.8	33.7	54.4	61.5	62.7	76.9	79.3	81.7	84.6	86.4	87.6	88.2
Nera 18mg	0	0	2	3	4	4	6	7	9	9	12	12	30	58	63	105	119	120	141	147	148	156	157	158	158
%	0.0	0.0	1.2	1.8	2.4	2.4	3.5	4.1	5.3	5.3	7.1	7.1	17.6	34.1	37.1	61.8	70.0	70.6	82.9	86.5	87.1	91.8	92.4	92.9	92.9

Study: 1305-0023

Figure I.2.1.1.1.2.1: 1 Time to death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (NIN background)

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BI Trial No.: x1305p3.hta

Figure I.2.1.1.1.2.1: 1

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I.2.1.1.1.2.2 Time to first confirmed acute ILD exacerbation

Table I.2.1.1.1.2.2: 1 Cox model for time to first confirmed acute ILD exacerbation over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	17	10.1	8.75	170	10	5.9	5.19	0.53	(0.24, 1.16)	0.1136	
Age												0.6064
<65 years	65	4	6.2	5.14	64	3	4.7	4.24	0.74	(0.16, 3.32)	0.6909	
>=65 years	104	13	12.5	11.16	106	7	6.6	5.74	0.46	(0.18, 1.17)	0.1029	
Sex												0.8702
Male	114	14	12.3	10.83	108	8	7.4	6.71	0.57	(0.24, 1.37)	0.2110	
Female	55	3	5.5	4.62	62	2	3.2	2.72	0.48	(0.08, 2.92)	0.4295	
Baseline FVC percent predicted												0.8956
<=70%	95	12	12.6	11.32	97	7	7.2	6.39	0.51	(0.20, 1.31)	0.1625	
>70%	74	5	6.8	5.66	73	3	4.1	3.61	0.58	(0.14, 2.43)	0.4519	
Baseline HRCT pattern												0.9881
UIP-like	116	12	10.3	8.99	121	10	8.3	7.21	0.72	(0.31, 1.67)	0.4388	
Other fibrotic patterns	53	5	9.4	8.23	49	0	0.0	0.00	0.00	(NC, NC)	0.9878	
Underlying ILD diagnosis												0.9994
iNSIP	32	0	0.0	0.00	27	4	14.8	14.69	>10	(NC, NC)	0.9900	
Unclassifiable IIP	46	8	17.4	15.97	32	2	6.3	5.31	0.31	(0.07, 1.49)	0.1445	
HP	38	3	7.9	6.67	43	1	2.3	2.10	0.25	(0.03, 2.40)	0.2274	
Autoimmune ILD	29	3	10.3	8.83	43	2	4.7	3.99	0.36	(0.06, 2.19)	0.2682	
Other ILD	24	3	12.5	10.71	25	1	4.0	3.31	0.31	(0.03, 3.08)	0.3207	
Region												0.6752
Europe	78	7	9.0	7.75	67	2	3.0	2.71	0.29	(0.06, 1.42)	0.1264	
Asia	45	7	15.6	13.17	41	5	12.2	10.30	0.64	(0.20, 2.02)	0.4435	
Canada and USA	30	2	6.7	5.77	37	3	8.1	7.10	1.30	(0.22, 7.83)	0.7713	
Rest of the World	16	1	6.3	6.19	25	0	0.0	0.00	0.00	(NC, NC)	0.9914	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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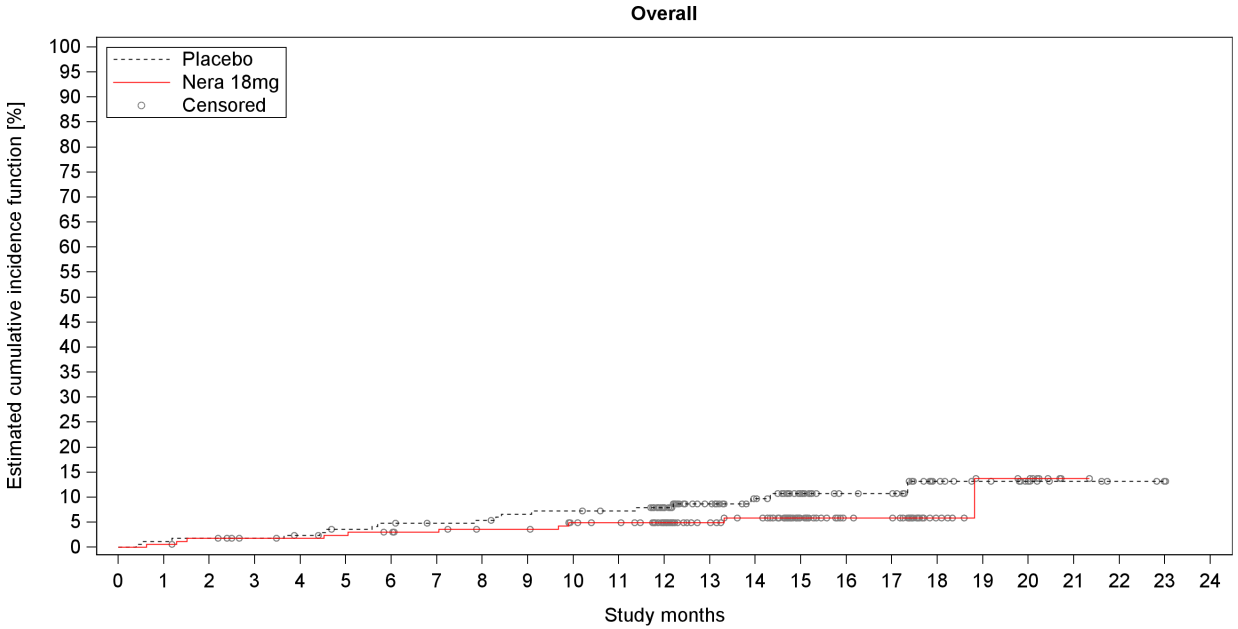

Number at risk (percentage relative to baseline)																									
Placebo	169	167	166	165	163	159	157	155	154	151	150	148	124	101	90	54	43	42	17	13	9	5	3	1	0
%	100.0	98.8	98.2	97.6	96.4	94.1	92.9	91.7	91.1	89.3	88.8	87.6	73.4	59.8	53.3	32.0	25.4	24.9	10.1	7.7	5.3	3.0	1.8	0.6	0.0
Nera 18mg	170	169	166	163	162	161	159	157	154	154	149	147	129	99	93	52	38	37	17	10	9	1	0	0	0
%	100.0	99.4	97.6	95.9	95.3	94.7	93.5	92.4	90.6	90.6	87.6	86.5	75.9	58.2	54.7	30.6	22.4	21.8	10.0	5.9	5.3	0.6	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	0	0	1	2	4	4	6	6	7	7	9	32	54	64	99	110	111	135	139	143	147	149	151	152
%	0.0	0.0	0.0	0.6	1.2	2.4	2.4	3.6	3.6	4.1	4.1	5.3	18.9	32.0	37.9	58.6	65.1	65.7	79.9	82.2	84.6	87.0	88.2	89.3	89.9
Nera 18mg	0	0	1	4	5	5	6	8	10	10	13	15	33	63	68	109	123	124	144	150	151	159	160	160	160
%	0.0	0.0	0.6	2.4	2.9	2.9	3.5	4.7	5.9	5.9	7.6	8.8	19.4	37.1	40.0	64.1	72.4	72.9	84.7	88.2	88.8	93.5	94.1	94.1	94.1

Study: 1305-0023

Figure I.2.1.1.1.2.2: 1 Time to first confirmed acute ILD exacerbation over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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Figure I.2.1.1.2.2: 1

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I.2.1.1.1.2.3 Time to first confirmed or suspected acute ILD exacerbation

Table I.2.1.1.1.2.3: 1 Cox model for time to first confirmed or suspected acute ILD exacerbation over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	22	13.0	11.50	170	13	7.6	6.78	0.53	(0.27, 1.07)	0.0752	
Age												0.2393
<65 years	65	5	7.7	6.45	64	5	7.8	7.17	1.00	(0.29, 3.48)	0.9977	
>=65 years	104	17	16.3	14.94	106	8	7.5	6.56	0.40	(0.17, 0.94)	0.0359	
Sex												0.8195
Male	114	17	14.9	13.35	108	9	8.3	7.55	0.52	(0.23, 1.16)	0.1112	
Female	55	5	9.1	7.81	62	4	6.5	5.51	0.62	(0.16, 2.33)	0.4775	
Baseline FVC percent predicted												0.9176
<=70%	95	16	16.8	15.29	97	10	10.3	9.21	0.54	(0.24, 1.20)	0.1285	
>70%	74	6	8.1	6.92	73	3	4.1	3.61	0.50	(0.12, 2.00)	0.3238	
Baseline HRCT pattern												0.4829
UIP-like	116	15	12.9	11.40	121	11	9.1	7.95	0.61	(0.28, 1.35)	0.2247	
Other fibrotic patterns	53	7	13.2	11.71	49	2	4.1	3.74	0.33	(0.07, 1.58)	0.1641	
Underlying ILD diagnosis												0.2152
iNSIP	32	2	6.3	5.61	27	5	18.5	18.37	3.03	(0.58, 15.88)	0.1906	
Unclassifiable IIP	46	8	17.4	15.97	32	2	6.3	5.31	0.33	(0.07, 1.59)	0.1682	
HP	38	4	10.5	8.94	43	1	2.3	2.10	0.19	(0.02, 1.71)	0.1379	
Autoimmune ILD	29	4	13.8	12.06	43	4	9.3	8.15	0.52	(0.13, 2.09)	0.3547	
Other ILD	24	4	16.7	14.47	25	1	4.0	3.31	0.25	(0.03, 2.29)	0.2204	
Region												0.7280
Europe	78	10	12.8	11.19	67	3	4.5	4.08	0.32	(0.09, 1.17)	0.0853	
Asia	45	7	15.6	13.17	41	6	14.6	12.52	0.74	(0.25, 2.22)	0.5916	
Canada and USA	30	4	13.3	12.22	37	4	10.8	9.47	0.86	(0.21, 3.46)	0.8344	
Rest of the World	16	1	6.3	6.19	25	0	0.0	0.00	0.00	(NC, NC)	0.9901	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb). The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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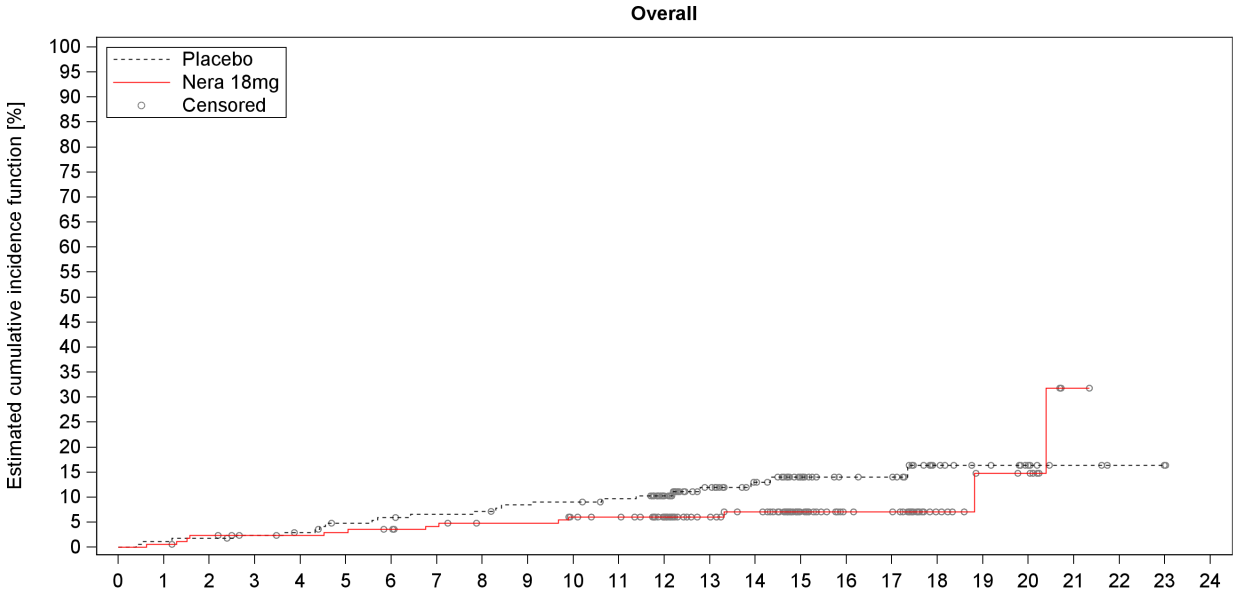

Number at risk (percentage relative to baseline)																									
Placebo	169	167	166	164	162	157	155	153	152	149	148	145	122	98	87	52	42	41	16	12	8	4	2	1	0
%	100.0	98.8	98.2	97.0	95.9	92.9	91.7	90.5	89.9	88.2	87.6	85.8	72.2	58.0	51.5	30.8	24.9	24.3	9.5	7.1	4.7	2.4	1.2	0.6	0.0
Nera 18mg	170	169	165	162	161	160	158	155	152	152	148	146	129	99	93	52	38	37	17	10	9	1	0	0	0
%	100.0	99.4	97.1	95.3	94.7	94.1	92.9	91.2	89.4	89.4	87.1	85.9	75.9	58.2	54.7	30.6	22.4	21.8	10.0	5.9	5.3	0.6	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	0	0	1	2	4	4	5	5	6	6	8	30	52	62	96	106	107	131	135	139	143	145	146	147
%	0.0	0.0	0.0	0.6	1.2	2.4	2.4	3.0	3.0	3.6	3.6	4.7	17.8	30.8	36.7	56.8	62.7	63.3	77.5	79.9	82.2	84.6	85.8	86.4	87.0
Nera 18mg	0	0	1	4	5	5	6	8	10	10	12	14	31	61	66	107	121	122	142	148	149	156	157	157	157
%	0.0	0.0	0.6	2.4	2.9	2.9	3.5	4.7	5.9	5.9	7.1	8.2	18.2	35.9	38.8	62.9	71.2	71.8	83.5	87.1	87.6	91.8	92.4	92.4	92.4

Study: 1305-0023

Figure I.2.1.1.1.2.3: 1 Time to first confirmed or suspected acute ILD exacerbation over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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I.2.1.1.1.2.4 Time to first respiratory hospitalisation

Table I.2.1.1.1.2.4: 1 Cox model for time to first respiratory hospitalisation over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	40	23.7	21.90	170	39	22.9	22.22	0.91	(0.58,	1.43)	0.6866	
Age													0.9434
<65 years	65	11	16.9	15.03	64	10	15.6	15.19	0.88	(0.36,	2.14)	0.7837	
>=65 years	104	29	27.9	26.48	106	29	27.4	26.44	0.92	(0.55,	1.54)	0.7424	
Sex													0.7395
Male	114	31	27.2	25.32	108	28	25.9	25.60	0.88	(0.52,	1.48)	0.6301	
Female	55	9	16.4	14.94	62	11	17.7	16.63	1.05	(0.43,	2.55)	0.9175	
Baseline FVC percent predicted													0.1895
<=70%	95	26	27.4	26.30	97	22	22.7	22.22	0.72	(0.41,	1.29)	0.2706	
>70%	74	14	18.9	16.70	73	17	23.3	22.23	1.34	(0.65,	2.73)	0.4258	
Baseline HRCT pattern													0.4267
UIP-like	116	27	23.3	21.35	121	32	26.4	25.55	1.01	(0.60,	1.70)	0.9554	
Other fibrotic patterns	53	13	24.5	23.13	49	7	14.3	13.93	0.66	(0.26,	1.66)	0.3777	
Underlying ILD diagnosis													0.8082
iNSIP	32	7	21.9	20.71	27	7	25.9	26.79	1.00	(0.35,	2.87)	0.9943	
Unclassifiable IIP	46	16	34.8	32.26	32	7	21.9	19.99	0.66	(0.27,	1.61)	0.3609	
HP	38	5	13.2	11.86	43	9	20.9	21.85	1.51	(0.50,	4.56)	0.4616	
Autoimmune ILD	29	6	20.7	19.00	43	10	23.3	21.94	0.80	(0.28,	2.26)	0.6692	
Other ILD	24	6	25.0	23.48	25	6	24.0	21.73	1.18	(0.38,	3.72)	0.7736	
Region													0.9778
Europe	78	17	21.8	20.27	67	14	20.9	20.94	0.92	(0.45,	1.88)	0.8201	
Asia	45	13	28.9	26.69	41	13	31.7	30.17	0.90	(0.42,	1.95)	0.7909	
Canada and USA	30	6	20.0	17.14	37	6	16.2	14.42	0.74	(0.23,	2.44)	0.6227	
Rest of the World	16	4	25.0	26.52	25	6	24.0	25.05	1.10	(0.31,	3.94)	0.8849	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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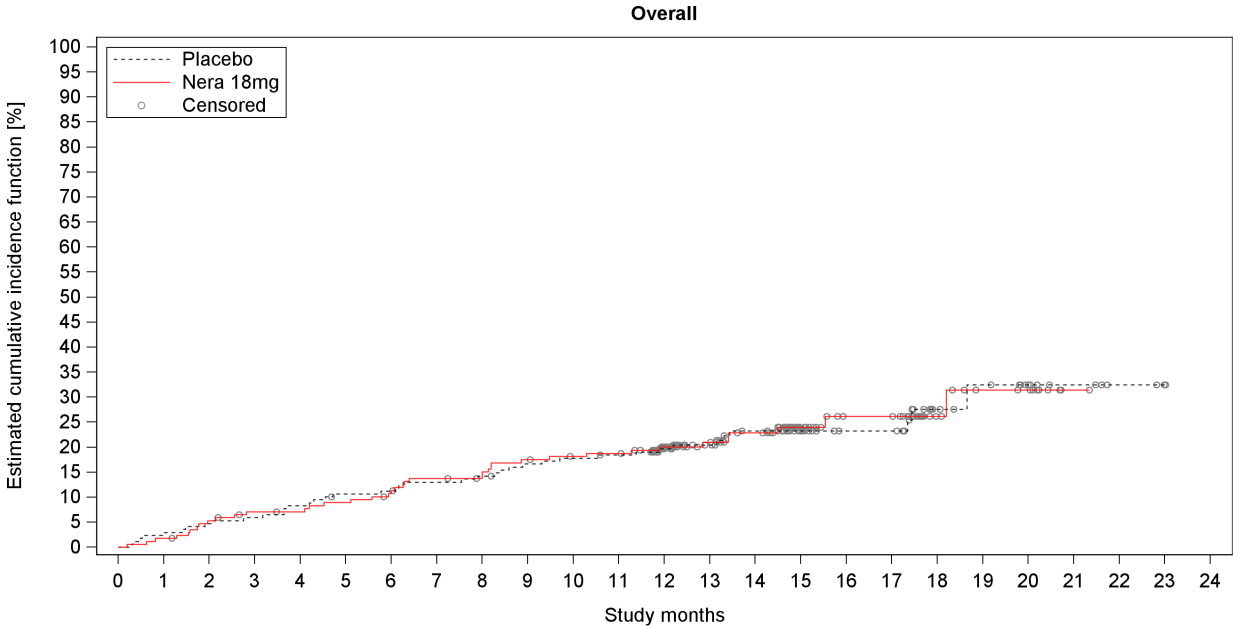

Number at risk (percentage relative to baseline)																									
Placebo	169	164	161	159	155	150	149	146	144	139	137	135	110	89	79	49	40	40	17	14	10	6	3	1	0
%	100.0	97.0	95.3	94.1	91.7	88.8	88.2	86.4	85.2	82.2	81.1	79.9	65.1	52.7	46.7	29.0	23.7	23.7	10.1	8.3	5.9	3.6	1.8	0.6	0.0
Nera 18mg	170	167	160	155	154	151	147	141	139	133	130	129	109	86	79	43	31	31	15	10	9	1	0	0	0
%	100.0	98.2	94.1	91.2	90.6	88.8	86.5	82.9	81.8	78.2	76.5	75.9	64.1	50.6	46.5	25.3	18.2	18.2	8.8	5.9	5.3	0.6	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	0	0	0	0	1	1	1	1	2	2	3	26	46	53	83	92	92	113	115	119	123	126	128	129
%	0.0	0.0	0.0	0.0	0.0	0.6	0.6	0.6	0.6	1.2	1.2	1.8	15.4	27.2	31.4	49.1	54.4	54.4	66.9	68.0	70.4	72.8	74.6	75.7	76.3
Nera 18mg	0	0	1	3	4	4	5	6	8	8	10	10	28	50	55	90	101	101	117	121	122	130	131	131	131
%	0.0	0.0	0.6	1.8	2.4	2.4	2.9	3.5	4.7	4.7	5.9	5.9	16.5	29.4	32.4	52.9	59.4	59.4	68.8	71.2	71.8	76.5	77.1	77.1	77.1

Study: 1305-0023

Figure I.2.1.1.1.2.4: 1 Time to first respiratory hospitalisation over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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Figure I.2.1.1.1.2.4: 1

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I.2.1.1.1.2.5 Time to first non-elective hospitalisation for any cause

Table I.2.1.1.1.2.5: 1 Cox model for time to first non-elective hospitalisation for any cause over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	50	29.6	28.36	170	57	33.5	34.76	1.13	(0.77, 1.66)	0.5411	
Age												0.8154
<65 years	65	14	21.5	19.40	64	16	25.0	25.49	1.20	(0.58, 2.49)	0.6272	
>=65 years	104	36	34.6	34.56	106	41	38.7	40.50	1.08	(0.69, 1.70)	0.7315	
Sex												0.4153
Male	114	38	33.3	32.46	108	39	36.1	37.56	1.02	(0.65, 1.61)	0.9179	
Female	55	12	21.8	20.25	62	18	29.0	29.92	1.47	(0.70, 3.06)	0.3089	
Baseline FVC percent predicted												0.0191
<=70%	95	34	35.8	36.26	97	31	32.0	32.75	0.78	(0.47, 1.27)	0.3158	
>70%	74	16	21.6	19.38	73	26	35.6	37.49	2.02	(1.08, 3.79)	0.0280	
Baseline HRCT pattern												0.9222
UIP-like	116	35	30.2	28.88	121	44	36.4	37.89	1.14	(0.73, 1.79)	0.5668	
Other fibrotic patterns	53	15	28.3	27.21	49	13	26.5	27.16	1.09	(0.52, 2.30)	0.8167	
Underlying ILD diagnosis												0.4609
iNSIP	32	8	25.0	24.58	27	10	37.0	41.77	1.35	(0.53, 3.47)	0.5273	
Unclassifiable IIP	46	20	43.5	43.01	32	10	31.3	29.02	0.70	(0.32, 1.50)	0.3566	
HP	38	6	15.8	14.53	43	11	25.6	27.02	1.64	(0.60, 4.47)	0.3300	
Autoimmune ILD	29	9	31.0	29.41	43	15	34.9	36.35	0.98	(0.42, 2.29)	0.9615	
Other ILD	24	7	29.2	27.58	25	11	44.0	46.57	1.96	(0.75, 5.13)	0.1696	
Region												0.9953
Europe	78	21	26.9	25.80	67	20	29.9	31.47	1.15	(0.62, 2.13)	0.6625	
Asia	45	19	42.2	41.50	41	21	51.2	55.80	1.08	(0.58, 2.02)	0.8083	
Canada and USA	30	6	20.0	17.62	37	9	24.3	23.16	1.16	(0.40, 3.34)	0.7881	
Rest of the World	16	4	25.0	26.52	25	7	28.0	29.23	1.29	(0.38, 4.45)	0.6844	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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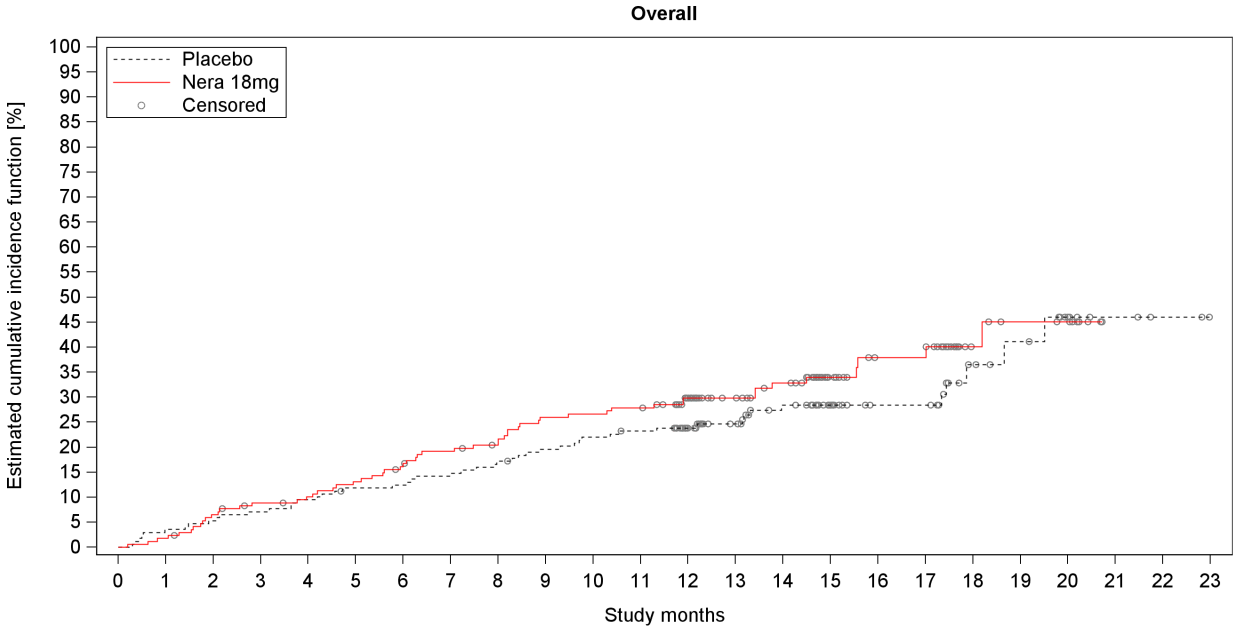

Number at risk (percentage relative to baseline)																									
Placebo	169	163	160	157	153	148	147	143	139	134	130	127	103	84	73	45	36	36	16	13	8	4	2	0
%	100.0	96.4	94.7	92.9	90.5	87.6	87.0	84.6	82.2	79.3	76.9	75.1	60.9	49.7	43.2	26.6	21.3	21.3	9.5	7.7	4.7	2.4	1.2	0.0
Nera 18mg	170	167	158	152	149	144	138	132	128	119	118	116	95	74	66	39	29	29	12	9	8	0	0	0
%	100.0	98.2	92.9	89.4	87.6	84.7	81.2	77.6	75.3	70.0	69.4	68.2	55.9	43.5	38.8	22.9	17.1	17.1	7.1	5.3	4.7	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	0	0	0	0	1	1	1	1	2	2	3	26	44	51	79	88	88	105	107	111	115	117	119
%	0.0	0.0	0.0	0.0	0.0	0.6	0.6	0.6	0.6	1.2	1.2	1.8	15.4	26.0	30.2	46.7	52.1	52.1	62.1	63.3	65.7	68.0	69.2	70.4
Nera 18mg	0	0	1	3	4	4	5	6	8	8	8	8	26	47	52	78	86	86	102	104	105	113	113	113
%	0.0	0.0	0.6	1.8	2.4	2.4	2.9	3.5	4.7	4.7	4.7	4.7	15.3	27.6	30.6	45.9	50.6	50.6	60.0	61.2	61.8	66.5	66.5	66.5

Study: 1305-0023

Figure I.2.1.1.1.2.5: 1 Time to first non-elective hospitalisation for any cause over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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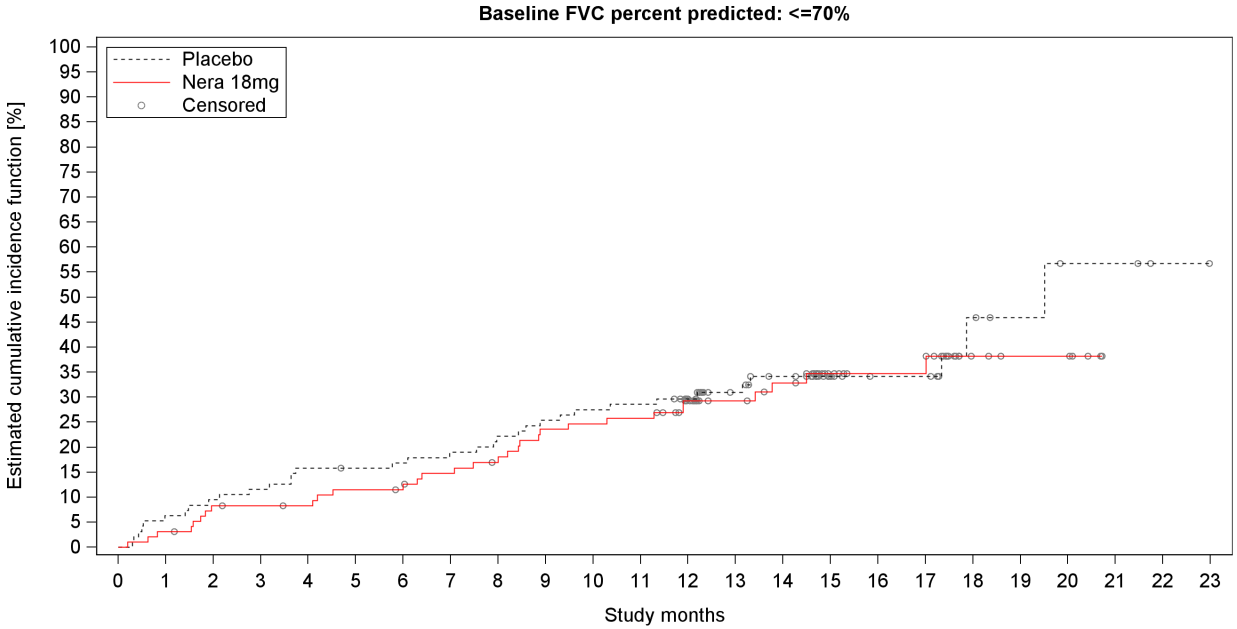

Number at risk (percentage relative to baseline)

Placebo	95	89	86	84	80	79	78	76	73	70	68	67	57	45	39	23	19	19	7	5	3	3	1	0
%	100.0	93.7	90.5	88.4	84.2	83.2	82.1	80.0	76.8	73.7	71.6	70.5	60.0	47.4	41.1	24.2	20.0	20.0	7.4	5.3	3.2	3.2	1.1	0.0
Nera 18mg	97	94	88	87	86	83	82	78	75	69	68	67	55	41	37	23	19	19	7	5	5	0	0	0
%	100.0	96.9	90.7	89.7	88.7	85.6	84.5	80.4	77.3	71.1	70.1	69.1	56.7	42.3	38.1	23.7	19.6	19.6	7.2	5.2	5.2	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	1	1	1	1	1	1	1	10	21	25	41	45	45	55	57	58	58	60	61
%	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	1.1	1.1	1.1	1.1	10.5	22.1	26.3	43.2	47.4	47.4	57.9	60.0	61.1	61.1	63.2	64.2
Nera 18mg	0	0	1	2	3	3	4	5	6	6	6	6	15	29	31	44	48	48	59	61	61	66	66	66
%	0.0	0.0	1.0	2.1	3.1	3.1	4.1	5.2	6.2	6.2	6.2	6.2	15.5	29.9	32.0	45.4	49.5	49.5	60.8	62.9	62.9	68.0	68.0	68.0

Study: 1305-0023

Figure I.2.1.1.1.2.5: 1 Time to first non-elective hospitalisation for any cause over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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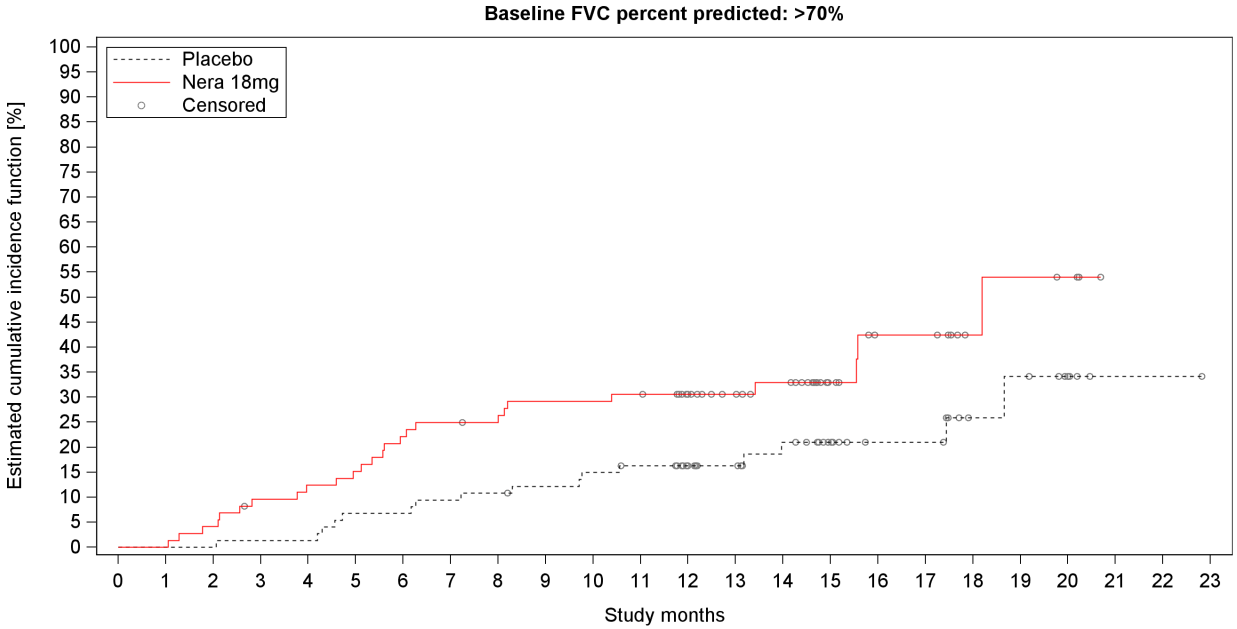

Number at risk (percentage relative to baseline)

Placebo	74	74	74	73	73	69	69	67	66	64	62	60	46	39	34	22	17	17	9	8	5	1	1	0
%	100.0	100.0	100.0	98.6	98.6	93.2	93.2	90.5	89.2	86.5	83.8	81.1	62.2	52.7	45.9	29.7	23.0	23.0	12.2	10.8	6.8	1.4	1.4	0.0
Nera 18mg	73	73	70	65	63	61	56	54	53	50	50	49	40	33	29	16	10	10	5	4	3	0	0	0
%	100.0	100.0	95.9	89.0	86.3	83.6	76.7	74.0	72.6	68.5	68.5	67.1	54.8	45.2	39.7	21.9	13.7	13.7	6.8	5.5	4.1	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	0	0	0	0	1	1	2	16	23	26	38	43	43	50	50	53	57	57	58
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.4	1.4	2.7	21.6	31.1	35.1	51.4	58.1	58.1	67.6	67.6	71.6	77.0	77.0	78.4
Nera 18mg	0	0	0	1	1	1	1	1	2	2	2	2	11	18	21	34	38	38	43	43	44	47	47	47
%	0.0	0.0	0.0	1.4	1.4	1.4	1.4	1.4	2.7	2.7	2.7	2.7	15.1	24.7	28.8	46.6	52.1	52.1	58.9	58.9	60.3	64.4	64.4	64.4

Study: 1305-0023

Figure I.2.1.1.1.2.5: 1 Time to first non-elective hospitalisation for any cause over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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I.2.1.1.1.3 Time to event analyses of quality of life

I.2.1.1.1.3.1 Living with Pulmonary Fibrosis (L-PF) total scores

Table I.2.1.1.1.3.1: 1 Cox model for time to first L-PF total score deterioration (increase >= 15) over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	71	42.0	47.58	170	63	37.1	42.66	0.91	(0.64,	1.28)	0.5733	
Age													0.4552
<65 years	65	25	38.5	39.35	64	23	35.9	42.04	1.08	(0.61,	1.91)	0.7928	
>=65 years	104	46	44.2	53.67	106	40	37.7	43.03	0.82	(0.53,	1.26)	0.3698	
Sex													0.0890
Male	114	51	44.7	51.98	108	47	43.5	55.58	1.14	(0.77,	1.71)	0.5123	
Female	55	20	36.4	39.11	62	16	25.8	25.35	0.58	(0.30,	1.13)	0.1094	
Baseline FVC percent predicted													0.4675
<=70%	95	39	41.1	47.19	97	39	40.2	46.75	1.01	(0.65,	1.58)	0.9704	
>70%	74	32	43.2	48.05	73	24	32.9	37.35	0.78	(0.46,	1.33)	0.3604	
Baseline HRCT pattern													0.8967
UIP-like	116	49	42.2	48.34	121	47	38.8	43.28	0.92	(0.61,	1.38)	0.6870	
Other fibrotic patterns	53	22	41.5	45.96	49	16	32.7	40.94	0.87	(0.46,	1.67)	0.6830	
Underlying ILD diagnosis													0.0600
iNSIP	32	11	34.4	39.12	27	6	22.2	29.86	0.72	(0.26,	1.95)	0.5146	
Unclassifiable IIP	46	21	45.7	51.65	32	13	40.6	41.71	0.87	(0.43,	1.74)	0.6867	
HP	38	21	55.3	60.16	43	17	39.5	43.95	0.83	(0.43,	1.60)	0.5779	
Autoimmune ILD	29	11	37.9	43.04	43	10	23.3	25.21	0.48	(0.20,	1.14)	0.0954	
Other ILD	24	7	29.2	35.01	25	17	68.0	94.07	2.98	(1.21,	7.30)	0.0171	
Region													0.3018
Europe	78	31	39.7	45.87	67	23	34.3	40.51	0.90	(0.52,	1.56)	0.7108	
Asia	45	22	48.9	53.44	41	12	29.3	31.56	0.53	(0.26,	1.10)	0.0883	
Canada and USA	30	11	36.7	38.79	37	18	48.6	57.63	1.46	(0.69,	3.10)	0.3245	
Rest of the World	16	7	43.8	57.73	25	10	40.0	46.19	1.00	(0.37,	2.67)	0.9977	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline total score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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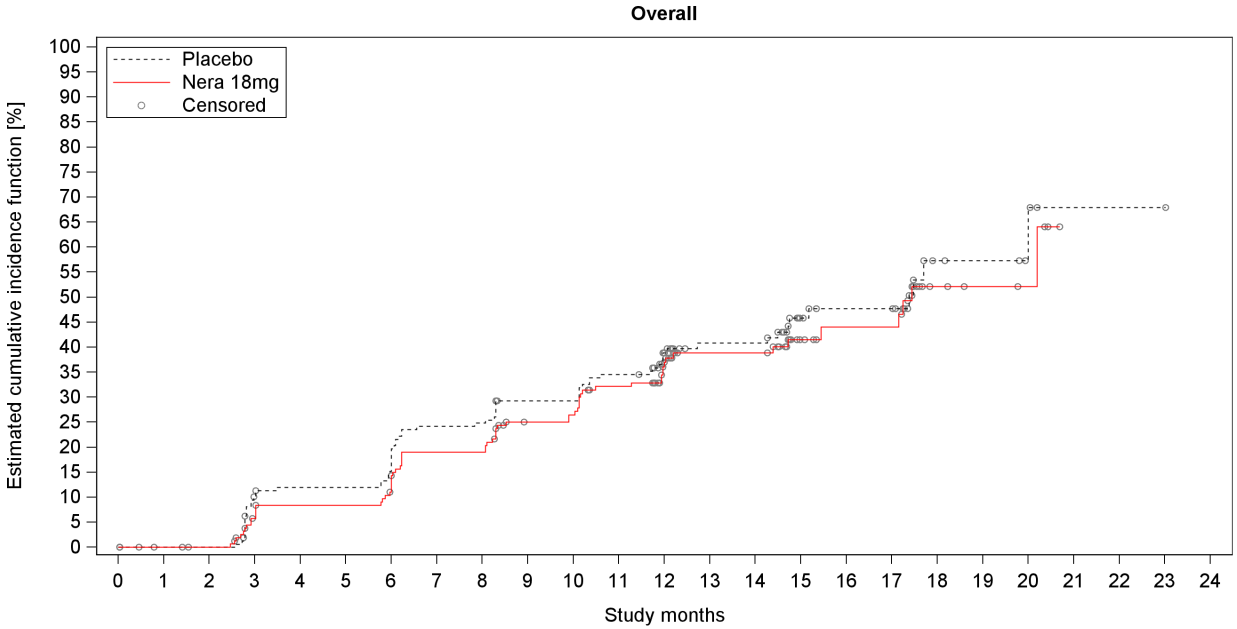

Number at risk (percentage relative to baseline)																									
Placebo	169	162	161	141	137	137	132	118	117	108	108	100	72	54	54	30	26	26	7	6	4	1	1	1	0
%	100.0	95.9	95.3	83.4	81.1	81.1	78.1	69.8	69.2	63.9	63.9	59.2	42.6	32.0	32.0	17.8	15.4	15.4	4.1	3.6	2.4	0.6	0.6	0.6	0.0
Nera 18mg	170	160	159	145	140	140	134	121	121	106	104	94	73	54	54	26	22	22	7	5	4	0	0	0	0
%	100.0	94.1	93.5	85.3	82.4	82.4	78.8	71.2	71.2	62.4	61.2	55.3	42.9	31.8	31.8	15.3	12.9	12.9	4.1	2.9	2.4	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	7	8	12	13	13	13	13	13	15	15	15	37	53	53	73	76	76	92	93	95	97	97	97	98
%	0.0	4.1	4.7	7.1	7.7	7.7	7.7	7.7	7.7	8.9	8.9	8.9	21.9	31.4	31.4	43.2	45.0	45.0	54.4	55.0	56.2	57.4	57.4	57.4	58.0
Nera 18mg	0	10	11	16	17	17	19	20	20	26	26	28	44	60	60	86	89	89	101	103	104	107	107	107	107
%	0.0	5.9	6.5	9.4	10.0	10.0	11.2	11.8	11.8	15.3	15.3	16.5	25.9	35.3	35.3	50.6	52.4	52.4	59.4	60.6	61.2	62.9	62.9	62.9	62.9

Study: 1305-0023

Figure I.2.1.1.1.3.1: 1 Time to first L-PF total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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Table I.2.1.1.1.3.1: 2 Cox model for time to first L-PF Impact total score deterioration (increase >= 15) over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	71	42.0	49.53	170	67	39.4	46.40	0.94	(0.67, 1.31)	0.7003	
Age												0.5481
<65 years	65	24	36.9	38.08	64	23	35.9	43.66	1.08	(0.61, 1.91)	0.7993	
>=65 years	104	47	45.2	58.51	106	44	41.5	47.98	0.87	(0.57, 1.32)	0.5009	
Sex												0.1377
Male	114	51	44.7	55.74	108	51	47.2	62.61	1.14	(0.77, 1.68)	0.5208	
Female	55	20	36.4	38.56	62	16	25.8	25.43	0.63	(0.33, 1.23)	0.1779	
Baseline FVC percent predicted												0.6363
<=70%	95	39	41.1	48.67	97	39	40.2	47.54	1.01	(0.64, 1.57)	0.9822	
>70%	74	32	43.2	50.62	73	28	38.4	44.91	0.85	(0.51, 1.42)	0.5429	
Baseline HRCT pattern												0.6167
UIP-like	116	49	42.2	51.05	121	48	39.7	44.95	0.88	(0.59, 1.32)	0.5497	
Other fibrotic patterns	53	22	41.5	46.44	49	19	38.8	50.53	1.07	(0.58, 1.98)	0.8338	
Underlying ILD diagnosis												0.1775
iNSIP	32	12	37.5	44.77	27	7	25.9	38.73	0.75	(0.29, 1.92)	0.5489	
Unclassifiable IIP	46	16	34.8	39.19	32	13	40.6	42.32	1.25	(0.60, 2.62)	0.5538	
HP	38	22	57.9	68.12	43	22	51.2	59.48	1.00	(0.55, 1.82)	0.9898	
Autoimmune ILD	29	11	37.9	43.17	43	9	20.9	22.44	0.40	(0.16, 0.97)	0.0434	
Other ILD	24	10	41.7	55.72	25	16	64.0	86.54	1.70	(0.76, 3.81)	0.1951	
Region												0.8580
Europe	78	35	44.9	55.04	67	23	34.3	41.50	0.80	(0.47, 1.36)	0.4046	
Asia	45	17	37.8	40.54	41	16	39.0	43.59	0.91	(0.45, 1.82)	0.7821	
Canada and USA	30	13	43.3	50.60	37	19	51.4	62.33	1.16	(0.57, 2.35)	0.6875	
Rest of the World	16	6	37.5	49.45	25	9	36.0	41.34	1.08	(0.38, 3.09)	0.8863	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline impact total score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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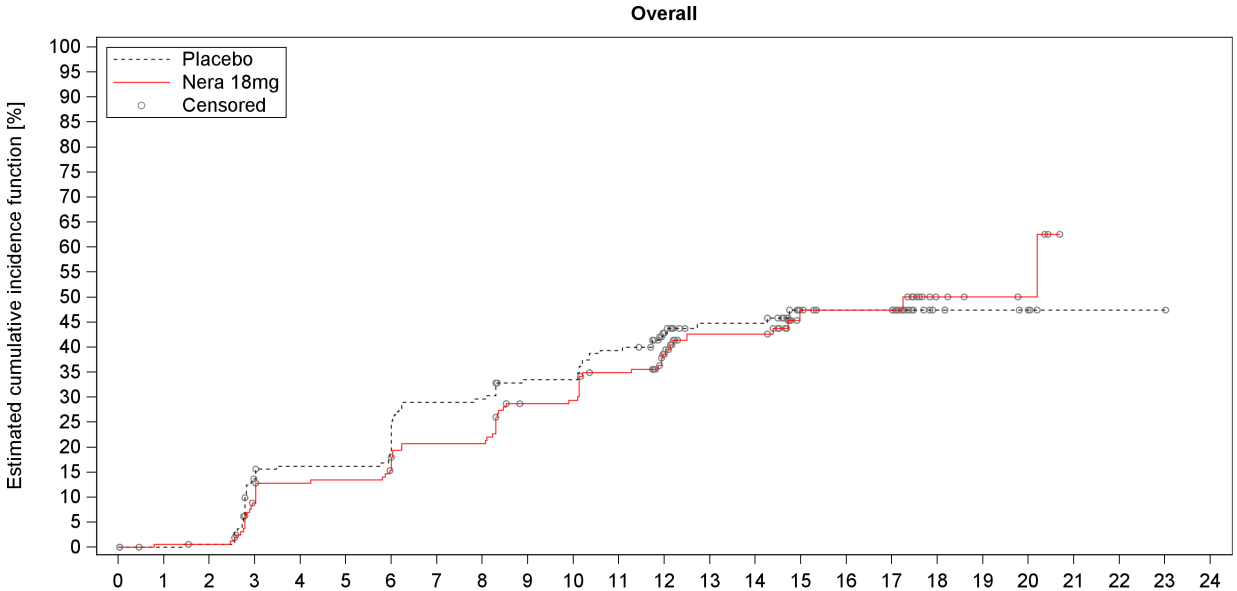

Number at risk (percentage relative to baseline)

Placebo	169	162	161	136	131	131	127	111	110	102	102	93	67	52	52	28	26	26	6	5	4	1	1	1	0
%	100.0	95.9	95.3	80.5	77.5	77.5	75.1	65.7	65.1	60.4	60.4	55.0	39.6	30.8	30.8	16.6	15.4	15.4	3.6	3.0	2.4	0.6	0.6	0.6	0.0
Nera 18mg	170	160	159	141	134	133	128	119	119	104	103	93	71	50	50	25	23	23	7	5	4	0	0	0	0
%	100.0	94.1	93.5	82.9	78.8	78.2	75.3	70.0	70.0	61.2	60.6	54.7	41.8	29.4	29.4	14.7	13.5	13.5	4.1	2.9	2.4	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	7	7	11	12	12	12	12	12	14	14	14	35	48	48	70	72	72	92	93	94	97	97	97	98
%	0.0	4.1	4.1	6.5	7.1	7.1	7.1	7.1	7.1	8.3	8.3	8.3	20.7	28.4	28.4	41.4	42.6	42.6	54.4	55.0	55.6	57.4	57.4	57.4	58.0
Nera 18mg	0	9	10	15	16	16	18	19	19	22	22	24	41	58	58	80	82	82	97	99	100	103	103	103	103
%	0.0	5.3	5.9	8.8	9.4	9.4	10.6	11.2	11.2	12.9	12.9	14.1	24.1	34.1	34.1	47.1	48.2	48.2	57.1	58.2	58.8	60.6	60.6	60.6	60.6

Study: 1305-0023

Figure I.2.1.1.1.3.1: 2 Time to first L-PF Impact total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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Table I.2.1.1.1.3.1: 3 Cox model for time to first L-PF Symptoms total score deterioration (increase >= 15) over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	74	43.8	48.71	170	72	42.4	50.80	1.07	(0.77,	1.48)	0.6891	
Age													0.8839
<65 years	65	27	41.5	43.35	64	26	40.6	50.24	1.10	(0.64,	1.90)	0.7225	
>=65 years	104	47	45.2	52.43	106	46	43.4	51.13	1.05	(0.69,	1.58)	0.8221	
Sex													0.2281
Male	114	52	45.6	52.06	108	52	48.1	63.20	1.25	(0.84,	1.84)	0.2675	
Female	55	22	40.0	42.27	62	20	32.3	33.64	0.80	(0.43,	1.47)	0.4681	
Baseline FVC percent predicted													0.5131
<=70%	95	45	47.4	56.18	97	47	48.5	61.63	1.16	(0.77,	1.75)	0.4743	
>70%	74	29	39.2	40.37	73	25	34.2	38.19	0.93	(0.54,	1.59)	0.7824	
Baseline HRCT pattern													0.5792
UIP-like	116	47	40.5	44.60	121	51	42.1	49.11	1.14	(0.76,	1.71)	0.5167	
Other fibrotic patterns	53	27	50.9	57.99	49	21	42.9	55.43	0.94	(0.53,	1.66)	0.8218	
Underlying ILD diagnosis													0.0406
iNSIP	32	10	31.3	31.23	27	8	29.6	37.01	1.08	(0.42,	2.75)	0.8757	
Unclassifiable IIP	46	24	52.2	64.60	32	13	40.6	46.75	0.86	(0.43,	1.69)	0.6578	
HP	38	22	57.9	65.84	43	21	48.8	58.22	0.95	(0.52,	1.76)	0.8819	
Autoimmune ILD	29	10	34.5	37.34	43	12	27.9	31.23	0.67	(0.29,	1.55)	0.3460	
Other ILD	24	8	33.3	35.46	25	18	72.0	101.07	3.75	(1.60,	8.78)	0.0023	
Region													0.3269
Europe	78	35	44.9	51.34	67	28	41.8	53.19	1.08	(0.65,	1.78)	0.7659	
Asia	45	22	48.9	54.45	41	13	31.7	36.83	0.68	(0.34,	1.36)	0.2717	
Canada and USA	30	10	33.3	32.47	37	19	51.4	59.47	1.81	(0.84,	3.89)	0.1305	
Rest of the World	16	7	43.8	55.78	25	12	48.0	54.95	1.11	(0.43,	2.86)	0.8323	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline symptoms total score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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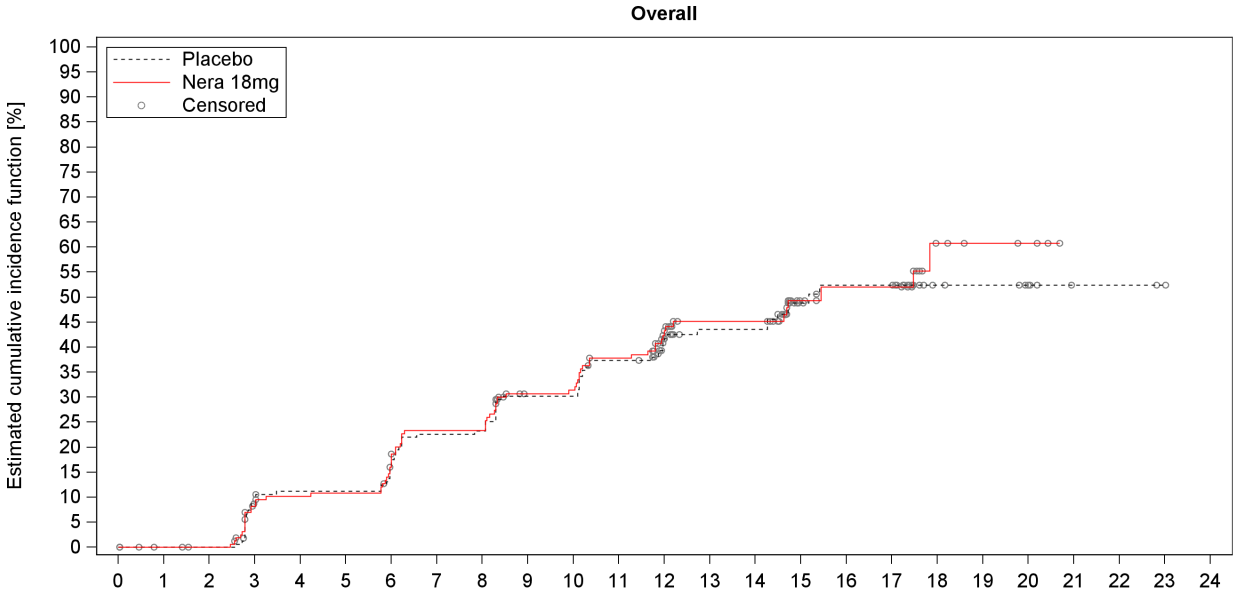

Number at risk (percentage relative to baseline)																									
Placebo	169	164	163	145	140	140	133	122	121	108	108	97	71	56	56	30	26	26	9	8	6	2	2	1	0
%	100.0	97.0	96.4	85.8	82.8	82.8	78.7	72.2	71.6	63.9	63.9	57.4	42.0	33.1	33.1	17.8	15.4	15.4	5.3	4.7	3.6	1.2	1.2	0.6	0.0
Nera 18mg	170	162	161	143	138	137	127	115	115	98	97	86	65	50	50	21	18	18	6	4	3	0	0	0	0
%	100.0	95.3	94.7	84.1	81.2	80.6	74.7	67.6	67.6	57.6	57.1	50.6	38.2	29.4	29.4	12.4	10.6	10.6	3.5	2.4	1.8	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	5	6	10	11	11	11	11	11	13	13	13	34	46	46	67	69	69	86	87	89	93	93	94	95
%	0.0	3.0	3.6	5.9	6.5	6.5	6.5	6.5	6.5	7.7	7.7	7.7	20.1	27.2	27.2	39.6	40.8	40.8	50.9	51.5	52.7	55.0	55.0	55.6	56.2
Nera 18mg	0	8	9	14	16	16	18	19	19	25	25	27	42	54	54	80	82	82	92	94	95	98	98	98	98
%	0.0	4.7	5.3	8.2	9.4	9.4	10.6	11.2	11.2	14.7	14.7	15.9	24.7	31.8	31.8	47.1	48.2	48.2	54.1	55.3	55.9	57.6	57.6	57.6	57.6

Study: 1305-0023

Figure I.2.1.1.1.3.1: 3 Time to first L-PF Symptoms total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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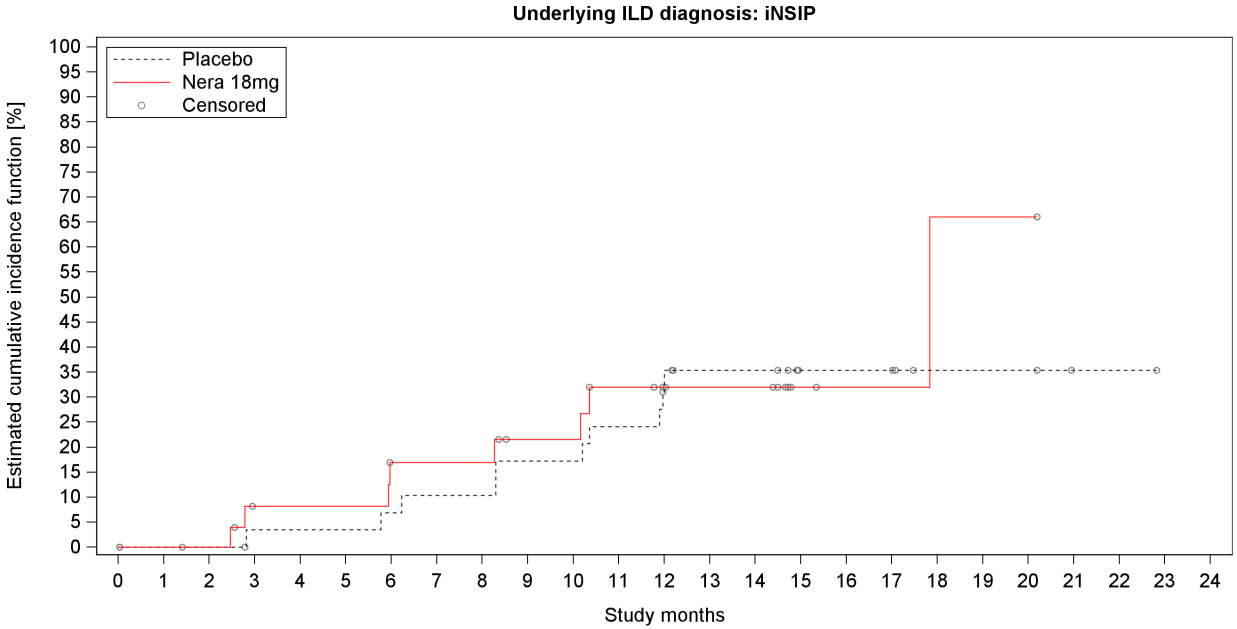

Number at risk (percentage relative to baseline)																									
Placebo	32	31	30	28	28	28	27	26	26	24	24	22	16	12	12	7	7	7	3	3	3	1	1	0	0
%	100.0	96.9	93.8	87.5	87.5	87.5	84.4	81.3	81.3	75.0	75.0	68.8	50.0	37.5	37.5	21.9	21.9	21.9	9.4	9.4	9.4	3.1	3.1	0.0	0.0
Nera 18mg	27	25	25	21	21	21	18	18	18	15	15	12	9	8	8	3	2	2	1	1	1	0	0	0	0
%	100.0	92.6	92.6	77.8	77.8	77.8	66.7	66.7	66.7	55.6	55.6	44.4	33.3	29.6	29.6	11.1	7.4	7.4	3.7	3.7	3.7	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	1	2	3	3	3	3	3	3	3	3	3	7	10	10	15	15	15	19	19	19	21	21	22	22
%	0.0	3.1	6.3	9.4	9.4	9.4	9.4	9.4	9.4	9.4	9.4	9.4	21.9	31.3	31.3	46.9	46.9	46.9	59.4	59.4	59.4	65.6	65.6	68.8	68.8
Nera 18mg	0	2	2	4	4	4	5	5	5	7	7	8	11	12	12	17	18	18	18	18	18	19	19	19	19
%	0.0	7.4	7.4	14.8	14.8	14.8	18.5	18.5	18.5	25.9	25.9	29.6	40.7	44.4	44.4	63.0	66.7	66.7	66.7	66.7	66.7	70.4	70.4	70.4	70.4

Study: 1305-0023

Figure I.2.1.1.1.3.1: 3 Time to first L-PF Symptoms total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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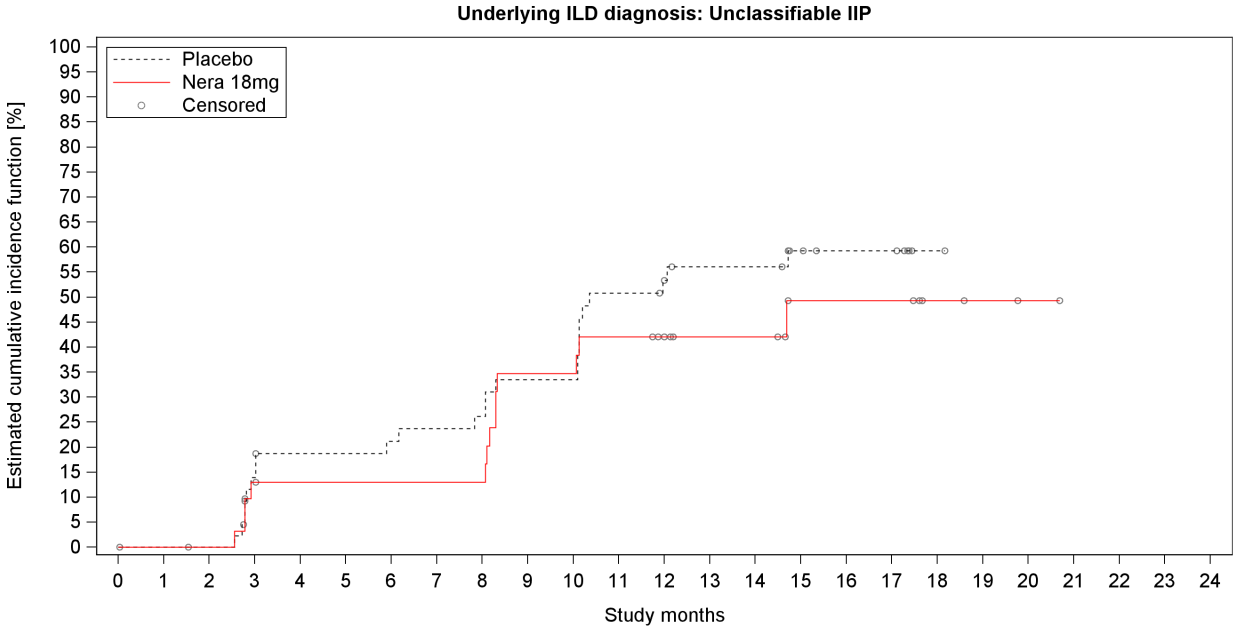

	Number at risk (percentage relative to baseline)																								
Placebo	46	44	44	36	33	33	32	31	30	27	27	20	18	15	15	8	6	6	1	0	0	0	0	0	0
%	100.0	95.7	95.7	78.3	71.7	71.7	69.6	67.4	65.2	58.7	58.7	43.5	39.1	32.6	32.6	17.4	13.0	13.0	2.2	0.0	0.0	0.0	0.0	0.0	0.0
Nera 18mg	32	32	31	26	24	24	24	24	24	18	18	16	13	10	10	6	6	6	3	2	1	0	0	0	0
%	100.0	100.0	96.9	81.3	75.0	75.0	75.0	75.0	75.0	56.3	56.3	50.0	40.6	31.3	31.3	18.8	18.8	18.8	9.4	6.3	3.1	0.0	0.0	0.0	0.0
	Number censored (percentage relative to number at risk at baseline)																								
Placebo	0	2	2	4	5	5	5	5	5	5	5	5	6	8	8	14	16	16	21	22	22	22	22	22	22
%	0.0	4.3	4.3	8.7	10.9	10.9	10.9	10.9	10.9	10.9	10.9	10.9	13.0	17.4	17.4	30.4	34.8	34.8	45.7	47.8	47.8	47.8	47.8	47.8	47.8
Nera 18mg	0	0	1	2	4	4	4	4	4	4	4	4	7	10	10	13	13	13	16	17	18	19	19	19	19
%	0.0	0.0	3.1	6.3	12.5	12.5	12.5	12.5	12.5	12.5	12.5	12.5	21.9	31.3	31.3	40.6	40.6	40.6	50.0	53.1	56.3	59.4	59.4	59.4	59.4

Study: 1305-0023

Figure I.2.1.1.1.3.1: 3 Time to first L-PF Symptoms total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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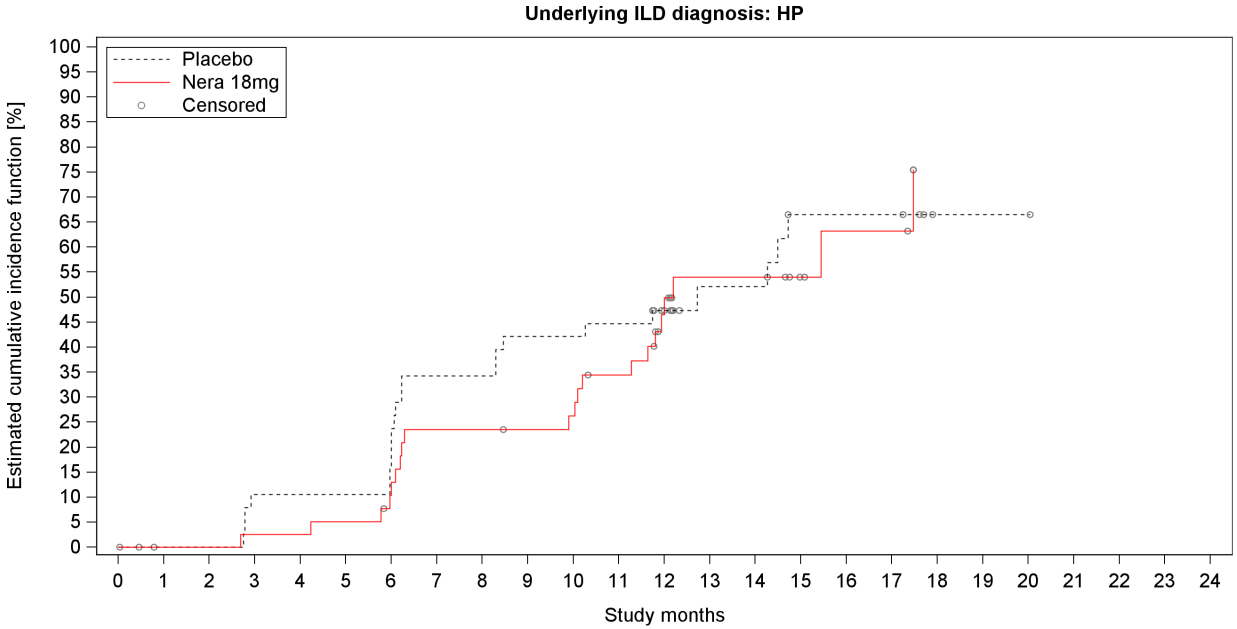

Number at risk (percentage relative to baseline)

Placebo	38	38	38	34	34	34	32	25	25	22	22	21	16	10	10	6	6	6	1	1	1	0	0	0	0
%	100.0	100.0	100.0	89.5	89.5	89.5	84.2	65.8	65.8	57.9	57.9	55.3	42.1	26.3	26.3	15.8	15.8	15.8	2.6	2.6	2.6	0.0	0.0	0.0	0.0
Nera 18mg	43	39	39	38	38	37	34	29	29	28	27	23	16	11	11	6	4	4	0	0	0	0	0	0	0
%	100.0	90.7	90.7	88.4	88.4	86.0	79.1	67.4	67.4	65.1	62.8	53.5	37.2	25.6	25.6	14.0	9.3	9.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	0	0	0	0	0	0	0	4	9	9	10	10	10	15	15	15	16	16	16	16
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	10.5	23.7	23.7	26.3	26.3	26.3	39.5	39.5	39.5	42.1	42.1	42.1	42.1
Nera 18mg	0	4	4	4	4	4	5	5	5	6	6	7	10	13	13	18	19	19	22	22	22	22	22	22	22
%	0.0	9.3	9.3	9.3	9.3	9.3	11.6	11.6	11.6	14.0	14.0	16.3	23.3	30.2	30.2	41.9	44.2	44.2	51.2	51.2	51.2	51.2	51.2	51.2	51.2

Study: 1305-0023

Figure I.2.1.1.1.3.1: 3 Time to first L-PF Symptoms total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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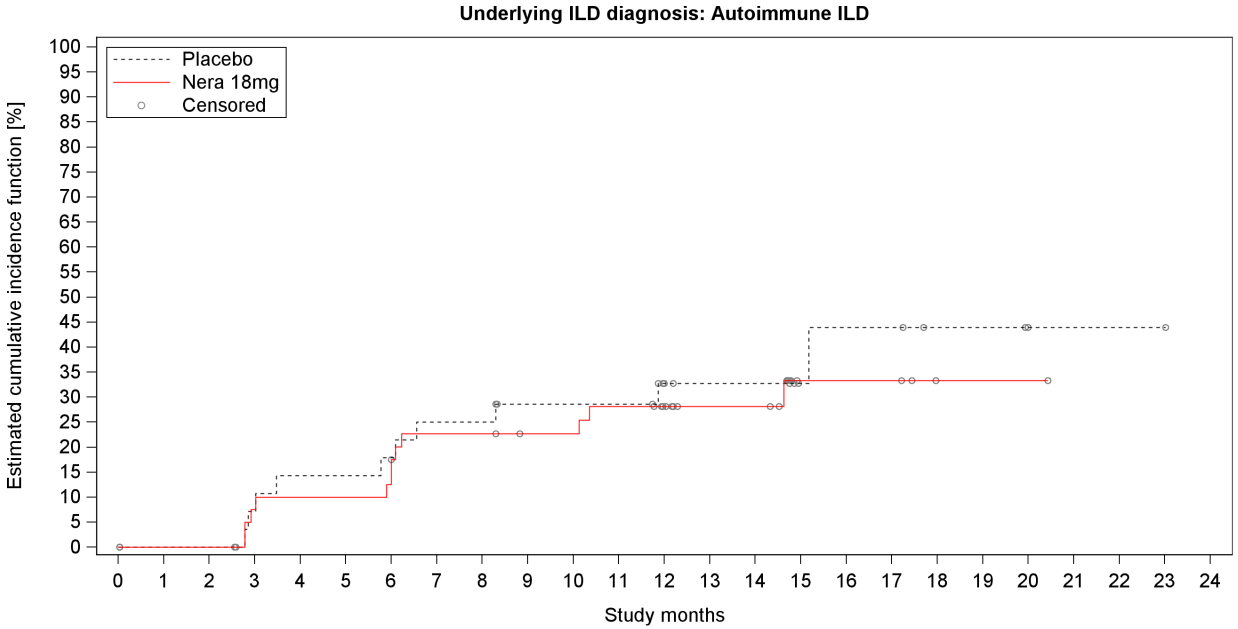

Number at risk (percentage relative to baseline)																									
Placebo	29	28	28	26	24	24	23	21	21	18	18	18	11	9	9	6	5	5	3	3	2	1	1	1	0
%	100.0	96.6	96.6	89.7	82.8	82.8	79.3	72.4	72.4	62.1	62.1	62.1	37.9	31.0	31.0	20.7	17.2	17.2	10.3	10.3	6.9	3.4	3.4	3.4	0.0
Nera 18mg	43	42	42	37	36	36	35	30	30	28	28	26	21	16	16	4	4	4	1	1	1	0	0	0	0
%	100.0	97.7	97.7	86.0	83.7	83.7	81.4	69.8	69.8	65.1	65.1	60.5	48.8	37.2	37.2	9.3	9.3	9.3	2.3	2.3	2.3	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	1	1	1	1	1	1	1	1	3	3	3	9	11	11	14	14	14	16	16	17	18	18	18	19
%	0.0	3.4	3.4	3.4	3.4	3.4	3.4	3.4	3.4	10.3	10.3	10.3	31.0	37.9	37.9	48.3	48.3	48.3	55.2	55.2	58.6	62.1	62.1	62.1	65.5
Nera 18mg	0	1	1	3	3	3	3	4	4	6	6	6	11	16	16	27	27	27	30	30	30	31	31	31	31
%	0.0	2.3	2.3	7.0	7.0	7.0	7.0	9.3	9.3	14.0	14.0	14.0	25.6	37.2	37.2	62.8	62.8	62.8	69.8	69.8	69.8	72.1	72.1	72.1	72.1

Study: 1305-0023

Figure I.2.1.1.1.3.1: 3 Time to first L-PF Symptoms total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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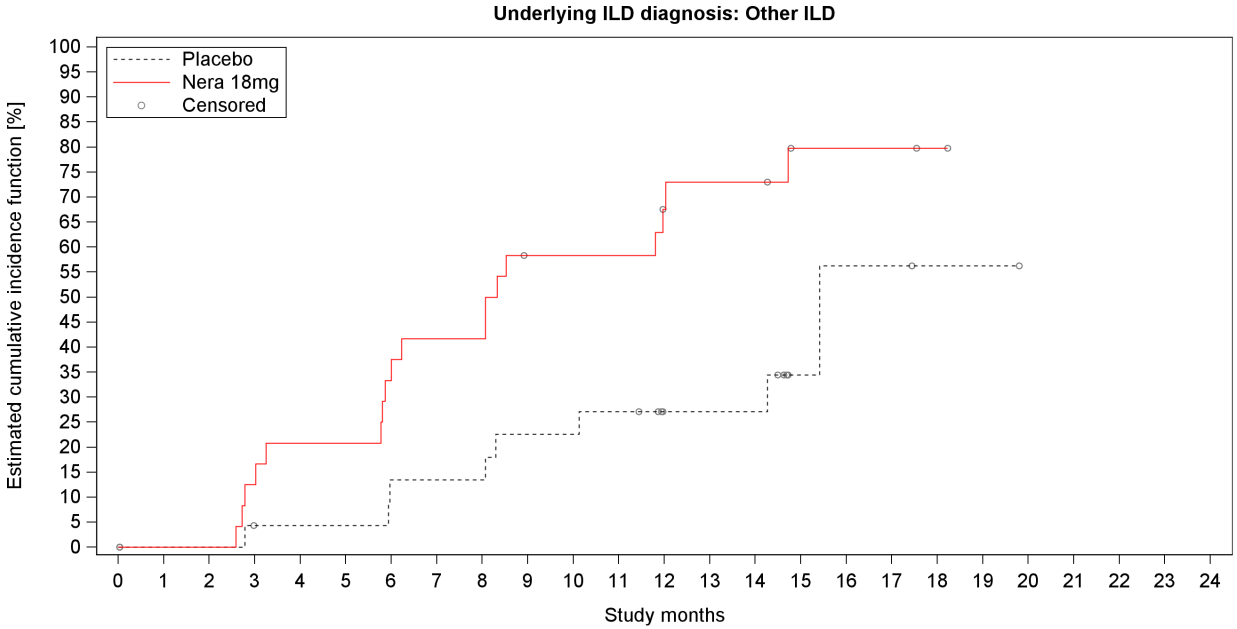

Number at risk (percentage relative to baseline)

Placebo	24	23	23	21	21	21	19	19	19	17	17	16	10	10	10	3	2	2	1	1	0	0	0	0	0
%	100.0	95.8	95.8	87.5	87.5	87.5	79.2	79.2	79.2	70.8	70.8	66.7	41.7	41.7	41.7	12.5	8.3	8.3	4.2	4.2	0.0	0.0	0.0	0.0	0.0
Nera 18mg	25	24	24	21	19	19	16	14	14	9	9	9	6	5	5	2	2	2	1	0	0	0	0	0	0
%	100.0	96.0	96.0	84.0	76.0	76.0	64.0	56.0	56.0	36.0	36.0	36.0	24.0	20.0	20.0	8.0	8.0	8.0	4.0	0.0	0.0	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	1	1	2	2	2	2	2	2	2	2	2	8	8	8	14	14	14	15	15	16	16	16	16	16
%	0.0	4.2	4.2	8.3	8.3	8.3	8.3	8.3	8.3	8.3	8.3	8.3	33.3	33.3	33.3	58.3	58.3	58.3	62.5	62.5	66.7	66.7	66.7	66.7	66.7
Nera 18mg	0	1	1	1	1	1	1	1	1	2	2	2	3	3	3	5	5	5	6	7	7	7	7	7	7
%	0.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	8.0	8.0	8.0	12.0	12.0	12.0	20.0	20.0	20.0	24.0	28.0	28.0	28.0	28.0	28.0	28.0

Study: 1305-0023

Figure I.2.1.1.1.3.1: 3 Time to first L-PF Symptoms total score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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I.2.1.1.1.3.2 Living with Pulmonary Fibrosis (L-PF) domain scores

Table I.2.1.1.1.3.2: 1 Cox model for time to first L-PF Cough domain score deterioration (increase >= 15) over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	91	53.8	69.03	170	86	50.6	68.77	1.02	(0.76,	1.38)	0.8898	
Age													0.7630
<65 years	65	36	55.4	68.54	64	35	54.7	79.81	1.08	(0.67,	1.73)	0.7463	
>=65 years	104	55	52.9	69.35	106	51	48.1	62.81	0.98	(0.67,	1.45)	0.9352	
Sex													0.4745
Male	114	62	54.4	70.85	108	60	55.6	83.85	1.11	(0.77,	1.60)	0.5691	
Female	55	29	52.7	65.43	62	26	41.9	48.60	0.87	(0.51,	1.50)	0.6253	
Baseline FVC percent predicted													0.8079
<=70%	95	53	55.8	74.72	97	53	54.6	78.46	1.05	(0.72,	1.55)	0.7963	
>70%	74	38	51.4	62.40	73	33	45.2	57.39	0.98	(0.61,	1.56)	0.9181	
Baseline HRCT pattern													0.7277
UIP-like	116	61	52.6	68.75	121	59	48.8	64.76	0.98	(0.68,	1.42)	0.9302	
Other fibrotic patterns	53	30	56.6	69.59	49	27	55.1	79.56	1.10	(0.65,	1.86)	0.7148	
Underlying ILD diagnosis													0.3112
iNSIP	32	15	46.9	58.84	27	12	44.4	66.30	1.07	(0.50,	2.31)	0.8620	
Unclassifiable IIP	46	28	60.9	91.99	32	17	53.1	75.59	0.93	(0.51,	1.72)	0.8253	
HP	38	25	65.8	88.89	43	21	48.8	65.46	0.82	(0.46,	1.48)	0.5188	
Autoimmune ILD	29	11	37.9	43.00	43	18	41.9	51.18	1.02	(0.47,	2.19)	0.9600	
Other ILD	24	12	50.0	54.08	25	18	72.0	104.57	2.24	(1.07,	4.71)	0.0326	
Region													0.6628
Europe	78	40	51.3	66.18	67	35	52.2	70.90	1.10	(0.69,	1.73)	0.6963	
Asia	45	25	55.6	68.63	41	15	36.6	46.07	0.71	(0.37,	1.37)	0.3079	
Canada and USA	30	17	56.7	70.50	37	22	59.5	87.02	1.22	(0.64,	2.32)	0.5495	
Rest of the World	16	9	56.3	82.99	25	14	56.0	78.48	0.91	(0.39,	2.13)	0.8257	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline cough domain score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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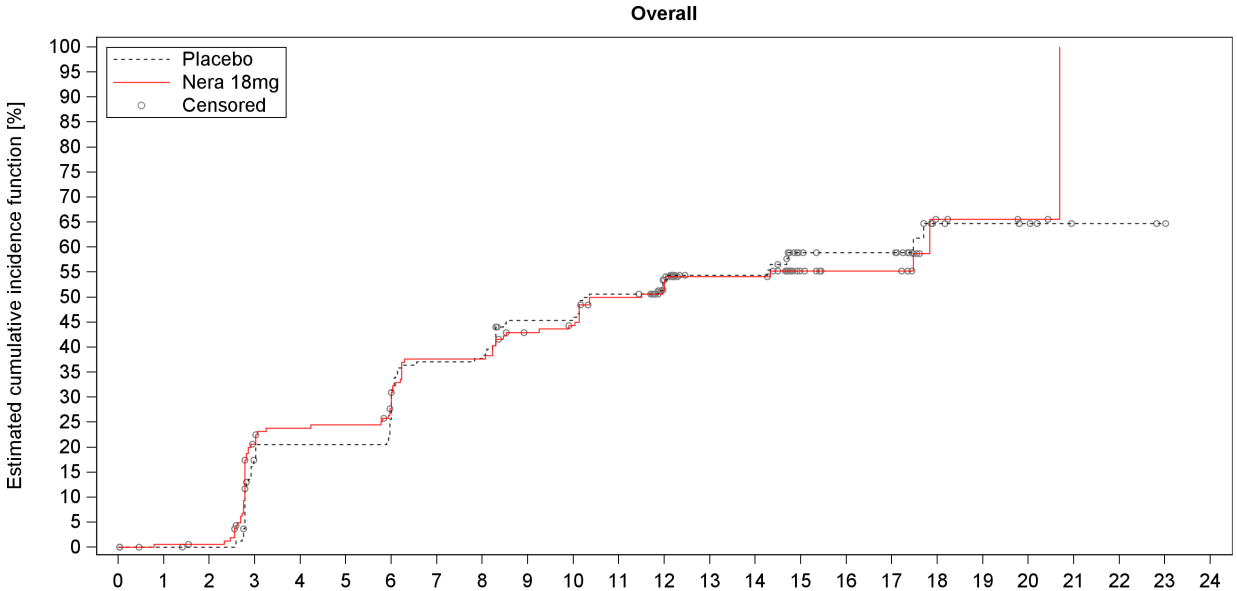

Number at risk (percentage relative to baseline)																									
Placebo	169	164	163	130	125	125	117	99	98	84	84	76	55	42	42	23	21	21	7	6	5	2	2	1	0
%	100.0	97.0	96.4	76.9	74.0	74.0	69.2	58.6	58.0	49.7	49.7	45.0	32.5	24.9	24.9	13.6	12.4	12.4	4.1	3.6	3.0	1.2	1.2	0.6	0.0
Nera 18mg	170	162	161	125	118	117	110	94	94	83	80	70	55	42	42	20	16	16	4	3	2	0	0	0	0
%	100.0	95.3	94.7	73.5	69.4	68.8	64.7	55.3	55.3	48.8	47.1	41.2	32.4	24.7	24.7	11.8	9.4	9.4	2.4	1.8	1.2	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	5	6	11	11	11	11	11	11	13	13	13	30	42	42	57	59	59	71	72	73	76	76	77	78
%	0.0	3.0	3.6	6.5	6.5	6.5	6.5	6.5	6.5	7.7	7.7	7.7	17.8	24.9	24.9	33.7	34.9	34.9	42.0	42.6	43.2	45.0	45.0	45.6	46.2
Nera 18mg	0	7	8	12	14	14	16	17	17	20	21	23	36	46	46	67	71	71	81	82	83	84	84	84	84
%	0.0	4.1	4.7	7.1	8.2	8.2	9.4	10.0	10.0	11.8	12.4	13.5	21.2	27.1	27.1	39.4	41.8	41.8	47.6	48.2	48.8	49.4	49.4	49.4	49.4

Study: 1305-0023

Figure I.2.1.1.1.3.2: 1 Time to first L-PF Cough domain score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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Table I.2.1.1.1.3.2: 2 Cox model for time to first L-PF Dyspnea domain score deterioration (increase >= 15) over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	63	37.3	39.44	170	64	37.6	44.08	1.09	(0.77, 1.55)	0.6191	
Age												0.4574
<65 years	65	23	35.4	34.81	64	19	29.7	33.43	0.90	(0.49, 1.66)	0.7323	
>=65 years	104	40	38.5	42.71	106	45	42.5	50.93	1.19	(0.78, 1.83)	0.4171	
Sex												0.5969
Male	114	46	40.4	44.03	108	41	38.0	46.52	1.03	(0.67, 1.57)	0.9071	
Female	55	17	30.9	30.77	62	23	37.1	40.32	1.26	(0.67, 2.37)	0.4726	
Baseline FVC percent predicted												0.5756
<=70%	95	39	41.1	46.66	97	43	44.3	54.80	1.18	(0.76, 1.82)	0.4580	
>70%	74	24	32.4	31.52	73	21	28.8	31.48	0.96	(0.53, 1.72)	0.8805	
Baseline HRCT pattern												0.0472
UIP-like	116	39	33.6	34.68	121	50	41.3	48.97	1.39	(0.91, 2.12)	0.1283	
Other fibrotic patterns	53	24	45.3	50.76	49	14	28.6	32.49	0.62	(0.32, 1.21)	0.1630	
Underlying ILD diagnosis												0.6689
iNSIP	32	5	15.6	14.65	27	7	25.9	32.51	2.04	(0.64, 6.48)	0.2249	
Unclassifiable IIP	46	22	47.8	54.29	32	15	46.9	56.98	1.32	(0.68, 2.56)	0.4174	
HP	38	18	47.4	53.09	43	17	39.5	47.25	0.81	(0.41, 1.60)	0.5431	
Autoimmune ILD	29	8	27.6	26.71	43	13	30.2	33.35	0.96	(0.40, 2.35)	0.9372	
Other ILD	24	10	41.7	47.13	25	12	48.0	53.63	1.33	(0.57, 3.09)	0.5108	
Region												0.4870
Europe	78	32	41.0	45.57	67	25	37.3	47.00	1.01	(0.60, 1.70)	0.9796	
Asia	45	18	40.0	40.55	41	14	34.1	40.13	0.84	(0.41, 1.70)	0.6201	
Canada and USA	30	8	26.7	25.83	37	15	40.5	41.13	1.60	(0.68, 3.78)	0.2853	
Rest of the World	16	5	31.3	35.35	25	10	40.0	48.47	1.95	(0.65, 5.83)	0.2338	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline dyspnea domain score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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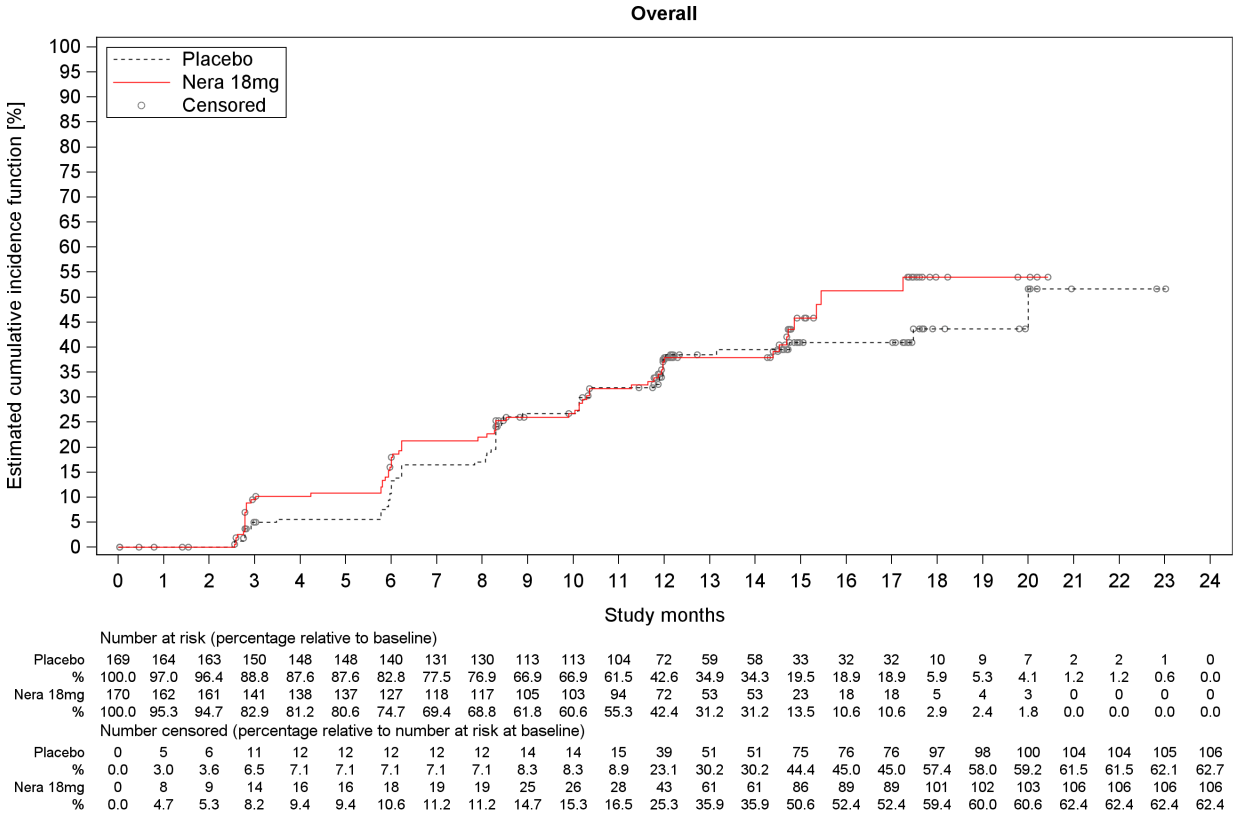

Number at risk (percentage relative to baseline)																									
Placebo	169	164	163	150	148	148	140	131	130	113	113	104	72	59	58	33	32	32	10	9	7	2	2	1	0
%	100.0	97.0	96.4	88.8	87.6	87.6	82.8	77.5	76.9	66.9	66.9	61.5	42.6	34.9	34.3	19.5	18.9	18.9	5.9	5.3	4.1	1.2	1.2	0.6	0.0
Nera 18mg	170	162	161	141	138	137	127	118	117	105	103	94	72	53	53	23	18	18	5	4	3	0	0	0	0
%	100.0	95.3	94.7	82.9	81.2	80.6	74.7	69.4	68.8	61.8	60.6	55.3	42.4	31.2	31.2	13.5	10.6	10.6	2.9	2.4	1.8	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	5	6	11	12	12	12	12	12	14	14	15	39	51	51	75	76	76	97	98	100	104	104	105	106
%	0.0	3.0	3.6	6.5	7.1	7.1	7.1	7.1	7.1	8.3	8.3	8.9	23.1	30.2	30.2	44.4	45.0	45.0	57.4	58.0	59.2	61.5	61.5	62.1	62.7
Nera 18mg	0	8	9	14	16	16	18	19	19	25	26	28	43	61	61	86	89	89	101	102	103	106	106	106	106
%	0.0	4.7	5.3	8.2	9.4	9.4	10.6	11.2	11.2	14.7	15.3	16.5	25.3	35.9	35.9	50.6	52.4	52.4	59.4	60.0	60.6	62.4	62.4	62.4	62.4

Study: 1305-0023

Figure I.2.1.1.1.3.2: 2 Time to first L-PF Dyspnea domain score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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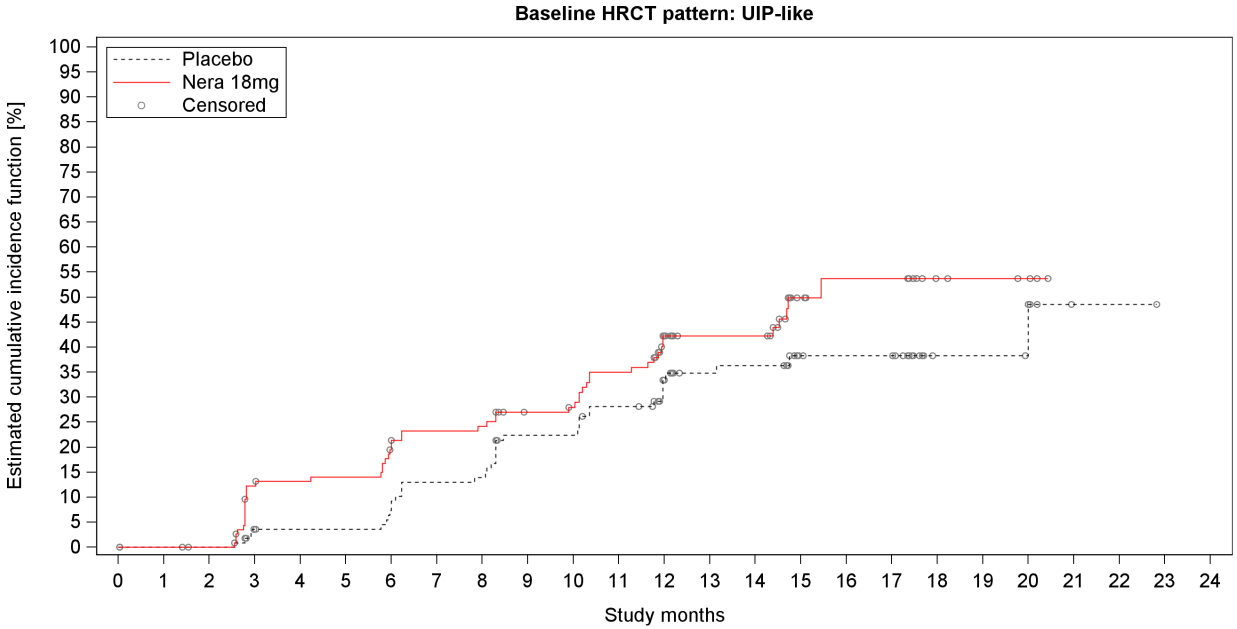

Number at risk (percentage relative to baseline)																									
Placebo	116	113	112	104	103	103	99	93	92	81	81	74	52	42	41	25	24	24	7	7	6	1	1	0	0
%	100.0	97.4	96.6	89.7	88.8	88.8	85.3	80.2	79.3	69.8	69.8	63.8	44.8	36.2	35.3	21.6	20.7	20.7	6.0	6.0	5.2	0.9	0.9	0.0	0.0
Nera 18mg	121	117	116	99	96	95	87	82	81	74	72	65	48	38	38	15	12	12	5	4	3	0	0	0	0
%	100.0	96.7	95.9	81.8	79.3	78.5	71.9	67.8	66.9	61.2	59.5	53.7	39.7	31.4	31.4	12.4	9.9	9.9	4.1	3.3	2.5	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	3	4	8	9	9	9	9	9	11	11	12	29	38	38	53	54	54	71	71	72	76	76	77	77
%	0.0	2.6	3.4	6.9	7.8	7.8	7.8	7.8	7.8	9.5	9.5	10.3	25.0	32.8	32.8	45.7	46.6	46.6	61.2	61.2	62.1	65.5	65.5	66.4	66.4
Nera 18mg	0	4	5	8	10	10	12	13	13	17	18	18	28	38	38	57	59	59	66	67	68	71	71	71	71
%	0.0	3.3	4.1	6.6	8.3	8.3	9.9	10.7	10.7	14.0	14.9	14.9	23.1	31.4	31.4	47.1	48.8	48.8	54.5	55.4	56.2	58.7	58.7	58.7	58.7

Study: 1305-0023

Figure I.2.1.1.1.3.2: 2 Time to first L-PF Dyspnea domain score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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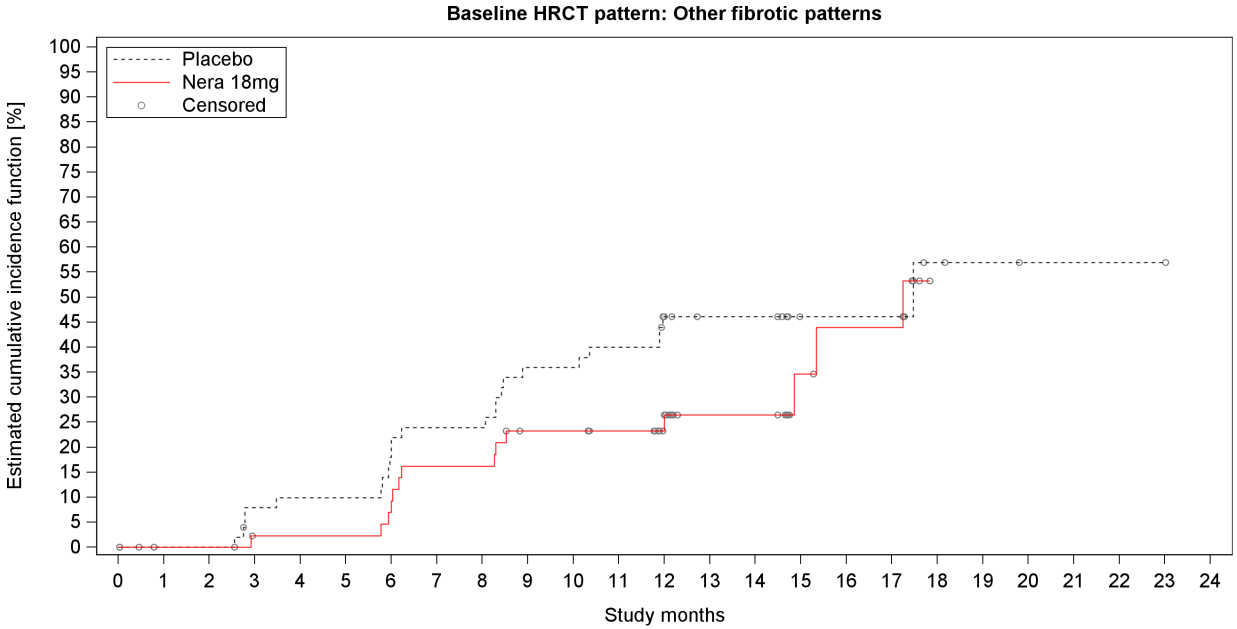

Number at risk (percentage relative to baseline)

Placebo	53	51	51	46	45	45	41	38	38	32	32	30	20	17	17	8	8	8	3	2	1	1	1	1	0
%	100.0	96.2	96.2	86.8	84.9	84.9	77.4	71.7	71.7	60.4	60.4	56.6	37.7	32.1	32.1	15.1	15.1	15.1	5.7	3.8	1.9	1.9	1.9	1.9	0.0
Nera 18mg	49	45	45	42	42	42	40	36	36	31	31	29	24	15	15	8	6	6	0	0	0	0	0	0	0
%	100.0	91.8	91.8	85.7	85.7	85.7	81.6	73.5	73.5	63.3	63.3	59.2	49.0	30.6	30.6	16.3	12.2	12.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	2	2	3	3	3	3	3	3	3	3	3	10	13	13	22	22	22	26	27	28	28	28	28	29
%	0.0	3.8	3.8	5.7	5.7	5.7	5.7	5.7	5.7	5.7	5.7	5.7	18.9	24.5	24.5	41.5	41.5	41.5	49.1	50.9	52.8	52.8	52.8	52.8	54.7
Nera 18mg	0	4	4	6	6	6	6	6	6	8	8	10	15	23	23	29	30	30	35	35	35	35	35	35	35
%	0.0	8.2	8.2	12.2	12.2	12.2	12.2	12.2	12.2	16.3	16.3	20.4	30.6	46.9	46.9	59.2	61.2	61.2	71.4	71.4	71.4	71.4	71.4	71.4	71.4

Study: 1305-0023

Figure I.2.1.1.1.3.2: 2 Time to first L-PF Dyspnea domain score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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Table I.2.1.1.1.3.2: 3 Cox model for time to first L-PF Fatigue domain score deterioration (increase >= 15) over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	89	52.7	66.68	170	95	55.9	74.61	1.15	(0.86,	1.55)	0.3367	
Age													0.7926
<65 years	65	32	49.2	57.15	64	33	51.6	67.80	1.09	(0.67,	1.79)	0.7219	
>=65 years	104	57	54.8	73.56	106	62	58.5	78.82	1.19	(0.82,	1.71)	0.3557	
Sex													0.6919
Male	114	67	58.8	79.66	108	62	57.4	83.60	1.13	(0.79,	1.61)	0.4965	
Female	55	22	40.0	44.56	62	33	53.2	62.07	1.29	(0.75,	2.23)	0.3615	
Baseline FVC percent predicted													0.9213
<=70%	95	55	57.9	78.59	97	59	60.8	84.70	1.15	(0.79,	1.67)	0.4690	
>70%	74	34	45.9	53.55	73	36	49.3	62.42	1.18	(0.74,	1.90)	0.4856	
Baseline HRCT pattern													0.8156
UIP-like	116	61	52.6	67.35	121	69	57.0	74.59	1.18	(0.83,	1.68)	0.3536	
Other fibrotic patterns	53	28	52.8	65.25	49	26	53.1	74.67	1.09	(0.64,	1.87)	0.7418	
Underlying ILD diagnosis													0.4424
iNSIP	32	15	46.9	56.16	27	17	63.0	103.83	1.88	(0.93,	3.81)	0.0807	
Unclassifiable IIP	46	25	54.3	73.65	32	21	65.6	80.82	1.22	(0.68,	2.20)	0.5079	
HP	38	23	60.5	70.51	43	19	44.2	55.40	1.00	(0.54,	1.86)	0.9950	
Autoimmune ILD	29	15	51.7	67.02	43	22	51.2	66.61	0.76	(0.39,	1.49)	0.4209	
Other ILD	24	11	45.8	61.73	25	16	64.0	90.66	1.36	(0.62,	2.95)	0.4407	
Region													0.8985
Europe	78	42	53.8	67.84	67	36	53.7	79.13	1.28	(0.81,	2.00)	0.2880	
Asia	45	23	51.1	67.30	41	22	53.7	68.04	0.96	(0.52,	1.77)	0.9056	
Canada and USA	30	15	50.0	57.93	37	24	64.9	81.17	1.27	(0.66,	2.44)	0.4703	
Rest of the World	16	9	56.3	78.29	25	13	52.0	65.22	1.15	(0.48,	2.73)	0.7564	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline fatigue domain score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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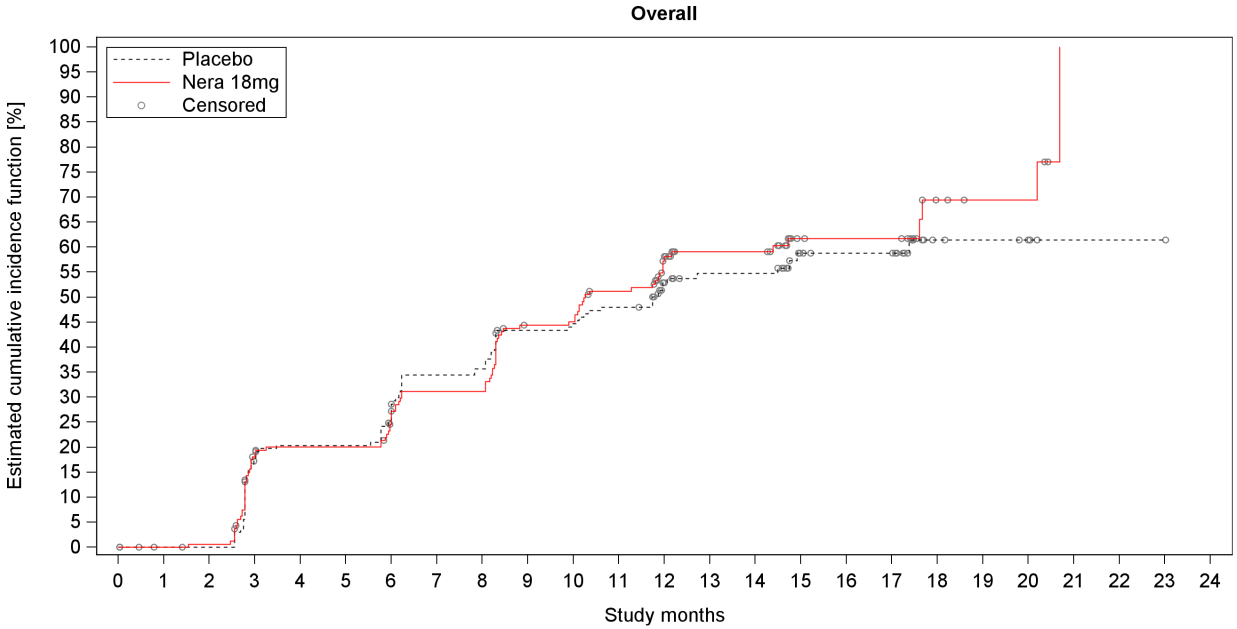

Number at risk (percentage relative to baseline)																									
Placebo	169	164	163	132	126	126	117	102	100	86	84	79	56	44	44	25	23	23	6	5	4	1	1	1	0
%	100.0	97.0	96.4	78.1	74.6	74.6	69.2	60.4	59.2	50.9	49.7	46.7	33.1	26.0	26.0	14.8	13.6	13.6	3.6	3.0	2.4	0.6	0.6	0.6	0.0
Nera 18mg	170	162	161	129	124	124	115	104	104	82	81	70	49	36	36	17	16	16	6	4	4	0	0	0	0
%	100.0	95.3	94.7	75.9	72.9	72.9	67.6	61.2	61.2	48.2	47.6	41.2	28.8	21.2	21.2	10.0	9.4	9.4	3.5	2.4	2.4	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	5	6	9	10	10	11	12	12	14	14	14	30	40	40	56	58	58	74	75	76	79	79	79	80
%	0.0	3.0	3.6	5.3	5.9	5.9	6.5	7.1	7.1	8.3	8.3	8.3	17.8	23.7	23.7	33.1	34.3	34.3	43.8	44.4	45.0	46.7	46.7	46.7	47.3
Nera 18mg	0	8	8	12	14	14	16	17	17	19	19	21	34	45	45	62	63	63	71	73	73	75	75	75	75
%	0.0	4.7	4.7	7.1	8.2	8.2	9.4	10.0	10.0	11.2	11.2	12.4	20.0	26.5	26.5	36.5	37.1	37.1	41.8	42.9	42.9	44.1	44.1	44.1	44.1

Study: 1305-0023

Figure I.2.1.1.1.3.2: 3 Time to first L-PF Fatigue domain score deterioration (increase >= 15) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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I.2.1.1.1.3.3 Patient Global Impression of Severity (PGI-S) scores

Table I.2.1.1.1.3.3: 1 Cox model for time to first PGI-S Cough score deterioration (increase >= 1) over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup	Placebo				Nera 18mg				Nera 18mg vs Placebo				
Category	N	n	%	Rate°	N	n	%	Rate°	Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	91	53.8	75.07	170	100	58.8	86.81	1.17	(0.88,	1.56)	0.2793	
Age													0.3057
<65 years	65	40	61.5	83.11	64	37	57.8	88.53	0.98	(0.62,	1.54)	0.9200	
>=65 years	104	51	49.0	69.78	106	63	59.4	85.82	1.33	(0.91,	1.94)	0.1374	
Sex													0.3921
Male	114	62	54.4	76.12	108	64	59.3	97.21	1.30	(0.91,	1.87)	0.1452	
Female	55	29	52.7	72.93	62	36	58.1	72.93	1.00	(0.61,	1.64)	0.9988	
Baseline FVC percent predicted													0.7250
<=70%	95	52	54.7	79.97	97	59	60.8	94.80	1.23	(0.84,	1.79)	0.2869	
>70%	74	39	52.7	69.41	73	41	56.2	77.41	1.11	(0.71,	1.72)	0.6555	
Baseline HRCT pattern													0.8877
UIP-like	116	63	54.3	74.83	121	72	59.5	84.00	1.16	(0.82,	1.64)	0.4136	
Other fibrotic patterns	53	28	52.8	75.63	49	28	57.1	94.95	1.21	(0.71,	2.05)	0.4786	
Underlying ILD diagnosis													0.5507
iNSIP	32	16	50.0	63.01	27	13	48.1	82.82	1.32	(0.63,	2.79)	0.4632	
Unclassifiable IIP	46	24	52.2	71.73	32	22	68.8	110.87	1.68	(0.94,	3.02)	0.0794	
HP	38	25	65.8	96.26	43	22	51.2	69.51	0.87	(0.49,	1.56)	0.6492	
Autoimmune ILD	29	11	37.9	45.36	43	24	55.8	70.14	1.38	(0.67,	2.85)	0.3824	
Other ILD	24	15	62.5	123.53	25	19	76.0	137.78	0.97	(0.49,	1.94)	0.9366	
Region													0.6918
Europe	78	44	56.4	85.78	67	40	59.7	92.77	1.03	(0.67,	1.58)	0.9017	
Asia	45	24	53.3	67.85	41	21	51.2	66.65	1.11	(0.61,	2.05)	0.7302	
Canada and USA	30	15	50.0	61.90	37	24	64.9	95.76	1.66	(0.86,	3.20)	0.1313	
Rest of the World	16	8	50.0	77.55	25	15	60.0	96.71	1.13	(0.47,	2.72)	0.7827	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline cough score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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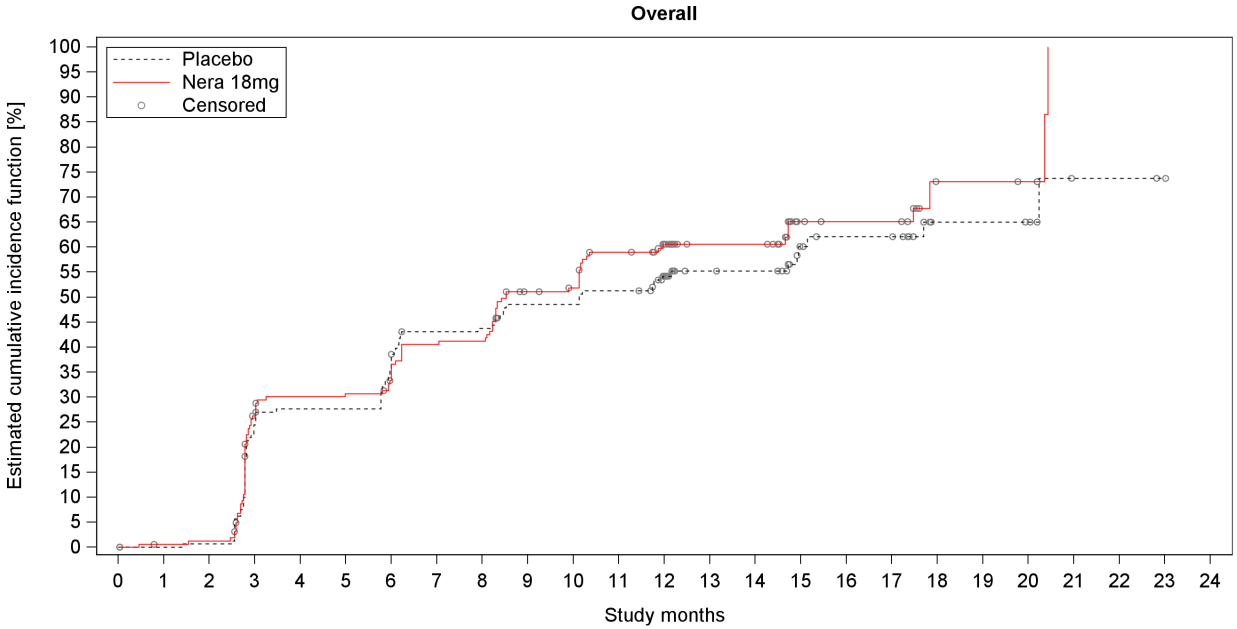

Number at risk (percentage relative to baseline)																									
Placebo	169	160	159	119	113	113	101	85	84	75	75	71	51	38	37	21	18	18	7	7	6	2	2	1	0
%	100.0	94.7	94.1	70.4	66.9	66.9	59.8	50.3	49.7	44.4	44.4	42.0	30.2	22.5	21.9	12.4	10.7	10.7	4.1	4.1	3.6	1.2	1.2	0.6	0.0
Nera 18mg	170	161	160	116	109	108	101	90	89	71	68	56	43	32	32	17	15	15	4	4	3	0	0	0	0
%	100.0	94.7	94.1	68.2	64.1	63.5	59.4	52.9	52.4	41.8	40.0	32.9	25.3	18.8	18.8	10.0	8.8	8.8	2.4	2.4	1.8	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	9	9	11	12	12	12	16	16	18	18	18	34	46	47	60	62	62	72	72	73	76	76	77	78
%	0.0	5.3	5.3	6.5	7.1	7.1	7.1	9.5	9.5	10.7	10.7	10.7	20.1	27.2	27.8	35.5	36.7	36.7	42.6	42.6	43.2	45.0	45.0	45.6	46.2
Nera 18mg	0	8	8	12	13	13	16	16	16	19	21	23	34	45	45	57	59	59	68	68	69	70	70	70	70
%	0.0	4.7	4.7	7.1	7.6	7.6	9.4	9.4	9.4	11.2	12.4	13.5	20.0	26.5	26.5	33.5	34.7	34.7	40.0	40.0	40.6	41.2	41.2	41.2	41.2

Study: 1305-0023

Figure I.2.1.1.1.3.3: 1 Time to first PGI-S Cough score deterioration (increase >= 1) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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BI Trial No.: x1305p3.hta

Figure I.2.1.1.1.3.3: 1

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Table I.2.1.1.1.3.3: 2 Cox model for time to first PGI-S Shortness of Breath score deterioration (increase >=1) over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	89	52.7	69.93	170	87	51.2	68.65	0.98	(0.72, 1.32)	0.8737	
Age												0.5492
<65 years	65	33	50.8	61.87	64	32	50.0	69.49	0.87	(0.53, 1.42)	0.5779	
>=65 years	104	56	53.8	75.75	106	55	51.9	68.17	1.05	(0.72, 1.55)	0.7896	
Sex												0.4197
Male	114	59	51.8	69.03	108	55	50.9	68.03	1.07	(0.73, 1.55)	0.7319	
Female	55	30	54.5	71.77	62	32	51.6	69.75	0.82	(0.49, 1.37)	0.4499	
Baseline FVC percent predicted												0.6795
<=70%	95	58	61.1	86.80	97	54	55.7	75.73	0.93	(0.64, 1.35)	0.7158	
>70%	74	31	41.9	51.29	73	33	45.2	59.55	1.06	(0.65, 1.75)	0.8088	
Baseline HRCT pattern												0.8241
UIP-like	116	60	51.7	68.88	121	63	52.1	66.61	1.00	(0.70, 1.43)	0.9947	
Other fibrotic patterns	53	29	54.7	72.21	49	24	49.0	74.67	0.93	(0.54, 1.59)	0.7849	
Underlying ILD diagnosis												0.2321
iNSIP	32	17	53.1	69.18	27	13	48.1	73.65	1.31	(0.63, 2.73)	0.4772	
Unclassifiable IIP	46	23	50.0	67.34	32	21	65.6	91.14	1.27	(0.70, 2.31)	0.4344	
HP	38	25	65.8	94.40	43	17	39.5	49.76	0.70	(0.37, 1.31)	0.2623	
Autoimmune ILD	29	16	55.2	69.86	43	22	51.2	65.22	0.68	(0.35, 1.31)	0.2473	
Other ILD	24	8	33.3	41.77	25	14	56.0	77.20	1.84	(0.77, 4.40)	0.1697	
Region												0.9993
Europe	78	40	51.3	70.76	67	33	49.3	65.98	0.97	(0.61, 1.55)	0.9143	
Asia	45	21	46.7	54.91	41	20	48.8	66.16	0.98	(0.52, 1.86)	0.9482	
Canada and USA	30	19	63.3	83.07	37	21	56.8	71.05	0.97	(0.52, 1.80)	0.9127	
Rest of the World	16	9	56.3	93.57	25	13	52.0	76.81	1.04	(0.44, 2.47)	0.9340	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb), baseline shortness of breath score. The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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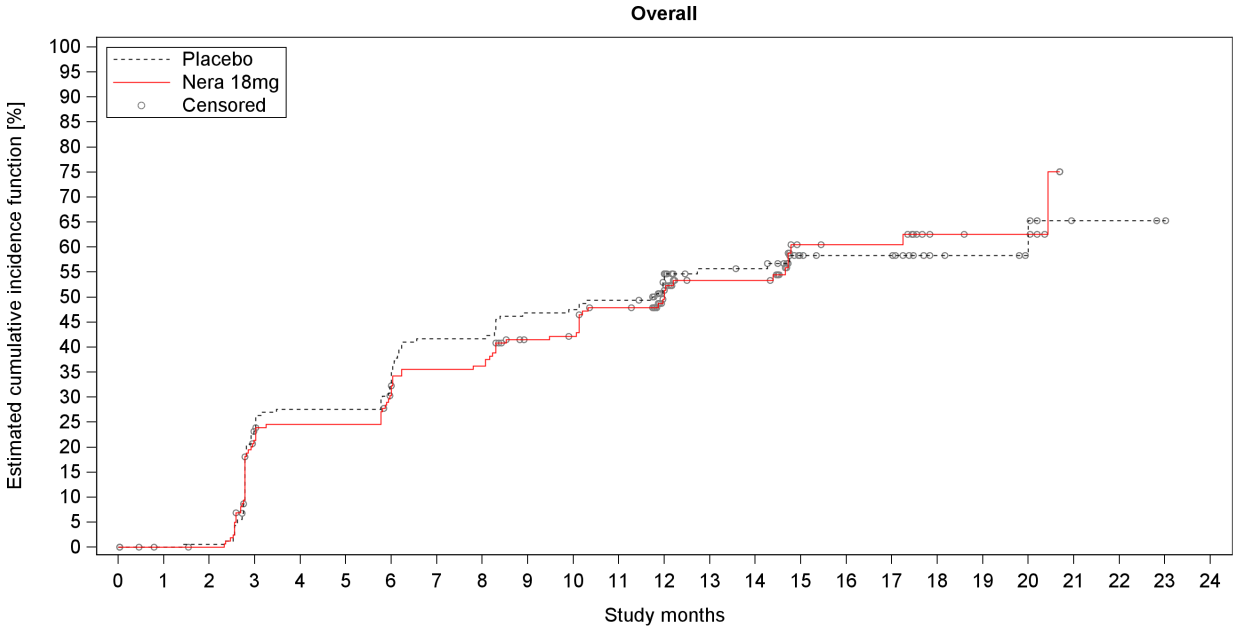

Number at risk (percentage relative to baseline)																									
Placebo	169	162	161	120	113	113	106	91	91	83	82	79	56	44	43	22	20	20	9	8	6	2	2	1	0
%	100.0	95.9	95.3	71.0	66.9	66.9	62.7	53.8	53.8	49.1	48.5	46.7	33.1	26.0	25.4	13.0	11.8	11.8	5.3	4.7	3.6	1.2	1.2	0.6	0.0
Nera 18mg	170	161	160	124	118	118	107	98	97	83	81	71	56	41	41	20	19	19	7	6	6	0	0	0	0
%	100.0	94.7	94.1	72.9	69.4	69.4	62.9	57.6	57.1	48.8	47.6	41.8	32.9	24.1	24.1	11.8	11.2	11.2	4.1	3.5	3.5	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	7	7	12	12	12	12	12	12	12	12	12	30	39	40	59	61	61	72	73	75	78	78	79	80
%	0.0	4.1	4.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	7.1	17.8	23.1	23.7	34.9	36.1	36.1	42.6	43.2	44.4	46.2	46.2	46.7	47.3
Nera 18mg	0	9	10	12	13	13	15	16	16	22	23	25	38	49	49	65	66	66	77	78	78	83	83	83	83
%	0.0	5.3	5.9	7.1	7.6	7.6	8.8	9.4	9.4	12.9	13.5	14.7	22.4	28.8	28.8	38.2	38.8	38.8	45.3	45.9	45.9	48.8	48.8	48.8	48.8

Study: 1305-0023

Figure I.2.1.1.1.3.3: 2 Time to first PGI-S Shortness of Breath score deterioration (increase >=1) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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Figure I.2.1.1.1.3.3: 2

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I.2.1.1.1.4 Time to event analyses of supplemental oxygen use

Table I.2.1.1.1.4: 1 Cox model for time to first use of supplemental oxygen (in patients without baseline use) over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	102	24	23.5	21.93	97	23	23.7	24.03	1.09	(0.62,	1.94)	0.7613	
Age													0.5897
<65 years	44	8	18.2	16.46	41	10	24.4	23.76	1.34	(0.52,	3.42)	0.5436	
>=65 years	58	16	27.6	26.30	56	13	23.2	24.24	0.96	(0.46,	2.01)	0.9185	
Sex													0.6655
Male	66	18	27.3	26.05	61	18	29.5	32.13	1.18	(0.61,	2.30)	0.6206	
Female	36	6	16.7	14.86	36	5	13.9	12.60	0.87	(0.26,	2.89)	0.8218	
Baseline FVC percent predicted													0.6465
<=70%	49	17	34.7	34.58	46	15	32.6	34.89	0.98	(0.49,	1.97)	0.9593	
>70%	53	7	13.2	11.61	51	8	15.7	15.18	1.31	(0.47,	3.63)	0.6016	
Baseline HRCT pattern													0.1801
UIP-like	74	16	21.6	19.90	73	19	26.0	26.16	1.39	(0.71,	2.72)	0.3378	
Other fibrotic patterns	28	8	28.6	27.51	24	4	16.7	17.33	0.54	(0.16,	1.80)	0.3130	
Underlying ILD diagnosis													0.8555
iNSIP	19	4	21.1	19.68	15	1	6.7	7.13	0.35	(0.04,	3.16)	0.3471	
Unclassifiable IIP	23	6	26.1	24.35	16	3	18.8	17.71	1.14	(0.27,	4.74)	0.8562	
HP	26	6	23.1	21.60	21	6	28.6	32.06	1.35	(0.43,	4.21)	0.6105	
Autoimmune ILD	19	3	15.8	14.05	25	6	24.0	22.43	1.01	(0.25,	4.13)	0.9893	
Other ILD	15	5	33.3	32.54	20	7	35.0	36.32	1.39	(0.44,	4.45)	0.5762	
Region													0.8195
Europe	48	11	22.9	20.75	42	8	19.0	21.57	1.18	(0.47,	2.94)	0.7272	
Asia	34	8	23.5	22.25	26	6	23.1	22.16	0.81	(0.28,	2.36)	0.6934	
Canada and USA	11	2	18.2	17.34	12	2	16.7	13.44	0.58	(0.08,	4.13)	0.5846	
Rest of the World	9	3	33.3	33.44	17	7	41.2	42.03	1.53	(0.37,	6.25)	0.5556	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb). The subgroup model additionally includes the subgroup and treatment by subgroup interaction. Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined). N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk. NC=not calculable.

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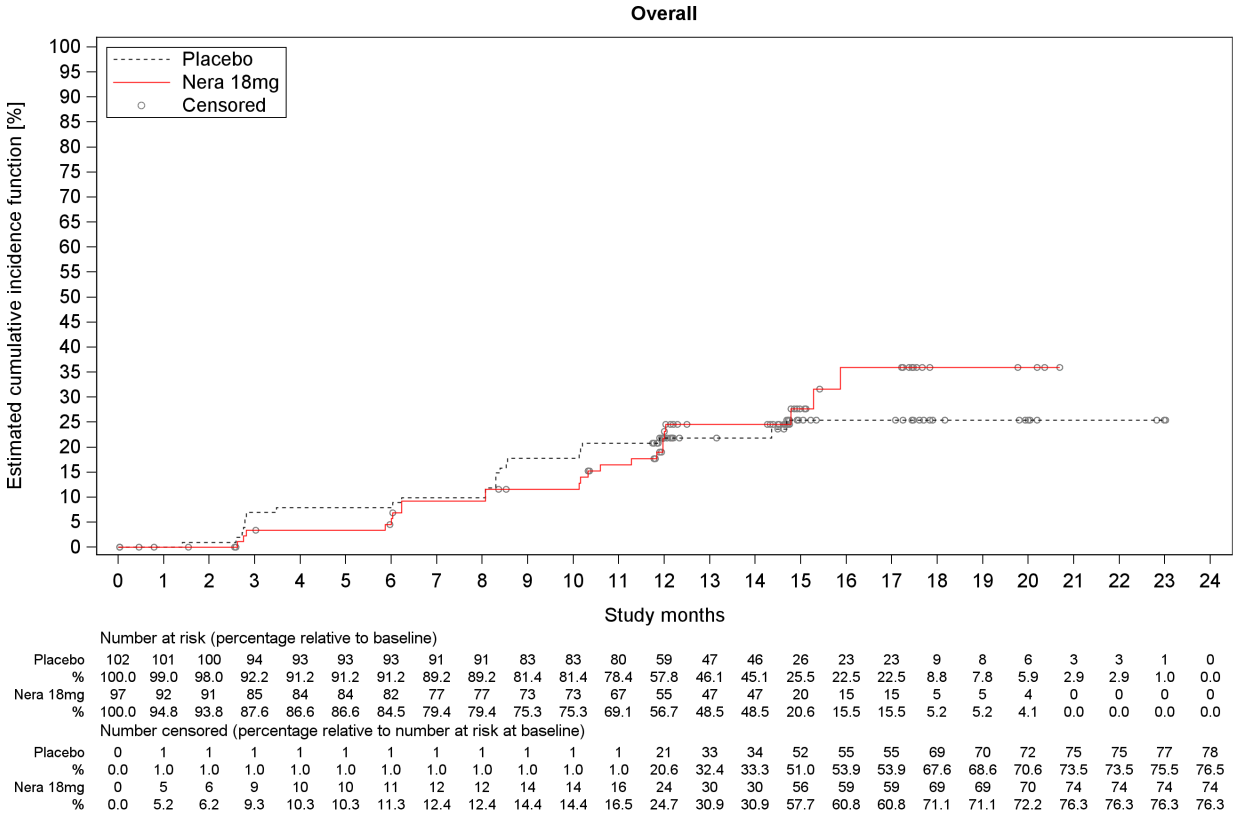

Number at risk (percentage relative to baseline)																									
Placebo	102	101	100	94	93	93	93	91	91	83	83	80	59	47	46	26	23	23	9	8	6	3	3	1	0
%	100.0	99.0	98.0	92.2	91.2	91.2	91.2	89.2	89.2	81.4	81.4	78.4	57.8	46.1	45.1	25.5	22.5	22.5	8.8	7.8	5.9	2.9	2.9	1.0	0.0
Nera 18mg	97	92	91	85	84	84	82	77	77	73	73	67	55	47	47	20	15	15	5	5	4	0	0	0	0
%	100.0	94.8	93.8	87.6	86.6	86.6	84.5	79.4	79.4	75.3	75.3	69.1	56.7	48.5	48.5	20.6	15.5	15.5	5.2	5.2	4.1	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	1	1	1	1	1	1	1	1	1	1	1	21	33	34	52	55	55	69	70	72	75	75	77	78
%	0.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	20.6	32.4	33.3	51.0	53.9	53.9	67.6	68.6	70.6	73.5	73.5	75.5	76.5
Nera 18mg	0	5	6	9	10	10	11	12	12	14	14	16	24	30	30	56	59	59	69	69	70	74	74	74	74
%	0.0	5.2	6.2	9.3	10.3	10.3	11.3	12.4	12.4	14.4	14.4	16.5	24.7	30.9	30.9	57.7	60.8	60.8	71.1	71.1	72.2	76.3	76.3	76.3	76.3

Study: 1305-0023

Figure I.2.1.1.1.4: 1 Time to first use of supplemental oxygen (in patients without baseline use) over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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Table I.2.1.1.1.4: 2 Cox model for time to first increase of supplemental oxygen use over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	169	71	42.0	48.93	170	73	42.9	53.20	1.00	(0.72,	1.39)	0.9990	
Age													0.8866
<65 years	65	23	35.4	38.86	64	25	39.1	46.49	0.96	(0.54,	1.71)	0.8874	
>=65 years	104	48	46.2	55.87	106	48	45.3	57.53	1.01	(0.67,	1.51)	0.9626	
Sex													0.7446
Male	114	51	44.7	53.57	108	48	44.4	59.40	0.97	(0.65,	1.45)	0.8787	
Female	55	20	36.4	40.08	62	25	40.3	44.32	1.09	(0.60,	1.99)	0.7697	
Baseline FVC percent predicted													0.5702
<=70%	95	50	52.6	70.61	97	52	53.6	71.10	0.94	(0.63,	1.38)	0.7438	
>70%	74	21	28.4	28.27	73	21	28.8	32.78	1.15	(0.63,	2.12)	0.6426	
Baseline HRCT pattern													0.3510
UIP-like	116	43	37.1	40.84	121	53	43.8	52.14	1.12	(0.75,	1.68)	0.5871	
Other fibrotic patterns	53	28	52.8	70.34	49	20	40.8	56.26	0.80	(0.45,	1.42)	0.4473	
Underlying ILD diagnosis													0.9713
iNSIP	32	10	31.3	34.35	27	10	37.0	55.04	1.37	(0.57,	3.32)	0.4855	
Unclassifiable IIP	46	23	50.0	66.69	32	14	43.8	53.60	1.04	(0.53,	2.03)	0.9108	
HP	38	18	47.4	52.38	43	19	44.2	58.84	0.93	(0.49,	1.79)	0.8351	
Autoimmune ILD	29	9	31.0	33.48	43	20	46.5	52.71	1.06	(0.47,	2.37)	0.8880	
Other ILD	24	11	45.8	54.32	25	10	40.0	44.09	0.95	(0.40,	2.24)	0.8981	
Region													0.8044
Europe	78	32	41.0	44.51	67	24	35.8	47.44	1.09	(0.64,	1.85)	0.7621	
Asia	45	14	31.1	33.12	41	16	39.0	43.04	0.94	(0.46,	1.94)	0.8734	
Canada and USA	30	17	56.7	83.74	37	20	54.1	66.74	0.72	(0.37,	1.40)	0.3386	
Rest of the World	16	8	50.0	75.25	25	13	52.0	66.75	0.79	(0.32,	1.94)	0.6059	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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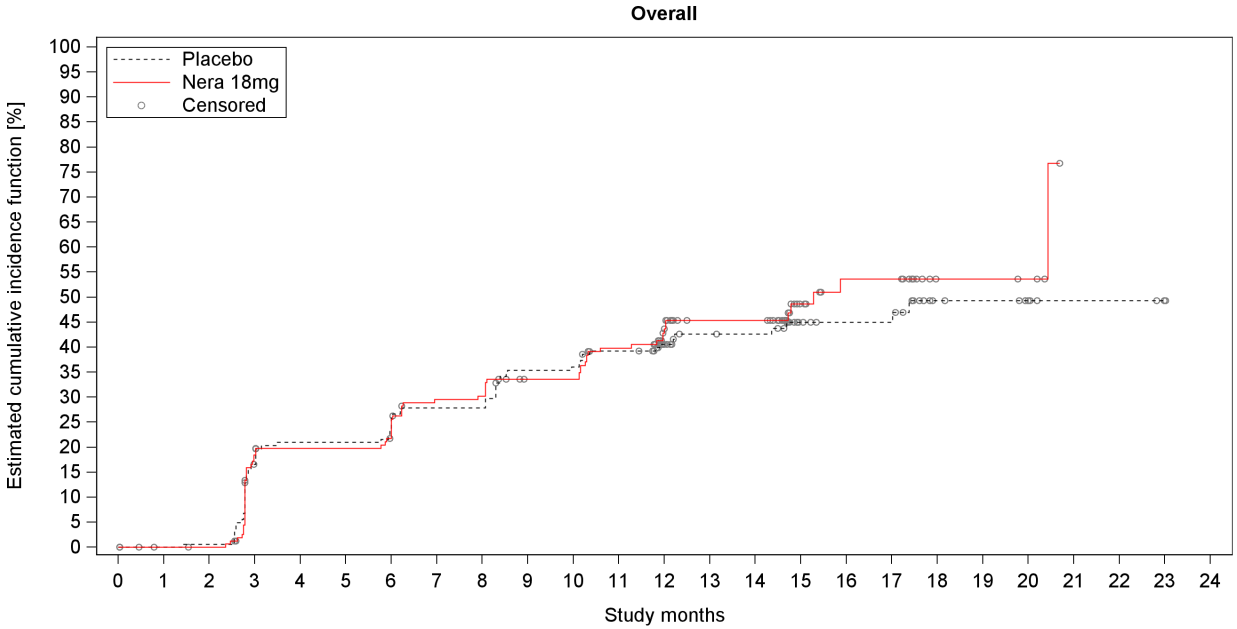

	Number at risk (percentage relative to baseline)																								
Placebo	169	163	162	134	126	126	122	115	115	102	101	95	68	54	53	30	27	27	9	8	6	3	3	1	0
%	100.0	96.4	95.9	79.3	74.6	74.6	72.2	68.0	68.0	60.4	59.8	56.2	40.2	32.0	31.4	17.8	16.0	16.0	5.3	4.7	3.6	1.8	1.8	0.6	0.0
Nera 18mg	170	161	160	127	124	124	120	106	105	96	96	85	69	54	54	24	18	18	6	6	5	0	0	0	0
%	100.0	94.7	94.1	74.7	72.9	72.9	70.6	62.4	61.8	56.5	56.5	50.0	40.6	31.8	31.8	14.1	10.6	10.6	3.5	3.5	2.9	0.0	0.0	0.0	0.0
	Number censored (percentage relative to number at risk at baseline)																								
Placebo	0	6	6	8	9	9	9	9	9	10	10	11	36	48	49	70	73	73	89	90	92	95	95	97	98
%	0.0	3.6	3.6	4.7	5.3	5.3	5.3	5.3	5.3	5.9	5.9	6.5	21.3	28.4	29.0	41.4	43.2	43.2	52.7	53.3	54.4	56.2	56.2	57.4	58.0
Nera 18mg	0	9	10	14	15	15	16	18	18	22	22	24	36	48	48	76	80	80	92	92	93	97	97	97	97
%	0.0	5.3	5.9	8.2	8.8	8.8	9.4	10.6	10.6	12.9	12.9	14.1	21.2	28.2	28.2	44.7	47.1	47.1	54.1	54.1	54.7	57.1	57.1	57.1	57.1

Study: 1305-0023

Figure I.2.1.1.1.4: 2 Time to first increase of supplemental oxygen use over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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I.2.1.2 Safety analysis

I.2.1.2.1 Safety analysis over the whole trial

I.2.1.2.1.1 Adverse events overall over the whole trial

Table I.2.1.2.1.1: 1 Proportion of patients with any adverse events over the whole trial (DBL1) - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	161	95.3	170	160	94.1	0.6372	0.99 (0.94, 1.04)	0.80 (0.31, 2.07)	-1.15 (-6.30, 3.93)	
Age											0.5534
<65 years	65	60	92.3	64	57	89.1	0.5258	0.96 (0.86, 1.08)	0.68 (0.20, 2.26)	-3.25 (-14.12, 7.39)	
>=65 years	104	101	97.1	106	103	97.2	0.9811	1.00 (0.96, 1.05)	1.02 (0.20, 5.17)	0.05 (-5.45, 5.63)	
Sex											0.3298
Male	114	108	94.7	108	103	95.4	0.8279	1.01 (0.95, 1.07)	1.14 (0.34, 3.87)	0.63 (-5.78, 6.96)	
Female	55	53	96.4	62	57	91.9	0.3135	0.95 (0.87, 1.04)	0.43 (0.08, 2.31)	-4.43 (-14.25, 5.39)	
Baseline FVC percent predicted											0.6880
<=70%	95	90	94.7	97	90	92.8	0.5761	0.98 (0.91, 1.05)	0.71 (0.22, 2.33)	-1.95 (-9.51, 5.49)	
>70%	74	71	95.9	73	70	95.9	0.9864	1.00 (0.93, 1.07)	0.99 (0.19, 5.05)	-0.06 (-7.82, 7.64)	
Baseline HRCT pattern											0.7434
UIP-like	116	111	95.7	121	115	95.0	0.8125	0.99 (0.94, 1.05)	0.86 (0.26, 2.91)	-0.65 (-6.62, 5.36)	
Other fibrotic patterns	53	50	94.3	49	45	91.8	0.6174	0.97 (0.88, 1.08)	0.68 (0.14, 3.18)	-2.50 (-14.14, 8.39)	
Underlying ILD diagnosis											0.3721
iNSIP	32	29	90.6	27	25	92.6	0.7869	1.02 (0.88, 1.19)	1.29 (0.20, 8.37)	1.97 (-15.13, 17.75)	
Unclassifiable IIP	46	44	95.7	32	32	100.0	0.2321	1.05 (0.98, 1.11)	NC (NC, NC)	4.35 (-6.82, 14.53)	
HP	38	36	94.7	43	40	93.0	0.7491	0.98 (0.88, 1.10)	0.74 (0.12, 4.69)	-1.71 (-13.95, 11.15)	
Autoimmune ILD	29	28	96.6	43	39	90.7	0.3379	0.94 (0.83, 1.06)	0.35 (0.04, 3.29)	-5.85 (-18.48, 8.98)	
Other ILD	24	24	100.0	25	24	96.0	0.3222	0.96 (0.89, 1.04)	0.00 (NC, NC)	-4.00 (-19.54, 10.18)	
Region											0.9349
Europe	78	75	96.2	67	63	94.0	0.5519	0.98 (0.91, 1.05)	0.63 (0.14, 2.92)	-2.12 (-10.90, 5.64)	
Asia	45	41	91.1	41	37	90.2	0.8900	0.99 (0.86, 1.13)	0.90 (0.21, 3.87)	-0.87 (-14.74, 12.36)	
Canada and USA	30	30	100.0	37	36	97.3	0.3643	0.97 (0.92, 1.03)	0.00 (NC, NC)	-2.70 (-13.82, 8.86)	
Rest of the World	16	15	93.8	25	24	96.0	0.7442	1.02 (0.88, 1.19)	1.60 (0.09, 27.55)	2.25 (-14.12, 24.57)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.1.2.1.1: 2 Proportion of patients with any adverse events (excluding disease-related events) over the whole trial (DBL1) - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	161	95.3	170	159	93.5	0.4870	0.98 (0.93, 1.03)	0.72 (0.28, 1.83)	-1.74 (-7.02, 3.43)	
Age											0.3971
<65 years	65	60	92.3	64	56	87.5	0.3644	0.95 (0.84, 1.06)	0.58 (0.18, 1.89)	-4.81 (-15.97, 6.09)	
>=65 years	104	101	97.1	106	103	97.2	0.9811	1.00 (0.96, 1.05)	1.02 (0.20, 5.17)	0.05 (-5.45, 5.63)	
Sex											0.4323
Male	114	108	94.7	108	102	94.4	0.9233	1.00 (0.94, 1.06)	0.94 (0.30, 3.02)	-0.29 (-6.96, 6.18)	
Female	55	53	96.4	62	57	91.9	0.3135	0.95 (0.87, 1.04)	0.43 (0.08, 2.31)	-4.43 (-14.25, 5.39)	
Baseline FVC percent predicted											0.9110
<=70%	95	90	94.7	97	90	92.8	0.5761	0.98 (0.91, 1.05)	0.71 (0.22, 2.33)	-1.95 (-9.51, 5.49)	
>70%	74	71	95.9	73	69	94.5	0.6849	0.99 (0.92, 1.06)	0.73 (0.16, 3.38)	-1.43 (-9.65, 6.51)	
Baseline HRCT pattern											0.8546
UIP-like	116	111	95.7	121	114	94.2	0.6047	0.98 (0.93, 1.04)	0.73 (0.23, 2.38)	-1.47 (-7.66, 4.67)	
Other fibrotic patterns	53	50	94.3	49	45	91.8	0.6174	0.97 (0.88, 1.08)	0.68 (0.14, 3.18)	-2.50 (-14.14, 8.39)	
Underlying ILD diagnosis											0.2619
iNSIP	32	29	90.6	27	25	92.6	0.7869	1.02 (0.88, 1.19)	1.29 (0.20, 8.37)	1.97 (-15.13, 17.75)	
Unclassifiable IIP	46	44	95.7	32	32	100.0	0.2321	1.05 (0.98, 1.11)	NC (NC, NC)	4.35 (-6.82, 14.53)	
HP	38	36	94.7	43	40	93.0	0.7491	0.98 (0.88, 1.10)	0.74 (0.12, 4.69)	-1.71 (-13.95, 11.15)	
Autoimmune ILD	29	28	96.6	43	39	90.7	0.3379	0.94 (0.83, 1.06)	0.35 (0.04, 3.29)	-5.85 (-18.48, 8.98)	
Other ILD	24	24	100.0	25	23	92.0	0.1571	0.92 (0.82, 1.03)	0.00 (NC, NC)	-8.00 (-24.97, 6.96)	
Region											0.9038
Europe	78	75	96.2	67	62	92.5	0.3416	0.96 (0.89, 1.04)	0.50 (0.11, 2.16)	-3.62 (-12.82, 4.45)	
Asia	45	41	91.1	41	37	90.2	0.8900	0.99 (0.86, 1.13)	0.90 (0.21, 3.87)	-0.87 (-14.74, 12.36)	
Canada and USA	30	30	100.0	37	36	97.3	0.3643	0.97 (0.92, 1.03)	0.00 (NC, NC)	-2.70 (-13.82, 8.86)	
Rest of the World	16	15	93.8	25	24	96.0	0.7442	1.02 (0.88, 1.19)	1.60 (0.09, 27.55)	2.25 (-14.12, 24.57)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.1.2.1.1: 3 Proportion of patients with serious adverse events over the whole trial (DBL1) - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	71	42.0	170	78	45.9	0.4728	1.09 (0.86, 1.39)	1.17 (0.76, 1.80)	3.87 (-6.63, 14.25)	
Age											0.7124
<65 years	65	23	35.4	64	23	35.9	0.9477	1.02 (0.64, 1.61)	1.02 (0.50, 2.11)	0.55 (-15.60, 16.69)	
>=65 years	104	48	46.2	106	55	51.9	0.4060	1.12 (0.85, 1.48)	1.26 (0.73, 2.16)	5.73 (-7.67, 18.85)	
Sex											0.8611
Male	114	51	44.7	108	54	50.0	0.4324	1.12 (0.85, 1.48)	1.24 (0.73, 2.09)	5.26 (-7.76, 18.05)	
Female	55	20	36.4	62	24	38.7	0.7937	1.06 (0.67, 1.70)	1.11 (0.52, 2.34)	2.35 (-14.93, 19.24)	
Baseline FVC percent predicted											0.0322
<=70%	95	47	49.5	97	42	43.3	0.3910	0.88 (0.64, 1.19)	0.78 (0.44, 1.38)	-6.17 (-19.82, 7.80)	
>70%	74	24	32.4	73	36	49.3	0.0373	1.52 (1.02, 2.27)	2.03 (1.04, 3.96)	16.88 (1.01, 31.62)	
Baseline HRCT pattern											0.7911
UIP-like	116	51	44.0	121	59	48.8	0.4594	1.11 (0.84, 1.46)	1.21 (0.73, 2.02)	4.79 (-7.80, 17.17)	
Other fibrotic patterns	53	20	37.7	49	19	38.8	0.9140	1.03 (0.63, 1.68)	1.05 (0.47, 2.32)	1.04 (-17.22, 19.33)	
Underlying ILD diagnosis											0.2424
iNSIP	32	11	34.4	27	11	40.7	0.6144	1.19 (0.61, 2.29)	1.31 (0.46, 3.78)	6.37 (-17.36, 29.57)	
Unclassifiable IIP	46	28	60.9	32	14	43.8	0.1357	0.72 (0.46, 1.13)	0.50 (0.20, 1.25)	-17.12 (-37.25, 5.11)	
HP	38	11	28.9	43	20	46.5	0.1046	1.61 (0.89, 2.91)	2.13 (0.85, 5.37)	17.56 (-3.55, 36.41)	
Autoimmune ILD	29	12	41.4	43	20	46.5	0.6673	1.12 (0.66, 1.93)	1.23 (0.48, 3.19)	5.13 (-17.58, 26.68)	
Other ILD	24	9	37.5	25	13	52.0	0.3077	1.39 (0.73, 2.63)	1.81 (0.58, 5.64)	14.50 (-12.59, 38.79)	
Region											0.8398
Europe	78	31	39.7	67	28	41.8	0.8024	1.05 (0.71, 1.56)	1.09 (0.56, 2.12)	2.05 (-13.61, 17.71)	
Asia	45	25	55.6	41	27	65.9	0.3293	1.19 (0.84, 1.67)	1.54 (0.64, 3.69)	10.30 (-10.11, 29.41)	
Canada and USA	30	9	30.0	37	10	27.0	0.7883	0.90 (0.42, 1.93)	0.86 (0.30, 2.51)	-2.97 (-24.30, 17.82)	
Rest of the World	16	6	37.5	25	13	52.0	0.3638	1.39 (0.66, 2.90)	1.81 (0.50, 6.50)	14.50 (-15.69, 40.66)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.1.2.1.1: 4 Proportion of patients with serious adverse events (excluding disease-related events) over the whole trial (DBL1) - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	67	39.6	170	74	43.5	0.4681	1.10 (0.85, 1.41)	1.17 (0.76, 1.81)	3.88 (-6.55, 14.20)	
Age											0.3989
<65 years	65	23	35.4	64	21	32.8	0.7580	0.93 (0.57, 1.50)	0.89 (0.43, 1.85)	-2.57 (-18.46, 13.52)	
>=65 years	104	44	42.3	106	53	50.0	0.2636	1.18 (0.88, 1.59)	1.36 (0.79, 2.35)	7.69 (-5.71, 20.71)	
Sex											0.8507
Male	114	47	41.2	108	50	46.3	0.4467	1.12 (0.83, 1.51)	1.23 (0.72, 2.09)	5.07 (-7.87, 17.79)	
Female	55	20	36.4	62	24	38.7	0.7937	1.06 (0.67, 1.70)	1.11 (0.52, 2.34)	2.35 (-14.93, 19.24)	
Baseline FVC percent predicted											0.0883
<=70%	95	43	45.3	97	40	41.2	0.5734	0.91 (0.66, 1.26)	0.85 (0.48, 1.50)	-4.03 (-17.67, 9.82)	
>70%	74	24	32.4	73	34	46.6	0.0794	1.44 (0.95, 2.16)	1.82 (0.93, 3.55)	14.14 (-1.62, 28.97)	
Baseline HRCT pattern											0.9585
UIP-like	116	48	41.4	121	55	45.5	0.5269	1.10 (0.82, 1.47)	1.18 (0.71, 1.97)	4.08 (-8.44, 16.40)	
Other fibrotic patterns	53	19	35.8	49	19	38.8	0.7600	1.08 (0.65, 1.79)	1.13 (0.51, 2.53)	2.93 (-15.34, 21.06)	
Underlying ILD diagnosis											0.2630
iNSIP	32	11	34.4	27	10	37.0	0.8315	1.08 (0.54, 2.14)	1.12 (0.39, 3.27)	2.66 (-20.58, 26.03)	
Unclassifiable IIP	46	25	54.3	32	12	37.5	0.1427	0.69 (0.41, 1.16)	0.50 (0.20, 1.27)	-16.85 (-36.71, 5.47)	
HP	38	11	28.9	43	20	46.5	0.1046	1.61 (0.89, 2.91)	2.13 (0.85, 5.37)	17.56 (-3.55, 36.41)	
Autoimmune ILD	29	12	41.4	43	20	46.5	0.6673	1.12 (0.66, 1.93)	1.23 (0.48, 3.19)	5.13 (-17.58, 26.68)	
Other ILD	24	8	33.3	25	12	48.0	0.2964	1.44 (0.72, 2.89)	1.85 (0.58, 5.86)	14.67 (-12.19, 38.71)	
Region											0.6850
Europe	78	30	38.5	67	26	38.8	0.9661	1.01 (0.67, 1.52)	1.01 (0.52, 1.98)	0.34 (-15.11, 15.95)	
Asia	45	24	53.3	41	26	63.4	0.3439	1.19 (0.83, 1.70)	1.52 (0.64, 3.60)	10.08 (-10.47, 29.37)	
Canada and USA	30	8	26.7	37	9	24.3	0.8266	0.91 (0.40, 2.07)	0.88 (0.29, 2.67)	-2.34 (-23.23, 17.79)	
Rest of the World	16	5	31.3	25	13	52.0	0.1916	1.66 (0.73, 3.77)	2.38 (0.64, 8.89)	20.75 (-9.83, 45.54)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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I.2.1.2.1.2 Adverse events by intensity over the whole trial

Table I.2.1.2.1.2: 1 Proportion of patients with any adverse events with CTCAE grade >=3 over the whole trial (DBL1) - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	62	36.7	170	79	46.5	0.0676	1.27 (0.98, 1.64)	1.50 (0.97, 2.31)	9.78 (-0.70, 19.97)	
Age											0.9400
<65 years	65	19	29.2	64	24	37.5	0.3192	1.28 (0.78, 2.10)	1.45 (0.70, 3.03)	8.27 (-7.87, 23.86)	
>=65 years	104	43	41.3	106	55	51.9	0.1258	1.25 (0.94, 1.68)	1.53 (0.89, 2.64)	10.54 (-2.91, 23.46)	
Sex											0.8075
Male	114	43	37.7	108	53	49.1	0.0878	1.30 (0.96, 1.76)	1.59 (0.93, 2.72)	11.35 (-1.65, 23.86)	
Female	55	19	34.5	62	26	41.9	0.4122	1.21 (0.76, 1.94)	1.37 (0.65, 2.90)	7.39 (-10.09, 24.09)	
Baseline FVC percent predicted											0.0934
<=70%	95	40	42.1	97	43	44.3	0.7557	1.05 (0.76, 1.46)	1.09 (0.62, 1.94)	2.22 (-11.59, 15.91)	
>70%	74	22	29.7	73	36	49.3	0.0151	1.66 (1.09, 2.53)	2.30 (1.17, 4.53)	19.59 (3.78, 34.09)	
Baseline HRCT pattern											0.9315
UIP-like	116	46	39.7	121	60	49.6	0.1242	1.25 (0.94, 1.67)	1.50 (0.89, 2.51)	9.93 (-2.70, 22.11)	
Other fibrotic patterns	53	16	30.2	49	19	38.8	0.3614	1.28 (0.75, 2.20)	1.46 (0.64, 3.33)	8.59 (-9.60, 26.17)	
Underlying ILD diagnosis											0.2578
iNSIP	32	11	34.4	27	10	37.0	0.8315	1.08 (0.54, 2.14)	1.12 (0.39, 3.27)	2.66 (-20.58, 26.03)	
Unclassifiable IIP	46	22	47.8	32	12	37.5	0.3657	0.78 (0.46, 1.34)	0.65 (0.26, 1.64)	-10.33 (-30.55, 11.70)	
HP	38	12	31.6	43	20	46.5	0.1701	1.47 (0.84, 2.60)	1.88 (0.76, 4.68)	14.93 (-6.24, 34.13)	
Autoimmune ILD	29	10	34.5	43	23	53.5	0.1124	1.55 (0.87, 2.75)	2.19 (0.83, 5.78)	19.01 (-4.29, 39.19)	
Other ILD	24	7	29.2	25	14	56.0	0.0578	1.92 (0.94, 3.92)	3.09 (0.95, 10.08)	26.83 (-0.71, 49.27)	
Region											0.9451
Europe	78	28	35.9	67	29	43.3	0.3640	1.21 (0.81, 1.81)	1.36 (0.70, 2.66)	7.39 (-8.35, 22.78)	
Asia	45	22	48.9	41	25	61.0	0.2608	1.25 (0.85, 1.84)	1.63 (0.69, 3.85)	12.09 (-8.69, 31.39)	
Canada and USA	30	5	16.7	37	10	27.0	0.3117	1.62 (0.62, 4.23)	1.85 (0.56, 6.17)	10.36 (-10.15, 28.84)	
Rest of the World	16	7	43.8	25	15	60.0	0.3087	1.37 (0.72, 2.60)	1.93 (0.54, 6.88)	16.25 (-13.80, 42.74)	

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.1.2.1.2: 2 Proportion of patients with any adverse events (excluding disease-related events) with CTCAE grade >=3 over the whole trial (DBL1) - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	58	34.3	170	75	44.1	0.0647	1.29 (0.98, 1.68)	1.51 (0.97, 2.34)	9.80 (-0.59, 19.89)	
Age											0.6797
<65 years	65	19	29.2	64	22	34.4	0.5304	1.18 (0.71, 1.95)	1.27 (0.60, 2.67)	5.14 (-10.74, 20.71)	
>=65 years	104	39	37.5	106	53	50.0	0.0679	1.33 (0.98, 1.82)	1.67 (0.96, 2.89)	12.50 (-0.90, 25.27)	
Sex											0.7613
Male	114	39	34.2	108	49	45.4	0.0893	1.33 (0.96, 1.84)	1.60 (0.93, 2.74)	11.16 (-1.68, 23.54)	
Female	55	19	34.5	62	26	41.9	0.4122	1.21 (0.76, 1.94)	1.37 (0.65, 2.90)	7.39 (-10.09, 24.09)	
Baseline FVC percent predicted											0.1446
<=70%	95	37	38.9	97	41	42.3	0.6395	1.09 (0.77, 1.53)	1.15 (0.64, 2.04)	3.32 (-10.41, 16.86)	
>70%	74	21	28.4	73	34	46.6	0.0226	1.64 (1.06, 2.54)	2.20 (1.11, 4.36)	18.20 (2.55, 32.67)	
Baseline HRCT pattern											0.5746
UIP-like	116	44	37.9	121	56	46.3	0.1932	1.22 (0.90, 1.65)	1.41 (0.84, 2.37)	8.35 (-4.18, 20.50)	
Other fibrotic patterns	53	14	26.4	49	19	38.8	0.1825	1.47 (0.83, 2.60)	1.76 (0.76, 4.08)	12.36 (-5.69, 29.53)	
Underlying ILD diagnosis											0.1673
iNSIP	32	11	34.4	27	9	33.3	0.9329	0.97 (0.47, 1.99)	0.95 (0.32, 2.82)	-1.04 (-23.75, 22.41)	
Unclassifiable IIP	46	20	43.5	32	10	31.3	0.2749	0.72 (0.39, 1.32)	0.59 (0.23, 1.52)	-12.23 (-31.74, 9.59)	
HP	38	11	28.9	43	20	46.5	0.1046	1.61 (0.89, 2.91)	2.13 (0.85, 5.37)	17.56 (-3.55, 36.41)	
Autoimmune ILD	29	10	34.5	43	23	53.5	0.1124	1.55 (0.87, 2.75)	2.19 (0.83, 5.78)	19.01 (-4.29, 39.19)	
Other ILD	24	6	25.0	25	13	52.0	0.0525	2.08 (0.95, 4.58)	3.25 (0.97, 10.92)	27.00 (-0.17, 49.18)	
Region											0.9101
Europe	78	26	33.3	67	27	40.3	0.3852	1.21 (0.79, 1.86)	1.35 (0.69, 2.66)	6.97 (-8.54, 22.21)	
Asia	45	21	46.7	41	24	58.5	0.2710	1.25 (0.84, 1.88)	1.61 (0.69, 3.79)	11.87 (-8.95, 31.27)	
Canada and USA	30	4	13.3	37	9	24.3	0.2579	1.82 (0.62, 5.34)	2.09 (0.57, 7.61)	10.99 (-8.69, 28.71)	
Rest of the World	16	7	43.8	25	15	60.0	0.3087	1.37 (0.72, 2.60)	1.93 (0.54, 6.88)	16.25 (-13.80, 42.74)	

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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I.2.1.2.1.3 Adverse events leading to treatment discontinuation over the whole trial

Table I.2.1.2.1.3: 1 Proportion of patients with any adverse events leading to treatment discontinuation over the whole trial (DBL1) - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	18	10.7	170	23	13.5	0.4164	1.27 (0.71, 2.27)	1.31 (0.68, 2.53)	2.88 (-4.17, 9.95)	
Age											0.2118
<65 years	65	2	3.1	64	6	9.4	0.1381	3.05 (0.64, 14.54)	3.26 (0.63, 16.79)	6.30 (-2.69, 16.16)	
>=65 years	104	16	15.4	106	17	16.0	0.8965	1.04 (0.56, 1.95)	1.05 (0.50, 2.21)	0.65 (-9.34, 10.59)	
Sex											0.0420
Male	114	17	14.9	108	14	13.0	0.6753	0.87 (0.45, 1.68)	0.85 (0.40, 1.82)	-1.95 (-11.16, 7.39)	
Female	55	1	1.8	62	9	14.5	0.0142	7.98 (1.04, 61.02)	9.17 (1.12, 74.92)	12.70 (2.43, 23.63)	
Baseline FVC percent predicted											0.4498
<=70%	95	12	12.6	97	13	13.4	0.8740	1.06 (0.51, 2.21)	1.07 (0.46, 2.48)	0.77 (-9.01, 10.50)	
>70%	74	6	8.1	73	10	13.7	0.2765	1.69 (0.65, 4.41)	1.80 (0.62, 5.24)	5.59 (-4.84, 16.23)	
Baseline HRCT pattern											0.5618
UIP-like	116	15	12.9	121	18	14.9	0.6655	1.15 (0.61, 2.17)	1.18 (0.56, 2.46)	1.94 (-7.06, 10.85)	
Other fibrotic patterns	53	3	5.7	49	5	10.2	0.3938	1.80 (0.45, 7.15)	1.89 (0.43, 8.38)	4.54 (-6.75, 16.68)	
Underlying ILD diagnosis											0.9198
iNSIP	32	5	15.6	27	5	18.5	0.7679	1.19 (0.38, 3.66)	1.23 (0.31, 4.79)	2.89 (-16.26, 23.07)	
Unclassifiable IIP	46	7	15.2	32	5	15.6	0.9609	1.03 (0.36, 2.95)	1.03 (0.30, 3.59)	0.41 (-15.27, 18.26)	
HP	38	1	2.6	43	3	7.0	0.3677	2.65 (0.29, 24.43)	2.78 (0.28, 27.87)	4.35 (-7.44, 16.18)	
Autoimmune ILD	29	2	6.9	43	6	14.0	0.3500	2.02 (0.44, 9.34)	2.19 (0.41, 11.69)	7.06 (-9.73, 21.27)	
Other ILD	24	3	12.5	25	4	16.0	0.7263	1.28 (0.32, 5.13)	1.33 (0.27, 6.70)	3.50 (-17.34, 23.86)	
Region											0.5851
Europe	78	9	11.5	67	11	16.4	0.3956	1.42 (0.63, 3.22)	1.51 (0.58, 3.89)	4.88 (-6.49, 16.79)	
Asia	45	5	11.1	41	9	22.0	0.1738	1.98 (0.72, 5.41)	2.25 (0.69, 7.38)	10.84 (-5.05, 26.87)	
Canada and USA	30	3	10.0	37	2	5.4	0.4767	0.54 (0.10, 3.03)	0.51 (0.08, 3.30)	-4.59 (-20.70, 9.34)	
Rest of the World	16	1	6.3	25	1	4.0	0.7442	0.64 (0.04, 9.52)	0.63 (0.04, 10.76)	-2.25 (-24.57, 14.12)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.1.2.1.3: 2 Proportion of patients with any adverse events leading to treatment discontinuation (excluding disease-related events) over the whole trial (DBL1) - 18mg - TS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	12	7.1	170	19	11.2	0.1930	1.57 (0.79, 3.14)	1.65 (0.77, 3.51)	4.08 (-2.19, 10.44)	
Age											0.7292
<65 years	65	2	3.1	64	4	6.3	0.3922	2.03 (0.39, 10.70)	2.10 (0.37, 11.89)	3.17 (-5.20, 12.20)	
>=65 years	104	10	9.6	106	15	14.2	0.3102	1.47 (0.69, 3.13)	1.55 (0.66, 3.63)	4.54 (-4.44, 13.53)	
Sex											0.0889
Male	114	11	9.6	108	11	10.2	0.8937	1.06 (0.48, 2.33)	1.06 (0.44, 2.56)	0.54 (-7.57, 8.81)	
Female	55	1	1.8	62	8	12.9	0.0247	7.10 (0.92, 54.96)	8.00 (0.97, 66.17)	11.09 (1.12, 21.74)	
Baseline FVC percent predicted											0.9198
<=70%	95	6	6.3	97	10	10.3	0.3168	1.63 (0.62, 4.31)	1.70 (0.59, 4.89)	3.99 (-4.21, 12.35)	
>70%	74	6	8.1	73	9	12.3	0.3980	1.52 (0.57, 4.06)	1.59 (0.54, 4.73)	4.22 (-5.99, 14.64)	
Baseline HRCT pattern											0.4379
UIP-like	116	10	8.6	121	14	11.6	0.4518	1.34 (0.62, 2.90)	1.39 (0.59, 3.26)	2.95 (-5.00, 10.88)	
Other fibrotic patterns	53	2	3.8	49	5	10.2	0.1993	2.70 (0.55, 13.30)	2.90 (0.54, 15.68)	6.43 (-4.24, 18.30)	
Underlying ILD diagnosis											
iNSIP	32	4	12.5	27	3	11.1					
Unclassifiable IIP	46	4	8.7	32	5	15.6					
HP	38	1	2.6	43	3	7.0					
Autoimmune ILD	29	1	3.4	43	5	11.6					
Other ILD	24	2	8.3	25	3	12.0					
Region											0.7917
Europe	78	7	9.0	67	9	13.4	0.3929	1.50 (0.59, 3.80)	1.57 (0.55, 4.48)	4.46 (-5.99, 15.60)	
Asia	45	3	6.7	41	7	17.1	0.1327	2.56 (0.71, 9.25)	2.88 (0.69, 12.00)	10.41 (-3.67, 25.25)	
Canada and USA	30	2	6.7	37	2	5.4	0.8285	0.81 (0.12, 5.42)	0.80 (0.11, 6.04)	-1.26 (-16.43, 11.95)	
Rest of the World	16	0	0.0	25	1	4.0	0.6668	1.96 (0.08, 45.40)	NC (NC, NC)	4.00 (-15.64, 19.54)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.1.2.1.3: 3 Descriptive statistics of patients with any adverse events leading to treatment discontinuation over the whole trial by SOC and PT (DBL1) - 18mg - TS (NIN background)

Primary System Organ Class Preferred Term	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %
Overall	169	18	10.7	170	23	13.5
General disorders and administration site conditions		9	5.3		6	3.5
Condition aggravated		7	4.1		6	3.5
Disease progression		1	0.6		0	0.0
Fatigue		1	0.6		0	0.0
Gastrointestinal disorders		3	1.8		7	4.1
Diarrhoea		2	1.2		7	4.1
Nausea		0	0.0		2	1.2
Anal haemorrhage		0	0.0		1	0.6
Frequent bowel movements		1	0.6		0	0.0
Investigations		1	0.6		3	1.8
Weight decreased		1	0.6		1	0.6
False positive tuberculosis test		0	0.0		1	0.6
Red blood cell sedimentation rate increased		0	0.0		1	0.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		0	0.0		4	2.4
Keratoacanthoma		0	0.0		1	0.6
Small cell lung cancer		0	0.0		1	0.6
Small intestine carcinoma		0	0.0		1	0.6
Squamous cell carcinoma		0	0.0		1	0.6
Respiratory, thoracic and mediastinal disorders		3	1.8		1	0.6
Dyspnoea		2	1.2		0	0.0
Acute respiratory failure		0	0.0		1	0.6
Hypoxia		1	0.6		0	0.0
Interstitial lung disease		1	0.6		0	0.0
Pneumothorax		1	0.6		0	0.0
Respiratory failure		1	0.6		0	0.0
Infections and infestations		1	0.6		2	1.2
Bacteraemia		1	0.6		0	0.0
Bacterial infection		0	0.0		1	0.6
Lower respiratory tract infection		0	0.0		1	0.6
Nervous system disorders		1	0.6		2	1.2
Headache		0	0.0		2	1.2
Dizziness		1	0.6		0	0.0

Study: 1305-0023. MedDRA version: 27.1
N is the number of patients, n the number of patients with at least one event.
Percentages are calculated using total number of patients per treatment as the denominator.

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Table I.2.1.2.1.3: 3 Descriptive statistics of patients with any adverse events leading to treatment discontinuation over the whole trial by SOC and PT (DBL1) - 18mg - TS (NIN background)

Primary System Organ Class Preferred Term	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %
Cardiac disorders		0	0.0		2	1.2
Palpitations		0	0.0		1	0.6
Ventricular extrasystoles		0	0.0		1	0.6
Injury, poisoning and procedural complications		1	0.6		0	0.0
Post procedural complication		1	0.6		0	0.0
Musculoskeletal and connective tissue disorders		1	0.6		0	0.0
Osteolysis		1	0.6		0	0.0
Reproductive system and breast disorders		1	0.6		0	0.0
Ejaculation failure		1	0.6		0	0.0
Erectile dysfunction		1	0.6		0	0.0
Vascular disorders		0	0.0		1	0.6
Hypertension		0	0.0		1	0.6

Study: 1305-0023. MedDRA version: 27.1
N is the number of patients, n the number of patients with at least one event.
Percentages are calculated using total number of patients per treatment as the denominator.

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I.2.1.2.1.4 Adverse events on SOC level over the whole trial

Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Cardiac disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	10	5.9	170	25	14.7	0.0078	2.49 (1.23, 5.01)	2.74 (1.27, 5.90)	8.79 (2.30, 15.45)	
Age											0.2282
<65 years	65	4	6.2	64	5	7.8	0.7116	1.27 (0.36, 4.51)	1.29 (0.33, 5.05)	1.66 (-8.04, 11.59)	
>=65 years	104	6	5.8	106	20	18.9	0.0040	3.27 (1.37, 7.82)	3.80 (1.46, 9.89)	13.10 (4.22, 22.13)	
Sex											0.5980
Male	114	8	7.0	108	17	15.7	0.0399	2.24 (1.01, 4.98)	2.48 (1.02, 6.00)	8.72 (0.30, 17.45)	
Female	55	2	3.6	62	8	12.9	0.0735	3.55 (0.79, 16.00)	3.93 (0.80, 19.35)	9.27 (-1.42, 20.14)	
Baseline FVC percent predicted											0.6064
<=70%	95	5	5.3	97	15	15.5	0.0207	2.94 (1.11, 7.76)	3.29 (1.15, 9.46)	10.20 (1.47, 19.21)	
>70%	74	5	6.8	73	10	13.7	0.1645	2.03 (0.73, 5.64)	2.19 (0.71, 6.76)	6.94 (-3.19, 17.39)	
Baseline HRCT pattern											0.1629
UIP-like	116	6	5.2	121	21	17.4	0.0032	3.36 (1.40, 8.02)	3.85 (1.49, 9.92)	12.18 (4.14, 20.39)	
Other fibrotic patterns	53	4	7.5	49	4	8.2	0.9079	1.08 (0.29, 4.09)	1.09 (0.26, 4.61)	0.62 (-10.82, 12.55)	
Underlying ILD diagnosis											0.4251
iNSIP	32	3	9.4	27	4	14.8	0.5197	1.58 (0.39, 6.45)	1.68 (0.34, 8.28)	5.44 (-11.87, 24.14)	
Unclassifiable IIP	46	4	8.7	32	2	6.3	0.6901	0.72 (0.14, 3.69)	0.70 (0.12, 4.07)	-2.45 (-14.92, 12.41)	
HP	38	1	2.6	43	3	7.0	0.3677	2.65 (0.29, 24.43)	2.78 (0.28, 27.87)	4.35 (-7.44, 16.18)	
Autoimmune ILD	29	0	0.0	43	12	27.9	0.0030	>10 (1.05, >99)	NC (NC, NC)	27.91 (11.74, 42.69)	
Other ILD	24	2	8.3	25	4	16.0	0.4131	1.92 (0.39, 9.53)	2.10 (0.35, 12.67)	7.67 (-12.31, 27.27)	
Region											0.4618
Europe	78	6	7.7	67	11	16.4	0.1035	2.13 (0.83, 5.46)	2.36 (0.82, 6.76)	8.73 (-1.97, 20.13)	
Asia	45	1	2.2	41	8	19.5	0.0089	8.78 (1.15, 67.21)	>10 (1.27, 89.52)	17.29 (4.12, 31.91)	
Canada and USA	30	2	6.7	37	5	13.5	0.3622	2.03 (0.42, 9.72)	2.19 (0.39, 12.17)	6.85 (-9.66, 22.09)	
Rest of the World	16	1	6.3	25	1	4.0	0.7442	0.64 (0.04, 9.52)	0.63 (0.04, 10.76)	-2.25 (-24.57, 14.12)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)

SOC: Eye disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	1	0.6	170	10	5.9	0.0060	9.94 (1.29, 76.80)	>10 (1.33, 82.96)	5.29 (1.51, 9.92)	
Age											
<65 years	65	0	0.0	64	2	3.1					
>=65 years	104	1	1.0	106	8	7.5					
Sex											
Male	114	1	0.9	108	7	6.5					
Female	55	0	0.0	62	3	4.8					
Baseline FVC percent predicted											
<=70%	95	1	1.1	97	6	6.2					
>70%	74	0	0.0	73	4	5.5					
Baseline HRCT pattern											
UIP-like	116	1	0.9	121	8	6.6					
Other fibrotic patterns	53	0	0.0	49	2	4.1					
Underlying ILD diagnosis											
iNSIP	32	0	0.0	27	2	7.4					
Unclassifiable IIP	46	1	2.2	32	2	6.3					
HP	38	0	0.0	43	2	4.7					
Autoimmune ILD	29	0	0.0	43	3	7.0					
Other ILD	24	0	0.0	25	1	4.0					
Region											
Europe	78	0	0.0	67	3	4.5					
Asia	45	0	0.0	41	2	4.9					
Canada and USA	30	1	3.3	37	3	8.1					
Rest of the World	16	0	0.0	25	2	8.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Gastrointestinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	101	59.8	170	105	61.8	0.7059	1.03 (0.87, 1.23)	1.09 (0.70, 1.68)	2.00 (-8.32, 12.26)	
Age											
<65 years	65	36	55.4	64	31	48.4					
>=65 years	104	65	62.5	106	74	69.8					
Sex											
Male	114	63	55.3	108	65	60.2					
Female	55	38	69.1	62	40	64.5					
Baseline FVC percent predicted											
<=70%	95	55	57.9	97	57	58.8					
>70%	74	46	62.2	73	48	65.8					
Baseline HRCT pattern											
UIP-like	116	71	61.2	121	74	61.2					
Other fibrotic patterns	53	30	56.6	49	31	63.3					
Underlying ILD diagnosis											
iNSIP	32	19	59.4	27	16	59.3					
Unclassifiable IIP	46	28	60.9	32	21	65.6					
HP	38	21	55.3	43	25	58.1					
Autoimmune ILD	29	17	58.6	43	27	62.8					
Other ILD	24	16	66.7	25	16	64.0					
Region											
Europe	78	50	64.1	67	40	59.7					
Asia	45	22	48.9	41	26	63.4					
Canada and USA	30	17	56.7	37	22	59.5					
Rest of the World	16	12	75.0	25	17	68.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: General disorders and administration site conditions

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	67	39.6	170	62	36.5	0.5472	0.92 (0.70, 1.21)	0.87 (0.56, 1.36)	-3.17 (-13.36, 7.10)	
Age											
<65 years	65	21	32.3	64	19	29.7					
>=65 years	104	46	44.2	106	43	40.6					
Sex											
Male	114	45	39.5	108	42	38.9					
Female	55	22	40.0	62	20	32.3					
Baseline FVC percent predicted											
<=70%	95	45	47.4	97	38	39.2					
>70%	74	22	29.7	73	24	32.9					
Baseline HRCT pattern											
UIP-like	116	45	38.8	121	46	38.0					
Other fibrotic patterns	53	22	41.5	49	16	32.7					
Underlying ILD diagnosis											
iNSIP	32	10	31.3	27	12	44.4					
Unclassifiable IIP	46	21	45.7	32	11	34.4					
HP	38	13	34.2	43	15	34.9					
Autoimmune ILD	29	10	34.5	43	15	34.9					
Other ILD	24	13	54.2	25	9	36.0					
Region											
Europe	78	38	48.7	67	22	32.8					
Asia	45	10	22.2	41	17	41.5					
Canada and USA	30	14	46.7	37	17	45.9					
Rest of the World	16	5	31.3	25	6	24.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	119	70.4	170	114	67.1	0.5052	0.95 (0.82, 1.10)	0.86 (0.54, 1.35)	-3.36 (-13.10, 6.48)	
Age											
<65 years	65	50	76.9	64	44	68.8					
>=65 years	104	69	66.3	106	70	66.0					
Sex											
Male	114	74	64.9	108	67	62.0					
Female	55	45	81.8	62	47	75.8					
Baseline FVC percent predicted											
<=70%	95	67	70.5	97	68	70.1					
>70%	74	52	70.3	73	46	63.0					
Baseline HRCT pattern											
UIP-like	116	83	71.6	121	86	71.1					
Other fibrotic patterns	53	36	67.9	49	28	57.1					
Underlying ILD diagnosis											
iNSIP	32	23	71.9	27	14	51.9					
Unclassifiable IIP	46	31	67.4	32	25	78.1					
HP	38	23	60.5	43	26	60.5					
Autoimmune ILD	29	22	75.9	43	33	76.7					
Other ILD	24	20	83.3	25	16	64.0					
Region											
Europe	78	58	74.4	67	47	70.1					
Asia	45	32	71.1	41	29	70.7					
Canada and USA	30	21	70.0	37	26	70.3					
Rest of the World	16	8	50.0	25	12	48.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Injury, poisoning and procedural complications

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	24	14.2	170	19	11.2	0.4028	0.79 (0.45, 1.38)	0.76 (0.40, 1.45)	-3.02 (-10.23, 4.15)	
Age											
<65 years	65	10	15.4	64	3	4.7					
>=65 years	104	14	13.5	106	16	15.1					
Sex											
Male	114	13	11.4	108	14	13.0					
Female	55	11	20.0	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	14	14.7	97	10	10.3					
>70%	74	10	13.5	73	9	12.3					
Baseline HRCT pattern											
UIP-like	116	14	12.1	121	14	11.6					
Other fibrotic patterns	53	10	18.9	49	5	10.2					
Underlying ILD diagnosis											
iNSIP	32	3	9.4	27	1	3.7					
Unclassifiable IIP	46	7	15.2	32	6	18.8					
HP	38	7	18.4	43	3	7.0					
Autoimmune ILD	29	3	10.3	43	4	9.3					
Other ILD	24	4	16.7	25	5	20.0					
Region											
Europe	78	15	19.2	67	10	14.9					
Asia	45	4	8.9	41	3	7.3					
Canada and USA	30	4	13.3	37	3	8.1					
Rest of the World	16	1	6.3	25	3	12.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Investigations

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	36	21.3	170	46	27.1	0.2158	1.27 (0.87, 1.86)	1.37 (0.83, 2.26)	5.76 (-3.37, 14.76)	
Age											
<65 years	65	12	18.5	64	11	17.2					
>=65 years	104	24	23.1	106	35	33.0					
Sex											
Male	114	20	17.5	108	32	29.6					
Female	55	16	29.1	62	14	22.6					
Baseline FVC percent predicted											
<=70%	95	19	20.0	97	26	26.8					
>70%	74	17	23.0	73	20	27.4					
Baseline HRCT pattern											
UIP-like	116	26	22.4	121	34	28.1					
Other fibrotic patterns	53	10	18.9	49	12	24.5					
Underlying ILD diagnosis											
iNSIP	32	4	12.5	27	6	22.2					
Unclassifiable IIP	46	14	30.4	32	11	34.4					
HP	38	4	10.5	43	11	25.6					
Autoimmune ILD	29	8	27.6	43	11	25.6					
Other ILD	24	6	25.0	25	7	28.0					
Region											
Europe	78	16	20.5	67	20	29.9					
Asia	45	14	31.1	41	16	39.0					
Canada and USA	30	4	13.3	37	6	16.2					
Rest of the World	16	2	12.5	25	4	16.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Metabolism and nutrition disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	30	17.8	170	33	19.4	0.6944	1.09 (0.70, 1.71)	1.12 (0.65, 1.93)	1.66 (-6.66, 9.95)	
Age											
<65 years	65	10	15.4	64	8	12.5					
>=65 years	104	20	19.2	106	25	23.6					
Sex											
Male	114	17	14.9	108	20	18.5					
Female	55	13	23.6	62	13	21.0					
Baseline FVC percent predicted											
<=70%	95	18	18.9	97	15	15.5					
>70%	74	12	16.2	73	18	24.7					
Baseline HRCT pattern											
UIP-like	116	20	17.2	121	28	23.1					
Other fibrotic patterns	53	10	18.9	49	5	10.2					
Underlying ILD diagnosis											
iNSIP	32	5	15.6	27	5	18.5					
Unclassifiable IIP	46	8	17.4	32	8	25.0					
HP	38	7	18.4	43	5	11.6					
Autoimmune ILD	29	4	13.8	43	14	32.6					
Other ILD	24	6	25.0	25	1	4.0					
Region											
Europe	78	19	24.4	67	10	14.9					
Asia	45	6	13.3	41	13	31.7					
Canada and USA	30	1	3.3	37	6	16.2					
Rest of the World	16	4	25.0	25	4	16.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Musculoskeletal and connective tissue disorders

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)		Odds ratio (95% CI)		Risk diff. (95% CI)		Interaction p-value**
Overall	169	42	24.9	170	41	24.1	0.8751	0.97 (0.67,	1.41)	0.96 (0.59,	1.58)	-0.73 (-9.85,	8.39)	
Age														
<65 years	65	15	23.1	64	16	25.0								
>=65 years	104	27	26.0	106	25	23.6								
Sex														
Male	114	24	21.1	108	23	21.3								
Female	55	18	32.7	62	18	29.0								
Baseline FVC percent predicted														
<=70%	95	22	23.2	97	26	26.8								
>70%	74	20	27.0	73	15	20.5								
Baseline HRCT pattern														
UIP-like	116	28	24.1	121	28	23.1								
Other fibrotic patterns	53	14	26.4	49	13	26.5								
Underlying ILD diagnosis														
iNSIP	32	3	9.4	27	5	18.5								
Unclassifiable IIP	46	10	21.7	32	13	40.6								
HP	38	13	34.2	43	7	16.3								
Autoimmune ILD	29	11	37.9	43	10	23.3								
Other ILD	24	5	20.8	25	6	24.0								
Region														
Europe	78	19	24.4	67	20	29.9								
Asia	45	17	37.8	41	7	17.1								
Canada and USA	30	5	16.7	37	10	27.0								
Rest of the World	16	1	6.3	25	4	16.0								

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	2	1.2	170	10	5.9	0.0192	4.97 (1.11, 22.35)	5.22 (1.13, 24.19)	4.70 (0.67, 9.38)	
Age											
<65 years	65	1	1.5	64	4	6.3					
>=65 years	104	1	1.0	106	6	5.7					
Sex											
Male	114	1	0.9	108	8	7.4					
Female	55	1	1.8	62	2	3.2					
Baseline FVC percent predicted											
<=70%	95	0	0.0	97	4	4.1					
>70%	74	2	2.7	73	6	8.2					
Baseline HRCT pattern											0.8425
UIP-like	116	2	1.7	121	8	6.6	0.0614	3.83 (0.83, 17.68)	4.04 (0.84, 19.42)	4.89 (-0.52, 10.91)	
Other fibrotic patterns	53	0	0.0	49	2	4.1	0.2149	5.40 (0.27, >99)	NC (NC, NC)	4.08 (-3.29, 13.71)	
Underlying ILD diagnosis											
iNSIP	32	0	0.0	27	1	3.7					
Unclassifiable IIP	46	1	2.2	32	2	6.3					
HP	38	0	0.0	43	3	7.0					
Autoimmune ILD	29	1	3.4	43	2	4.7					
Other ILD	24	0	0.0	25	2	8.0					
Region											
Europe	78	1	1.3	67	2	3.0					
Asia	45	1	2.2	41	4	9.8					
Canada and USA	30	0	0.0	37	3	8.1					
Rest of the World	16	0	0.0	25	1	4.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Nervous system disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	24	14.2	170	34	20.0	0.1563	1.41 (0.87, 2.27)	1.51 (0.85, 2.68)	5.80 (-2.27, 13.81)	
Age											
<65 years	65	8	12.3	64	11	17.2					
>=65 years	104	16	15.4	106	23	21.7					
Sex											
Male	114	15	13.2	108	23	21.3					
Female	55	9	16.4	62	11	17.7					
Baseline FVC percent predicted											
<=70%	95	16	16.8	97	20	20.6					
>70%	74	8	10.8	73	14	19.2					
Baseline HRCT pattern											
UIP-like	116	17	14.7	121	25	20.7					
Other fibrotic patterns	53	7	13.2	49	9	18.4					
Underlying ILD diagnosis											
iNSIP	32	7	21.9	27	3	11.1					
Unclassifiable IIP	46	8	17.4	32	6	18.8					
HP	38	5	13.2	43	8	18.6					
Autoimmune ILD	29	1	3.4	43	10	23.3					
Other ILD	24	3	12.5	25	7	28.0					
Region											
Europe	78	15	19.2	67	13	19.4					
Asia	45	2	4.4	41	5	12.2					
Canada and USA	30	4	13.3	37	10	27.0					
Rest of the World	16	3	18.8	25	6	24.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Psychiatric disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	40	23.7	170	43	25.3	0.7278	1.07 (0.74, 1.55)	1.09 (0.67, 1.79)	1.63 (-7.52, 10.73)	
Age											
<65 years	65	14	21.5	64	12	18.8					
>=65 years	104	26	25.0	106	31	29.2					
Sex											
Male	114	26	22.8	108	27	25.0					
Female	55	14	25.5	62	16	25.8					
Baseline FVC percent predicted											
<=70%	95	26	27.4	97	32	33.0					
>70%	74	14	18.9	73	11	15.1					
Baseline HRCT pattern											
UIP-like	116	27	23.3	121	33	27.3					
Other fibrotic patterns	53	13	24.5	49	10	20.4					
Underlying ILD diagnosis											
iNSIP	32	7	21.9	27	6	22.2					
Unclassifiable IIP	46	11	23.9	32	8	25.0					
HP	38	7	18.4	43	10	23.3					
Autoimmune ILD	29	6	20.7	43	9	20.9					
Other ILD	24	9	37.5	25	10	40.0					
Region											
Europe	78	21	26.9	67	19	28.4					
Asia	45	12	26.7	41	12	29.3					
Canada and USA	30	3	10.0	37	5	13.5					
Rest of the World	16	4	25.0	25	7	28.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Renal and urinary disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	12	7.1	170	13	7.6	0.8474	1.08 (0.51, 2.29)	1.08 (0.48, 2.45)	0.55 (-5.26, 6.37)	
Age											
<65 years	65	6	9.2	64	7	10.9					
>=65 years	104	6	5.8	106	6	5.7					
Sex											
Male	114	8	7.0	108	8	7.4					
Female	55	4	7.3	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	8	8.4	97	8	8.2					
>70%	74	4	5.4	73	5	6.8					
Baseline HRCT pattern											
UIP-like	116	11	9.5	121	10	8.3					
Other fibrotic patterns	53	1	1.9	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	2	6.3	27	2	7.4					
Unclassifiable IIP	46	5	10.9	32	2	6.3					
HP	38	3	7.9	43	3	7.0					
Autoimmune ILD	29	1	3.4	43	2	4.7					
Other ILD	24	1	4.2	25	4	16.0					
Region											
Europe	78	7	9.0	67	6	9.0					
Asia	45	1	2.2	41	3	7.3					
Canada and USA	30	3	10.0	37	4	10.8					
Rest of the World	16	1	6.3	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)		Odds ratio (95% CI)	Risk diff.	(95% CI)	Interaction p-value**
Overall	169	75	44.4	170	69	40.6	0.4802	0.91 (0.71, | 1.17)	0.86 (0.56, 1.32)	-3.79	(-14.14, 6.67)	
Age													
<65 years	65	31	47.7	64	24	37.5							
>=65 years	104	44	42.3	106	45	42.5							
Sex													
Male	114	54	47.4	108	49	45.4							
Female	55	21	38.2	62	20	32.3							
Baseline FVC percent predicted													
<=70%	95	51	53.7	97	39	40.2							
>70%	74	24	32.4	73	30	41.1							
Baseline HRCT pattern													
UIP-like	116	51	44.0	121	55	45.5							
Other fibrotic patterns	53	24	45.3	49	14	28.6							
Underlying ILD diagnosis													
iNSIP	32	9	28.1	27	10	37.0							
Unclassifiable IIP	46	24	52.2	32	13	40.6							
HP	38	20	52.6	43	16	37.2							
Autoimmune ILD	29	11	37.9	43	16	37.2							
Other ILD	24	11	45.8	25	14	56.0							
Region													
Europe	78	39	50.0	67	24	35.8							
Asia	45	18	40.0	41	19	46.3							
Canada and USA	30	14	46.7	37	18	48.6							
Rest of the World	16	4	25.0	25	8	32.0							

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Skin and subcutaneous tissue disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff.	(95% CI)	Interaction p-value**
Overall	169	30	17.8	170	26	15.3	0.5424	0.86 (0.53, 1.39)	0.84 (0.47, 1.49)	-2.46	(-10.41, 5.50)	
Age												
<65 years	65	12	18.5	64	7	10.9						
>=65 years	104	18	17.3	106	19	17.9						
Sex												
Male	114	18	15.8	108	16	14.8						
Female	55	12	21.8	62	10	16.1						
Baseline FVC percent predicted												
<=70%	95	13	13.7	97	16	16.5						
>70%	74	17	23.0	73	10	13.7						
Baseline HRCT pattern												
UIP-like	116	21	18.1	121	19	15.7						
Other fibrotic patterns	53	9	17.0	49	7	14.3						
Underlying ILD diagnosis												
iNSIP	32	5	15.6	27	3	11.1						
Unclassifiable IIP	46	6	13.0	32	5	15.6						
HP	38	6	15.8	43	6	14.0						
Autoimmune ILD	29	7	24.1	43	7	16.3						
Other ILD	24	6	25.0	25	5	20.0						
Region												
Europe	78	19	24.4	67	10	14.9						
Asia	45	7	15.6	41	8	19.5						
Canada and USA	30	1	3.3	37	4	10.8						
Rest of the World	16	3	18.8	25	4	16.0						

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Vascular disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	9	5.3	170	20	11.8	0.0341	2.21 (1.04, 4.71)	2.37 (1.05, 5.37)	6.44 (0.42, 12.67)	
Age											0.9171
<65 years	65	2	3.1	64	4	6.3	0.3922	2.03 (0.39, 10.70)	2.10 (0.37, 11.89)	3.17 (-5.20, 12.20)	
>=65 years	104	7	6.7	106	16	15.1	0.0523	2.24 (0.96, 5.23)	2.46 (0.97, 6.26)	8.36 (-0.22, 17.09)	
Sex											0.0384
Male	114	3	2.6	108	14	13.0	0.0038	4.93 (1.46, 16.67)	5.51 (1.54, 19.76)	10.33 (3.33, 18.15)	
Female	55	6	10.9	62	6	9.7	0.8265	0.89 (0.30, 2.59)	0.88 (0.26, 2.89)	-1.23 (-13.31, 10.22)	
Baseline FVC percent predicted											0.6164
<=70%	95	4	4.2	97	11	11.3	0.0657	2.69 (0.89, 8.16)	2.91 (0.89, 9.49)	7.13 (-0.70, 15.37)	
>70%	74	5	6.8	73	9	12.3	0.2499	1.82 (0.64, 5.18)	1.94 (0.62, 6.10)	5.57 (-4.34, 15.79)	
Baseline HRCT pattern											0.4009
UIP-like	116	7	6.0	121	13	10.7	0.1923	1.78 (0.74, 4.30)	1.87 (0.72, 4.88)	4.71 (-2.62, 12.15)	
Other fibrotic patterns	53	2	3.8	49	7	14.3	0.0615	3.79 (0.83, 17.36)	4.25 (0.84, 21.55)	10.51 (-0.99, 23.19)	
Underlying ILD diagnosis											0.5094
iNSIP	32	3	9.4	27	6	22.2	0.1715	2.37 (0.65, 8.59)	2.76 (0.62, 12.32)	12.85 (-6.00, 32.37)	
Unclassifiable IIP	46	0	0.0	32	3	9.4	0.0539	9.97 (0.53, >99)	NC (NC, NC)	9.38 (-0.48, 24.22)	
HP	38	0	0.0	43	2	4.7	0.2838	4.43 (0.22, 89.52)	NC (NC, NC)	4.65 (-5.13, 15.46)	
Autoimmune ILD	29	3	10.3	43	7	16.3	0.4752	1.57 (0.44, 5.59)	1.69 (0.40, 7.14)	5.93 (-12.06, 21.21)	
Other ILD	24	3	12.5	25	2	8.0	0.6029	0.64 (0.12, 3.50)	0.61 (0.09, 4.01)	-4.50 (-23.89, 14.32)	
Region											0.6508
Europe	78	6	7.7	67	10	14.9	0.1658	1.94 (0.74, 5.06)	2.11 (0.72, 6.14)	7.23 (-3.22, 18.43)	
Asia	45	1	2.2	41	6	14.6	0.0355	6.59 (0.83, 52.41)	7.54 (0.87, 65.60)	12.41 (0.27, 26.34)	
Canada and USA	30	2	6.7	37	4	10.8	0.5547	1.62 (0.32, 8.26)	1.70 (0.29, 9.97)	4.14 (-11.90, 18.85)	
Rest of the World	16	0	0.0	25	0	0.0	0.8285	0.65 (0.01, 31.41)	NC (NC, NC)	0.00 (NC, NC)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Cardiac disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	7	4.1	170	10	5.9	0.4629	1.42 (0.55, 3.64)	1.45 (0.54, 3.89)	1.74 (-3.20, 6.81)	
Age											
<65 years	65	2	3.1	64	2	3.1					
>=65 years	104	5	4.8	106	8	7.5					
Sex											
Male	114	6	5.3	108	5	4.6					
Female	55	1	1.8	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	4	4.2	97	3	3.1					
>70%	74	3	4.1	73	7	9.6					
Baseline HRCT pattern											
UIP-like	116	5	4.3	121	8	6.6					
Other fibrotic patterns	53	2	3.8	49	2	4.1					
Underlying ILD diagnosis											
iNSIP	32	3	9.4	27	1	3.7					
Unclassifiable IIP	46	2	4.3	32	1	3.1					
HP	38	0	0.0	43	1	2.3					
Autoimmune ILD	29	0	0.0	43	5	11.6					
Other ILD	24	2	8.3	25	2	8.0					
Region											
Europe	78	4	5.1	67	2	3.0					
Asia	45	0	0.0	41	4	9.8					
Canada and USA	30	2	6.7	37	4	10.8					
Rest of the World	16	1	6.3	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: General disorders and administration site conditions

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	25	14.8	170	15	8.8	0.0885	0.60 (0.33, 1.09)	0.56 (0.28, 1.10)	-5.97 (-12.98, 0.97)	
Age											
<65 years	65	6	9.2	64	5	7.8					
>=65 years	104	19	18.3	106	10	9.4					
Sex											
Male	114	20	17.5	108	13	12.0					
Female	55	5	9.1	62	2	3.2					
Baseline FVC percent predicted											
<=70%	95	16	16.8	97	8	8.2					
>70%	74	9	12.2	73	7	9.6					
Baseline HRCT pattern											
UIP-like	116	16	13.8	121	14	11.6					
Other fibrotic patterns	53	9	17.0	49	1	2.0					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	4	14.8					
Unclassifiable IIP	46	11	23.9	32	4	12.5					
HP	38	3	7.9	43	3	7.0					
Autoimmune ILD	29	5	17.2	43	2	4.7					
Other ILD	24	5	20.8	25	2	8.0					
Region											
Europe	78	11	14.1	67	5	7.5					
Asia	45	9	20.0	41	6	14.6					
Canada and USA	30	2	6.7	37	2	5.4					
Rest of the World	16	3	18.8	25	2	8.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	24	14.2	170	27	15.9	0.6651	1.12 (0.67, 1.86)	1.14 (0.63, 2.07)	1.68 (-6.01, 9.36)	
Age											
<65 years	65	7	10.8	64	6	9.4					
>=65 years	104	17	16.3	106	21	19.8					
Sex											
Male	114	16	14.0	108	18	16.7					
Female	55	8	14.5	62	9	14.5					
Baseline FVC percent predicted											
<=70%	95	13	13.7	97	15	15.5					
>70%	74	11	14.9	73	12	16.4					
Baseline HRCT pattern											
UIP-like	116	17	14.7	121	22	18.2					
Other fibrotic patterns	53	7	13.2	49	5	10.2					
Underlying ILD diagnosis											
iNSIP	32	6	18.8	27	5	18.5					
Unclassifiable IIP	46	6	13.0	32	4	12.5					
HP	38	3	7.9	43	7	16.3					
Autoimmune ILD	29	6	20.7	43	6	14.0					
Other ILD	24	3	12.5	25	5	20.0					
Region											
Europe	78	10	12.8	67	11	16.4					
Asia	45	9	20.0	41	8	19.5					
Canada and USA	30	3	10.0	37	3	8.1					
Rest of the World	16	2	12.5	25	5	20.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	Risk p-value*	ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	0	0.0	170	9	5.3	0.0040	>10 (1.11, >99)	NC (NC, NC)	5.29 (1.96, 9.75)	
Age											
<65 years	65	0	0.0	64	4	6.3					
>=65 years	104	0	0.0	106	5	4.7					
Sex											
Male	114	0	0.0	108	8	7.4					
Female	55	0	0.0	62	1	1.6					
Baseline FVC percent predicted											
<=70%	95	0	0.0	97	4	4.1					
>70%	74	0	0.0	73	5	6.8					
Baseline HRCT pattern											
UIP-like	116	0	0.0	121	7	5.8					
Other fibrotic patterns	53	0	0.0	49	2	4.1					
Underlying ILD diagnosis											
iNSIP	32	0	0.0	27	1	3.7					
Unclassifiable IIP	46	0	0.0	32	2	6.3					
HP	38	0	0.0	43	3	7.0					
Autoimmune ILD	29	0	0.0	43	1	2.3					
Other ILD	24	0	0.0	25	2	8.0					
Region											
Europe	78	0	0.0	67	2	3.0					
Asia	45	0	0.0	41	4	9.8					
Canada and USA	30	0	0.0	37	2	5.4					
Rest of the World	16	0	0.0	25	1	4.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)		Odds ratio (95% CI)	Risk diff.	(95% CI)	Interaction p-value**
Overall	169	31	18.3	170	24	14.1	0.2914	0.77 (0.47, | 1.25)	0.73 (0.41, 1.31)	-4.23	(-12.11, 3.68)	
Age													
<65 years	65	10	15.4	64	8	12.5							
>=65 years	104	21	20.2	106	16	15.1							
Sex													
Male	114	24	21.1	108	17	15.7							
Female	55	7	12.7	62	7	11.3							
Baseline FVC percent predicted													
<=70%	95	22	23.2	97	15	15.5							
>70%	74	9	12.2	73	9	12.3							
Baseline HRCT pattern													
UIP-like	116	23	19.8	121	18	14.9							
Other fibrotic patterns	53	8	15.1	49	6	12.2							
Underlying ILD diagnosis													
iNSIP	32	4	12.5	27	5	18.5							
Unclassifiable IIP	46	13	28.3	32	5	15.6							
HP	38	6	15.8	43	2	4.7							
Autoimmune ILD	29	5	17.2	43	8	18.6							
Other ILD	24	3	12.5	25	4	16.0							
Region													
Europe	78	12	15.4	67	6	9.0							
Asia	45	12	26.7	41	11	26.8							
Canada and USA	30	5	16.7	37	4	10.8							
Rest of the World	16	2	12.5	25	3	12.0							

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Cardiac disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	5	3.0	170	11	6.5	0.1274	2.19 (0.78, 6.16)	2.27 (0.77, 6.68)	3.51 (-1.20, 8.55)	
Age											
<65 years	65	1	1.5	64	2	3.1					
>=65 years	104	4	3.8	106	9	8.5					
Sex											
Male	114	4	3.5	108	6	5.6					
Female	55	1	1.8	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	3	3.2	97	4	4.1					
>70%	74	2	2.7	73	7	9.6					
Baseline HRCT pattern											
UIP-like	116	4	3.4	121	8	6.6					
Other fibrotic patterns	53	1	1.9	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	3	9.4	27	1	3.7					
Unclassifiable IIP	46	1	2.2	32	1	3.1					
HP	38	0	0.0	43	1	2.3					
Autoimmune ILD	29	0	0.0	43	6	14.0					
Other ILD	24	1	4.2	25	2	8.0					
Region											
Europe	78	4	5.1	67	4	6.0					
Asia	45	0	0.0	41	3	7.3					
Canada and USA	30	1	3.3	37	4	10.8					
Rest of the World	16	0	0.0	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: General disorders and administration site conditions

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)		Odds ratio (95% CI)		Risk diff. (95% CI)	Interaction p-value**
Overall	169	24	14.2	170	15	8.8	0.1208	0.62 (0.34,	1.14)	0.58 (0.30,	1.16)	-5.38 (-12.33, 1.50)	
Age													
<65 years	65	5	7.7	64	5	7.8							
>=65 years	104	19	18.3	106	10	9.4							
Sex													
Male	114	20	17.5	108	12	11.1							
Female	55	4	7.3	62	3	4.8							
Baseline FVC percent predicted													
<=70%	95	15	15.8	97	9	9.3							
>70%	74	9	12.2	73	6	8.2							
Baseline HRCT pattern													
UIP-like	116	16	13.8	121	14	11.6							
Other fibrotic patterns	53	8	15.1	49	1	2.0							
Underlying ILD diagnosis													
iNSIP	32	1	3.1	27	4	14.8							
Unclassifiable IIP	46	11	23.9	32	4	12.5							
HP	38	3	7.9	43	2	4.7							
Autoimmune ILD	29	4	13.8	43	3	7.0							
Other ILD	24	5	20.8	25	2	8.0							
Region													
Europe	78	11	14.1	67	5	7.5							
Asia	45	8	17.8	41	7	17.1							
Canada and USA	30	2	6.7	37	1	2.7							
Rest of the World	16	3	18.8	25	2	8.0							

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Infections and infestations

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)		Odds ratio (95% CI)		Risk diff. (95% CI)	Interaction p-value**
Overall	169	21	12.4	170	27	15.9	0.3614	1.28 (0.75,	2.17)	1.33 (0.72,	2.46)	3.46 (-4.05, 10.95)	
Age													
<65 years	65	7	10.8	64	6	9.4							
>=65 years	104	14	13.5	106	21	19.8							
Sex													
Male	114	14	12.3	108	18	16.7							
Female	55	7	12.7	62	9	14.5							
Baseline FVC percent predicted													
<=70%	95	12	12.6	97	15	15.5							
>70%	74	9	12.2	73	12	16.4							
Baseline HRCT pattern													
UIP-like	116	17	14.7	121	22	18.2							
Other fibrotic patterns	53	4	7.5	49	5	10.2							
Underlying ILD diagnosis													
iNSIP	32	5	15.6	27	5	18.5							
Unclassifiable IIP	46	5	10.9	32	4	12.5							
HP	38	2	5.3	43	7	16.3							
Autoimmune ILD	29	6	20.7	43	6	14.0							
Other ILD	24	3	12.5	25	5	20.0							
Region													
Europe	78	7	9.0	67	11	16.4							
Asia	45	9	20.0	41	8	19.5							
Canada and USA	30	2	6.7	37	3	8.1							
Rest of the World	16	3	18.8	25	5	20.0							

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff.	(95% CI)	Interaction p-value**
Overall	169	23	13.6	170	16	9.4	0.2259	0.69 (0.38, 1.26)	0.66 (0.34, 1.30)	-4.20	(-11.15, 2.69)	
Age												
<65 years	65	7	10.8	64	5	7.8						
>=65 years	104	16	15.4	106	11	10.4						
Sex												
Male	114	18	15.8	108	12	11.1						
Female	55	5	9.1	62	4	6.5						
Baseline FVC percent predicted												
<=70%	95	15	15.8	97	11	11.3						
>70%	74	8	10.8	73	5	6.8						
Baseline HRCT pattern												
UIP-like	116	18	15.5	121	12	9.9						
Other fibrotic patterns	53	5	9.4	49	4	8.2						
Underlying ILD diagnosis												
iNSIP	32	3	9.4	27	3	11.1						
Unclassifiable IIP	46	9	19.6	32	2	6.3						
HP	38	5	13.2	43	3	7.0						
Autoimmune ILD	29	4	13.8	43	5	11.6						
Other ILD	24	2	8.3	25	3	12.0						
Region												
Europe	78	10	12.8	67	4	6.0						
Asia	45	8	17.8	41	6	14.6						
Canada and USA	30	4	13.3	37	4	10.8						
Rest of the World	16	1	6.3	25	2	8.0						

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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I.2.1.2.1.5 Adverse events on PT level over the whole trial

Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Gastrointestinal disorders
PT: Constipation

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	11	6.5	170	9	5.3	0.6351	0.81 (0.35, 1.91)	0.80 (0.32, 1.99)	-1.21 (-6.59, 4.07)	
Age											
<65 years	65	0	0.0	64	2	3.1					
>=65 years	104	11	10.6	106	7	6.6					
Sex											
Male	114	7	6.1	108	4	3.7					
Female	55	4	7.3	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	5	5.3	97	4	4.1					
>70%	74	6	8.1	73	5	6.8					
Baseline HRCT pattern											
UIP-like	116	10	8.6	121	8	6.6					
Other fibrotic patterns	53	1	1.9	49	1	2.0					
Underlying ILD diagnosis											
iNSIP	32	0	0.0	27	1	3.7					
Unclassifiable IIP	46	7	15.2	32	2	6.3					
HP	38	0	0.0	43	1	2.3					
Autoimmune ILD	29	3	10.3	43	4	9.3					
Other ILD	24	1	4.2	25	1	4.0					
Region											
Europe	78	6	7.7	67	4	6.0					
Asia	45	3	6.7	41	4	9.8					
Canada and USA	30	0	0.0	37	1	2.7					
Rest of the World	16	2	12.5	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	63	37.3	170	85	50.0	0.0182	1.34 (1.05, 1.72)	1.68 (1.09, 2.59)	12.72 (2.16, 22.89)	
Age											0.2351
<65 years	65	22	33.8	64	23	35.9	0.8032	1.06 (0.66, 1.70)	1.10 (0.53, 2.26)	2.09 (-14.04, 18.10)	
>=65 years	104	41	39.4	106	62	58.5	0.0057	1.48 (1.11, 1.98)	2.17 (1.25, 3.76)	19.07 (5.54, 31.64)	
Sex											0.4282
Male	114	41	36.0	108	56	51.9	0.0171	1.44 (1.06, 1.96)	1.92 (1.12, 3.28)	15.89 (2.83, 28.22)	
Female	55	22	40.0	62	29	46.8	0.4608	1.17 (0.77, 1.78)	1.32 (0.63, 2.75)	6.77 (-10.97, 23.83)	
Baseline FVC percent predicted											0.2859
<=70%	95	40	42.1	97	49	50.5	0.2426	1.20 (0.88, 1.63)	1.40 (0.79, 2.48)	8.41 (-5.61, 21.97)	
>70%	74	23	31.1	73	36	49.3	0.0241	1.59 (1.05, 2.39)	2.16 (1.10, 4.23)	18.23 (2.39, 32.86)	
Baseline HRCT pattern											0.6492
UIP-like	116	43	37.1	121	58	47.9	0.0909	1.29 (0.96, 1.75)	1.56 (0.93, 2.63)	10.86 (-1.70, 22.94)	
Other fibrotic patterns	53	20	37.7	49	27	55.1	0.0788	1.46 (0.95, 2.24)	2.03 (0.92, 4.47)	17.37 (-1.90, 34.96)	
Underlying ILD diagnosis											0.9072
iNSIP	32	10	31.3	27	14	51.9	0.1085	1.66 (0.88, 3.11)	2.37 (0.82, 6.85)	20.60 (-4.28, 42.51)	
Unclassifiable IIP	46	20	43.5	32	16	50.0	0.5698	1.15 (0.71, 1.86)	1.30 (0.53, 3.22)	6.52 (-15.20, 27.59)	
HP	38	14	36.8	43	23	53.5	0.1334	1.45 (0.88, 2.40)	1.97 (0.81, 4.80)	16.65 (-4.90, 36.07)	
Autoimmune ILD	29	9	31.0	43	19	44.2	0.2616	1.42 (0.75, 2.70)	1.76 (0.65, 4.74)	13.15 (-9.66, 33.29)	
Other ILD	24	10	41.7	25	13	52.0	0.4687	1.25 (0.68, 2.29)	1.52 (0.49, 4.69)	10.33 (-16.55, 35.21)	
Region											0.9440
Europe	78	31	39.7	67	34	50.7	0.1841	1.28 (0.89, 1.83)	1.56 (0.81, 3.02)	11.00 (-5.11, 26.41)	
Asia	45	15	33.3	41	21	51.2	0.0931	1.54 (0.92, 2.56)	2.10 (0.88, 5.02)	17.89 (-2.85, 36.71)	
Canada and USA	30	12	40.0	37	19	51.4	0.3541	1.28 (0.75, 2.20)	1.58 (0.60, 4.19)	11.35 (-12.13, 33.00)	
Rest of the World	16	5	31.3	25	11	44.0	0.4143	1.41 (0.60, 3.30)	1.73 (0.46, 6.47)	12.75 (-17.14, 38.25)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	21	12.4	170	28	16.5	0.2897	1.33 (0.78, 2.24)	1.39 (0.75, 2.56)	4.04 (-3.52, 11.59)	
Age											
<65 years	65	11	16.9	64	7	10.9					
>=65 years	104	10	9.6	106	21	19.8					
Sex											
Male	114	10	8.8	108	18	16.7					
Female	55	11	20.0	62	10	16.1					
Baseline FVC percent predicted											
<=70%	95	9	9.5	97	12	12.4					
>70%	74	12	16.2	73	16	21.9					
Baseline HRCT pattern											
UIP-like	116	17	14.7	121	21	17.4					
Other fibrotic patterns	53	4	7.5	49	7	14.3					
Underlying ILD diagnosis											
iNSIP	32	6	18.8	27	3	11.1					
Unclassifiable IIP	46	2	4.3	32	5	15.6					
HP	38	3	7.9	43	7	16.3					
Autoimmune ILD	29	5	17.2	43	9	20.9					
Other ILD	24	5	20.8	25	4	16.0					
Region											
Europe	78	14	17.9	67	13	19.4					
Asia	45	3	6.7	41	3	7.3					
Canada and USA	30	1	3.3	37	8	21.6					
Rest of the World	16	3	18.8	25	4	16.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Gastrointestinal disorders
PT: Vomiting

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	21	12.4	170	17	10.0	0.4790	0.80 (0.44, 1.47)	0.78 (0.40, 1.54)	-2.43 (-9.31, 4.41)	
Age											
<65 years	65	8	12.3	64	5	7.8					
>=65 years	104	13	12.5	106	12	11.3					
Sex											
Male	114	9	7.9	108	8	7.4					
Female	55	12	21.8	62	9	14.5					
Baseline FVC percent predicted											
<=70%	95	14	14.7	97	8	8.2					
>70%	74	7	9.5	73	9	12.3					
Baseline HRCT pattern											
UIP-like	116	10	8.6	121	13	10.7					
Other fibrotic patterns	53	11	20.8	49	4	8.2					
Underlying ILD diagnosis											
iNSIP	32	5	15.6	27	2	7.4					
Unclassifiable IIP	46	4	8.7	32	6	18.8					
HP	38	5	13.2	43	4	9.3					
Autoimmune ILD	29	5	17.2	43	0	0.0					
Other ILD	24	2	8.3	25	5	20.0					
Region											
Europe	78	11	14.1	67	9	13.4					
Asia	45	1	2.2	41	4	9.8					
Canada and USA	30	5	16.7	37	3	8.1					
Rest of the World	16	4	25.0	25	1	4.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: General disorders and administration site conditions
PT: Chest pain

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	2	1.2	170	10	5.9	0.0192	4.97 (1.11, 22.35)	5.22 (1.13, 24.19)	4.70 (0.67, 9.38)	
Age											
<65 years	65	2	3.1	64	5	7.8					
>=65 years	104	0	0.0	106	5	4.7					
Sex											
Male	114	0	0.0	108	8	7.4					
Female	55	2	3.6	62	2	3.2					
Baseline FVC percent predicted											0.8364
<=70%	95	2	2.1	97	9	9.3	0.0325	4.41 (0.98, 19.87)	4.76 (1.00, 22.62)	7.17 (0.38, 14.75)	
>70%	74	0	0.0	73	1	1.4	0.4706	3.04 (0.13, 73.44)	NC (NC, NC)	1.37 (-3.69, 7.36)	
Baseline HRCT pattern											
UIP-like	116	2	1.7	121	7	5.8					
Other fibrotic patterns	53	0	0.0	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	0	0.0	27	1	3.7					
Unclassifiable IIP	46	0	0.0	32	2	6.3					
HP	38	1	2.6	43	3	7.0					
Autoimmune ILD	29	0	0.0	43	2	4.7					
Other ILD	24	1	4.2	25	2	8.0					
Region											
Europe	78	2	2.6	67	3	4.5					
Asia	45	0	0.0	41	2	4.9					
Canada and USA	30	0	0.0	37	4	10.8					
Rest of the World	16	0	0.0	25	1	4.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	28	16.6	170	19	11.2	0.1509	0.67 (0.39, 1.16)	0.63 (0.34, 1.19)	-5.39 (-12.83, 2.03)	
Age											
<65 years	65	7	10.8	64	6	9.4					
>=65 years	104	21	20.2	106	13	12.3					
Sex											
Male	114	22	19.3	108	13	12.0					
Female	55	6	10.9	62	6	9.7					
Baseline FVC percent predicted											
<=70%	95	21	22.1	97	12	12.4					
>70%	74	7	9.5	73	7	9.6					
Baseline HRCT pattern											
UIP-like	116	18	15.5	121	16	13.2					
Other fibrotic patterns	53	10	18.9	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	2	6.3	27	6	22.2					
Unclassifiable IIP	46	9	19.6	32	3	9.4					
HP	38	6	15.8	43	2	4.7					
Autoimmune ILD	29	6	20.7	43	5	11.6					
Other ILD	24	5	20.8	25	3	12.0					
Region											
Europe	78	11	14.1	67	4	6.0					
Asia	45	9	20.0	41	8	19.5					
Canada and USA	30	5	16.7	37	5	13.5					
Rest of the World	16	3	18.8	25	2	8.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: General disorders and administration site conditions
PT: Fatigue

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	14	8.3	170	14	8.2	0.9870	0.99 (0.49, 2.02)	0.99 (0.46, 2.15)	-0.05 (-6.14, 6.03)	
Age											
<65 years	65	5	7.7	64	3	4.7					
>=65 years	104	9	8.7	106	11	10.4					
Sex											
Male	114	9	7.9	108	9	8.3					
Female	55	5	9.1	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	10	10.5	97	10	10.3					
>70%	74	4	5.4	73	4	5.5					
Baseline HRCT pattern											
UIP-like	116	10	8.6	121	10	8.3					
Other fibrotic patterns	53	4	7.5	49	4	8.2					
Underlying ILD diagnosis											
iNSIP	32	2	6.3	27	4	14.8					
Unclassifiable IIP	46	6	13.0	32	2	6.3					
HP	38	2	5.3	43	2	4.7					
Autoimmune ILD	29	1	3.4	43	2	4.7					
Other ILD	24	3	12.5	25	4	16.0					
Region											
Europe	78	7	9.0	67	4	6.0					
Asia	45	0	0.0	41	2	4.9					
Canada and USA	30	6	20.0	37	7	18.9					
Rest of the World	16	1	6.3	25	1	4.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Bronchitis

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	12	7.1	170	11	6.5	0.8176	0.91 (0.41, 2.01)	0.91 (0.39, 2.11)	-0.63 (-6.28, 4.98)	
Age											
<65 years	65	4	6.2	64	3	4.7					
>=65 years	104	8	7.7	106	8	7.5					
Sex											
Male	114	8	7.0	108	7	6.5					
Female	55	4	7.3	62	4	6.5					
Baseline FVC percent predicted											
<=70%	95	8	8.4	97	8	8.2					
>70%	74	4	5.4	73	3	4.1					
Baseline HRCT pattern											
UIP-like	116	10	8.6	121	9	7.4					
Other fibrotic patterns	53	2	3.8	49	2	4.1					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	1	3.7					
Unclassifiable IIP	46	2	4.3	32	2	6.3					
HP	38	2	5.3	43	2	4.7					
Autoimmune ILD	29	2	6.9	43	5	11.6					
Other ILD	24	5	20.8	25	1	4.0					
Region											
Europe	78	8	10.3	67	6	9.0					
Asia	45	4	8.9	41	4	9.8					
Canada and USA	30	0	0.0	37	1	2.7					
Rest of the World	16	0	0.0	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: COVID-19

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	33	19.5	170	22	12.9	0.1001	0.66 (0.40, 1.09)	0.61 (0.34, 1.10)	-6.59 (-14.45, 1.31)	
Age											
<65 years	65	12	18.5	64	10	15.6					
>=65 years	104	21	20.2	106	12	11.3					
Sex											
Male	114	22	19.3	108	13	12.0					
Female	55	11	20.0	62	9	14.5					
Baseline FVC percent predicted											
<=70%	95	18	18.9	97	11	11.3					
>70%	74	15	20.3	73	11	15.1					
Baseline HRCT pattern											
UIP-like	116	26	22.4	121	19	15.7					
Other fibrotic patterns	53	7	13.2	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	7	21.9	27	5	18.5					
Unclassifiable IIP	46	11	23.9	32	5	15.6					
HP	38	7	18.4	43	4	9.3					
Autoimmune ILD	29	6	20.7	43	5	11.6					
Other ILD	24	2	8.3	25	3	12.0					
Region											
Europe	78	14	17.9	67	7	10.4					
Asia	45	8	17.8	41	9	22.0					
Canada and USA	30	9	30.0	37	5	13.5					
Rest of the World	16	2	12.5	25	1	4.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Influenza

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	12	7.1	170	11	6.5	0.8176	0.91 (0.41, 2.01)	0.91 (0.39, 2.11)	-0.63 (-6.28, 4.98)	
Age											
<65 years	65	7	10.8	64	7	10.9					
>=65 years	104	5	4.8	106	4	3.8					
Sex											
Male	114	10	8.8	108	5	4.6					
Female	55	2	3.6	62	6	9.7					
Baseline FVC percent predicted											
<=70%	95	6	6.3	97	6	6.2					
>70%	74	6	8.1	73	5	6.8					
Baseline HRCT pattern											
UIP-like	116	11	9.5	121	6	5.0					
Other fibrotic patterns	53	1	1.9	49	5	10.2					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	4	14.8					
Unclassifiable IIP	46	4	8.7	32	1	3.1					
HP	38	3	7.9	43	1	2.3					
Autoimmune ILD	29	2	6.9	43	3	7.0					
Other ILD	24	2	8.3	25	2	8.0					
Region											
Europe	78	7	9.0	67	6	9.0					
Asia	45	5	11.1	41	3	7.3					
Canada and USA	30	0	0.0	37	2	5.4					
Rest of the World	16	0	0.0	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Lower respiratory tract infection

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	6	3.6	170	10	5.9	0.3114	1.66 (0.62, 4.46)	1.70 (0.60, 4.78)	2.33 (-2.45, 7.32)	
Age											
<65 years	65	4	6.2	64	4	6.3					
>=65 years	104	2	1.9	106	6	5.7					
Sex											
Male	114	5	4.4	108	7	6.5					
Female	55	1	1.8	62	3	4.8					
Baseline FVC percent predicted											
<=70%	95	6	6.3	97	4	4.1					
>70%	74	0	0.0	73	6	8.2					
Baseline HRCT pattern											
UIP-like	116	4	3.4	121	7	5.8					
Other fibrotic patterns	53	2	3.8	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	0	0.0	27	1	3.7					
Unclassifiable IIP	46	2	4.3	32	2	6.3					
HP	38	0	0.0	43	3	7.0					
Autoimmune ILD	29	0	0.0	43	3	7.0					
Other ILD	24	4	16.7	25	1	4.0					
Region											
Europe	78	6	7.7	67	7	10.4					
Asia	45	0	0.0	41	0	0.0					
Canada and USA	30	0	0.0	37	0	0.0					
Rest of the World	16	0	0.0	25	3	12.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Nasopharyngitis

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	25	14.8	170	21	12.4	0.5119	0.84 (0.49, 1.43)	0.81 (0.44, 1.51)	-2.44 (-9.83, 4.94)	
Age											
<65 years	65	11	16.9	64	8	12.5					
>=65 years	104	14	13.5	106	13	12.3					
Sex											
Male	114	15	13.2	108	11	10.2					
Female	55	10	18.2	62	10	16.1					
Baseline FVC percent predicted											
<=70%	95	13	13.7	97	11	11.3					
>70%	74	12	16.2	73	10	13.7					
Baseline HRCT pattern											
UIP-like	116	16	13.8	121	18	14.9					
Other fibrotic patterns	53	9	17.0	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	5	15.6	27	3	11.1					
Unclassifiable IIP	46	6	13.0	32	5	15.6					
HP	38	5	13.2	43	4	9.3					
Autoimmune ILD	29	3	10.3	43	6	14.0					
Other ILD	24	6	25.0	25	3	12.0					
Region											
Europe	78	17	21.8	67	6	9.0					
Asia	45	5	11.1	41	8	19.5					
Canada and USA	30	1	3.3	37	5	13.5					
Rest of the World	16	2	12.5	25	2	8.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Pneumonia

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	12	7.1	170	18	10.6	0.2583	1.49 (0.74, 3.00)	1.55 (0.72, 3.33)	3.49 (-2.70, 9.77)	
Age											
<65 years	65	5	7.7	64	6	9.4					
>=65 years	104	7	6.7	106	12	11.3					
Sex											
Male	114	8	7.0	108	11	10.2					
Female	55	4	7.3	62	7	11.3					
Baseline FVC percent predicted											
<=70%	95	7	7.4	97	12	12.4					
>70%	74	5	6.8	73	6	8.2					
Baseline HRCT pattern											
UIP-like	116	9	7.8	121	12	9.9					
Other fibrotic patterns	53	3	5.7	49	6	12.2					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	1	3.7					
Unclassifiable IIP	46	3	6.5	32	4	12.5					
HP	38	3	7.9	43	5	11.6					
Autoimmune ILD	29	4	13.8	43	4	9.3					
Other ILD	24	1	4.2	25	4	16.0					
Region											
Europe	78	4	5.1	67	6	9.0					
Asia	45	7	15.6	41	6	14.6					
Canada and USA	30	0	0.0	37	4	10.8					
Rest of the World	16	1	6.3	25	2	8.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Respiratory tract infection

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	8	4.7	170	10	5.9	0.6372	1.24 (0.50, 3.07)	1.26 (0.48, 3.27)	1.15 (-3.93, 6.30)	
Age											
<65 years	65	4	6.2	64	5	7.8					
>=65 years	104	4	3.8	106	5	4.7					
Sex											
Male	114	3	2.6	108	6	5.6					
Female	55	5	9.1	62	4	6.5					
Baseline FVC percent predicted											
<=70%	95	4	4.2	97	5	5.2					
>70%	74	4	5.4	73	5	6.8					
Baseline HRCT pattern											
UIP-like	116	5	4.3	121	9	7.4					
Other fibrotic patterns	53	3	5.7	49	1	2.0					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	0	0.0					
Unclassifiable IIP	46	0	0.0	32	2	6.3					
HP	38	4	10.5	43	3	7.0					
Autoimmune ILD	29	3	10.3	43	4	9.3					
Other ILD	24	0	0.0	25	1	4.0					
Region											
Europe	78	6	7.7	67	8	11.9					
Asia	45	1	2.2	41	0	0.0					
Canada and USA	30	1	3.3	37	1	2.7					
Rest of the World	16	0	0.0	25	1	4.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Upper respiratory tract infection

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	18	10.7	170	17	10.0	0.8439	0.94 (0.50, 1.76)	0.93 (0.46, 1.88)	-0.65 (-7.31, 5.98)	
Age											
<65 years	65	12	18.5	64	8	12.5					
>=65 years	104	6	5.8	106	9	8.5					
Sex											
Male	114	13	11.4	108	12	11.1					
Female	55	5	9.1	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	11	11.6	97	15	15.5					
>70%	74	7	9.5	73	2	2.7					
Baseline HRCT pattern											
UIP-like	116	11	9.5	121	12	9.9					
Other fibrotic patterns	53	7	13.2	49	5	10.2					
Underlying ILD diagnosis											
iNSIP	32	6	18.8	27	1	3.7					
Unclassifiable IIP	46	4	8.7	32	5	15.6					
HP	38	4	10.5	43	2	4.7					
Autoimmune ILD	29	3	10.3	43	6	14.0					
Other ILD	24	1	4.2	25	3	12.0					
Region											
Europe	78	6	7.7	67	4	6.0					
Asia	45	9	20.0	41	5	12.2					
Canada and USA	30	3	10.0	37	8	21.6					
Rest of the World	16	0	0.0	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Urinary tract infection

Subgroup / Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	10	5.9	170	7	4.1	0.4478	0.70 (0.27, 1.79)	0.68 (0.25, 1.84)	-1.80 (-6.89, 3.12)	
Age											
<65 years	65	3	4.6	64	2	3.1					
>=65 years	104	7	6.7	106	5	4.7					
Sex											
Male	114	1	0.9	108	2	1.9					
Female	55	9	16.4	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	5	5.3	97	5	5.2					
>70%	74	5	6.8	73	2	2.7					
Baseline HRCT pattern											
UIP-like	116	8	6.9	121	4	3.3					
Other fibrotic patterns	53	2	3.8	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	0	0.0	27	1	3.7					
Unclassifiable IIP	46	1	2.2	32	0	0.0					
HP	38	0	0.0	43	3	7.0					
Autoimmune ILD	29	6	20.7	43	2	4.7					
Other ILD	24	3	12.5	25	1	4.0					
Region											
Europe	78	5	6.4	67	5	7.5					
Asia	45	2	4.4	41	1	2.4					
Canada and USA	30	3	10.0	37	0	0.0					
Rest of the World	16	0	0.0	25	1	4.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Investigations
PT: Weight decreased

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	15	8.9	170	22	12.9	0.2300	1.46 (0.78, 2.71)	1.53 (0.76, 3.05)	4.07 (-2.68, 10.87)	
Age											
<65 years	65	6	9.2	64	3	4.7					
>=65 years	104	9	8.7	106	19	17.9					
Sex											
Male	114	9	7.9	108	16	14.8					
Female	55	6	10.9	62	6	9.7					
Baseline FVC percent predicted											
<=70%	95	11	11.6	97	13	13.4					
>70%	74	4	5.4	73	9	12.3					
Baseline HRCT pattern											
UIP-like	116	12	10.3	121	18	14.9					
Other fibrotic patterns	53	3	5.7	49	4	8.2					
Underlying ILD diagnosis											
iNSIP	32	2	6.3	27	1	3.7					
Unclassifiable IIP	46	8	17.4	32	3	9.4					
HP	38	1	2.6	43	5	11.6					
Autoimmune ILD	29	1	3.4	43	6	14.0					
Other ILD	24	3	12.5	25	7	28.0					
Region											
Europe	78	6	7.7	67	9	13.4					
Asia	45	7	15.6	41	10	24.4					
Canada and USA	30	1	3.3	37	1	2.7					
Rest of the World	16	1	6.3	25	2	8.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	15	8.9	170	21	12.4	0.2988	1.39 (0.74, 2.61)	1.45 (0.72, 2.91)	3.48 (-3.20, 10.21)	
Age											
<65 years	65	3	4.6	64	3	4.7					
>=65 years	104	12	11.5	106	18	17.0					
Sex											
Male	114	8	7.0	108	12	11.1					
Female	55	7	12.7	62	9	14.5					
Baseline FVC percent predicted											
<=70%	95	9	9.5	97	9	9.3					
>70%	74	6	8.1	73	12	16.4					
Baseline HRCT pattern											
UIP-like	116	8	6.9	121	19	15.7					
Other fibrotic patterns	53	7	13.2	49	2	4.1					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	1	3.7					
Unclassifiable IIP	46	4	8.7	32	6	18.8					
HP	38	3	7.9	43	4	9.3					
Autoimmune ILD	29	2	6.9	43	9	20.9					
Other ILD	24	5	20.8	25	1	4.0					
Region											
Europe	78	9	11.5	67	4	6.0					
Asia	45	3	6.7	41	9	22.0					
Canada and USA	30	0	0.0	37	4	10.8					
Rest of the World	16	3	18.8	25	4	16.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	7	4.1	170	13	7.6	0.1709	1.85 (0.76, 4.51)	1.92 (0.75, 4.93)	3.51 (-1.70, 8.93)	
Age											
<65 years	65	2	3.1	64	3	4.7					
>=65 years	104	5	4.8	106	10	9.4					
Sex											
Male	114	3	2.6	108	8	7.4					
Female	55	4	7.3	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	4	4.2	97	4	4.1					
>70%	74	3	4.1	73	9	12.3					
Baseline HRCT pattern											
UIP-like	116	4	3.4	121	9	7.4					
Other fibrotic patterns	53	3	5.7	49	4	8.2					
Underlying ILD diagnosis											
iNSIP	32	0	0.0	27	1	3.7					
Unclassifiable IIP	46	1	2.2	32	4	12.5					
HP	38	2	5.3	43	2	4.7					
Autoimmune ILD	29	2	6.9	43	4	9.3					
Other ILD	24	2	8.3	25	2	8.0					
Region											
Europe	78	4	5.1	67	7	10.4					
Asia	45	1	2.2	41	1	2.4					
Canada and USA	30	1	3.3	37	5	13.5					
Rest of the World	16	1	6.3	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Musculoskeletal and connective tissue disorders
PT: Back pain

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	5	3.0	170	10	5.9	0.1906	1.99 (0.69, 5.69)	2.05 (0.69, 6.13)	2.92 (-1.70, 7.83)	
Age											
<65 years	65	4	6.2	64	1	1.6					
>=65 years	104	1	1.0	106	9	8.5					
Sex											
Male	114	4	3.5	108	5	4.6					
Female	55	1	1.8	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	3	3.2	97	6	6.2					
>70%	74	2	2.7	73	4	5.5					
Baseline HRCT pattern											
UIP-like	116	4	3.4	121	9	7.4					
Other fibrotic patterns	53	1	1.9	49	1	2.0					
Underlying ILD diagnosis											
iNSIP	32	0	0.0	27	2	7.4					
Unclassifiable IIP	46	0	0.0	32	3	9.4					
HP	38	2	5.3	43	1	2.3					
Autoimmune ILD	29	0	0.0	43	2	4.7					
Other ILD	24	3	12.5	25	2	8.0					
Region											
Europe	78	3	3.8	67	6	9.0					
Asia	45	2	4.4	41	2	4.9					
Canada and USA	30	0	0.0	37	1	2.7					
Rest of the World	16	0	0.0	25	1	4.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Nervous system disorders
PT: Headache

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	9	5.3	170	12	7.1	0.5080	1.33 (0.57, 3.06)	1.35 (0.55, 3.29)	1.73 (-3.65, 7.21)	
Age											
<65 years	65	4	6.2	64	5	7.8					
>=65 years	104	5	4.8	106	7	6.6					
Sex											
Male	114	4	3.5	108	6	5.6					
Female	55	5	9.1	62	6	9.7					
Baseline FVC percent predicted											
<=70%	95	7	7.4	97	7	7.2					
>70%	74	2	2.7	73	5	6.8					
Baseline HRCT pattern											
UIP-like	116	5	4.3	121	8	6.6					
Other fibrotic patterns	53	4	7.5	49	4	8.2					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	1	3.7					
Unclassifiable IIP	46	2	4.3	32	4	12.5					
HP	38	3	7.9	43	2	4.7					
Autoimmune ILD	29	0	0.0	43	3	7.0					
Other ILD	24	3	12.5	25	2	8.0					
Region											
Europe	78	8	10.3	67	8	11.9					
Asia	45	0	0.0	41	0	0.0					
Canada and USA	30	1	3.3	37	4	10.8					
Rest of the World	16	0	0.0	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Psychiatric disorders
PT: Anxiety

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk ratio (95% CI) p-value*	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	17	10.1	170	21	12.4	0.5033	1.23 (0.67, 2.24)	1.26 (0.64, 2.48)	2.29 (-4.55, 9.16)	
Age											
<65 years	65	8	12.3	64	6	9.4					
>=65 years	104	9	8.7	106	15	14.2					
Sex											
Male	114	11	9.6	108	14	13.0					
Female	55	6	10.9	62	7	11.3					
Baseline FVC percent predicted											
<=70%	95	11	11.6	97	17	17.5					
>70%	74	6	8.1	73	4	5.5					
Baseline HRCT pattern											
UIP-like	116	13	11.2	121	15	12.4					
Other fibrotic patterns	53	4	7.5	49	6	12.2					
Underlying ILD diagnosis											
iNSIP	32	4	12.5	27	2	7.4					
Unclassifiable IIP	46	4	8.7	32	6	18.8					
HP	38	1	2.6	43	5	11.6					
Autoimmune ILD	29	3	10.3	43	4	9.3					
Other ILD	24	5	20.8	25	4	16.0					
Region											
Europe	78	9	11.5	67	7	10.4					
Asia	45	5	11.1	41	6	14.6					
Canada and USA	30	0	0.0	37	4	10.8					
Rest of the World	16	3	18.8	25	4	16.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Psychiatric disorders
PT: Depression

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	22	13.0	170	21	12.4	0.8541	0.95 (0.54, 1.66)	0.94 (0.50, 1.79)	-0.66 (-7.87, 6.53)	
Age											
<65 years	65	9	13.8	64	6	9.4					
>=65 years	104	13	12.5	106	15	14.2					
Sex											
Male	114	17	14.9	108	14	13.0					
Female	55	5	9.1	62	7	11.3					
Baseline FVC percent predicted											
<=70%	95	18	18.9	97	17	17.5					
>70%	74	4	5.4	73	4	5.5					
Baseline HRCT pattern											
UIP-like	116	15	12.9	121	17	14.0					
Other fibrotic patterns	53	7	13.2	49	4	8.2					
Underlying ILD diagnosis											
iNSIP	32	5	15.6	27	3	11.1					
Unclassifiable IIP	46	6	13.0	32	3	9.4					
HP	38	1	2.6	43	5	11.6					
Autoimmune ILD	29	3	10.3	43	5	11.6					
Other ILD	24	7	29.2	25	5	20.0					
Region											
Europe	78	13	16.7	67	8	11.9					
Asia	45	6	13.3	41	8	19.5					
Canada and USA	30	1	3.3	37	2	5.4					
Rest of the World	16	2	12.5	25	3	12.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	28	16.6	170	24	14.1	0.5313	0.85 (0.52, 1.41)	0.83 (0.46, 1.50)	-2.45 (-10.19, 5.29)	
Age											
<65 years	65	12	18.5	64	9	14.1					
>=65 years	104	16	15.4	106	15	14.2					
Sex											
Male	114	20	17.5	108	17	15.7					
Female	55	8	14.5	62	7	11.3					
Baseline FVC percent predicted											
<=70%	95	21	22.1	97	13	13.4					
>70%	74	7	9.5	73	11	15.1					
Baseline HRCT pattern											
UIP-like	116	19	16.4	121	19	15.7					
Other fibrotic patterns	53	9	17.0	49	5	10.2					
Underlying ILD diagnosis											
iNSIP	32	4	12.5	27	2	7.4					
Unclassifiable IIP	46	6	13.0	32	4	12.5					
HP	38	10	26.3	43	7	16.3					
Autoimmune ILD	29	2	6.9	43	4	9.3					
Other ILD	24	6	25.0	25	7	28.0					
Region											
Europe	78	21	26.9	67	8	11.9					
Asia	45	3	6.7	41	2	4.9					
Canada and USA	30	2	6.7	37	11	29.7					
Rest of the World	16	2	12.5	25	3	12.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff.	(95% CI)	Interaction p-value**
Overall	169	25	14.8	170	17	10.0	0.1805	0.68 (0.38, 1.21)	0.64 (0.33, 1.23)	-4.79	(-11.94, 2.30)	
Age												
<65 years	65	5	7.7	64	5	7.8						
>=65 years	104	20	19.2	106	12	11.3						
Sex												
Male	114	17	14.9	108	14	13.0						
Female	55	8	14.5	62	3	4.8						
Baseline FVC percent predicted												
<=70%	95	16	16.8	97	11	11.3						
>70%	74	9	12.2	73	6	8.2						
Baseline HRCT pattern												
UIP-like	116	16	13.8	121	14	11.6						
Other fibrotic patterns	53	9	17.0	49	3	6.1						
Underlying ILD diagnosis												
iNSIP	32	2	6.3	27	2	7.4						
Unclassifiable IIP	46	8	17.4	32	4	12.5						
HP	38	9	23.7	43	7	16.3						
Autoimmune ILD	29	3	10.3	43	2	4.7						
Other ILD	24	3	12.5	25	2	8.0						
Region												
Europe	78	13	16.7	67	8	11.9						
Asia	45	2	4.4	41	0	0.0						
Canada and USA	30	8	26.7	37	4	10.8						
Rest of the World	16	2	12.5	25	5	20.0						

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Vascular disorders
PT: Hypertension

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	4	2.4	170	10	5.9	0.1038	2.49 (0.79, 7.77)	2.58 (0.79, 8.39)	3.52 (-0.93, 8.34)	
Age											
<65 years	65	0	0.0	64	2	3.1					
>=65 years	104	4	3.8	106	8	7.5					
Sex											
Male	114	1	0.9	108	5	4.6					
Female	55	3	5.5	62	5	8.1					
Baseline FVC percent predicted											
<=70%	95	2	2.1	97	4	4.1					
>70%	74	2	2.7	73	6	8.2					
Baseline HRCT pattern											
UIP-like	116	3	2.6	121	7	5.8					
Other fibrotic patterns	53	1	1.9	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	2	7.4					
Unclassifiable IIP	46	0	0.0	32	3	9.4					
HP	38	0	0.0	43	0	0.0					
Autoimmune ILD	29	1	3.4	43	4	9.3					
Other ILD	24	2	8.3	25	1	4.0					
Region											
Europe	78	3	3.8	67	5	7.5					
Asia	45	0	0.0	41	4	9.8					
Canada and USA	30	1	3.3	37	1	2.7					
Rest of the World	16	0	0.0	25	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 2 Proportion of patients with frequent serious AEs by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	21	12.4	170	10	5.9	0.0366	0.47 (0.23, 0.97)	0.44 (0.20, 0.97)	-6.54 (-12.94, -0.34)	
Age											0.3179
<65 years	65	5	7.7	64	4	6.3	0.7478	0.81 (0.23, 2.89)	0.80 (0.20, 3.13)	-1.44 (-11.29, 8.33)	
>=65 years	104	16	15.4	106	6	5.7	0.0214	0.37 (0.15, 0.90)	0.33 (0.12, 0.88)	-9.72 (-18.43, -1.35)	
Sex											0.6640
Male	114	16	14.0	108	8	7.4	0.1119	0.53 (0.24, 1.18)	0.49 (0.20, 1.20)	-6.63 (-15.00, 1.73)	
Female	55	5	9.1	62	2	3.2	0.1819	0.35 (0.07, 1.76)	0.33 (0.06, 1.79)	-5.87 (-16.61, 3.47)	
Baseline FVC percent predicted											0.8988
<=70%	95	15	15.8	97	7	7.2	0.0622	0.46 (0.20, 1.07)	0.41 (0.16, 1.07)	-8.57 (-17.96, 0.59)	
>70%	74	6	8.1	73	3	4.1	0.3120	0.51 (0.13, 1.95)	0.49 (0.12, 2.02)	-4.00 (-12.89, 4.49)	
Baseline HRCT pattern											0.1331
UIP-like	116	14	12.1	121	10	8.3	0.3318	0.68 (0.32, 1.48)	0.66 (0.28, 1.54)	-3.80 (-11.88, 4.07)	
Other fibrotic patterns	53	7	13.2	49	0	0.0	0.0137	0.07 (0.00, 1.23)	0.00 (NC, NC)	-13.21 (-24.84, -3.35)	
Underlying ILD diagnosis											0.3109
iNSIP	32	1	3.1	27	3	11.1	0.2241	3.56 (0.39, 32.23)	3.88 (0.38, 39.63)	7.99 (-6.57, 25.13)	
Unclassifiable IIP	46	8	17.4	32	3	9.4	0.3170	0.54 (0.15, 1.88)	0.49 (0.12, 2.02)	-8.02 (-22.69, 8.99)	
HP	38	3	7.9	43	1	2.3	0.2483	0.29 (0.03, 2.71)	0.28 (0.03, 2.79)	-5.57 (-18.61, 5.45)	
Autoimmune ILD	29	5	17.2	43	1	2.3	0.0247	0.13 (0.02, 1.10)	0.11 (0.01, 1.04)	-14.92 (-32.33, -1.21)	
Other ILD	24	4	16.7	25	2	8.0	0.3549	0.48 (0.10, 2.38)	0.43 (0.07, 2.63)	-8.67 (-28.70, 11.02)	
Region											0.5734
Europe	78	9	11.5	67	2	3.0	0.0525	0.26 (0.06, 1.16)	0.24 (0.05, 1.13)	-8.55 (-17.77, 0.46)	
Asia	45	9	20.0	41	5	12.2	0.3275	0.61 (0.22, 1.67)	0.56 (0.17, 1.82)	-7.80 (-23.24, 8.35)	
Canada and USA	30	1	3.3	37	2	5.4	0.6834	1.62 (0.15, 17.03)	1.66 (0.14, 19.21)	2.07 (-11.83, 14.67)	
Rest of the World	16	2	12.5	25	1	4.0	0.3080	0.32 (0.03, 3.25)	0.29 (0.02, 3.52)	-8.50 (-32.25, 9.46)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 2 Proportion of patients with frequent serious AEs by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Pneumonia

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	8	4.7	170	10	5.9	0.6372	1.24 (0.50, 3.07)	1.26 (0.48, 3.27)	1.15 (-3.93, 6.30)	
Age											
<65 years	65	4	6.2	64	3	4.7					
>=65 years	104	4	3.8	106	7	6.6					
Sex											
Male	114	5	4.4	108	6	5.6					
Female	55	3	5.5	62	4	6.5					
Baseline FVC percent predicted											
<=70%	95	5	5.3	97	8	8.2					
>70%	74	3	4.1	73	2	2.7					
Baseline HRCT pattern											
UIP-like	116	6	5.2	121	7	5.8					
Other fibrotic patterns	53	2	3.8	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	1	3.7					
Unclassifiable IIP	46	1	2.2	32	2	6.3					
HP	38	1	2.6	43	3	7.0					
Autoimmune ILD	29	4	13.8	43	3	7.0					
Other ILD	24	1	4.2	25	1	4.0					
Region											
Europe	78	3	3.8	67	4	6.0					
Asia	45	5	11.1	41	4	9.8					
Canada and USA	30	0	0.0	37	0	0.0					
Rest of the World	16	0	0.0	25	2	8.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff.	(95% CI)	Interaction p-value**
Overall	169	20	11.8	170	10	5.9	0.0537	0.50 (0.24, 1.03)	0.47 (0.21, 1.03)	-5.95	(-12.27, 0.18)	
Age												
<65 years	65	4	6.2	64	4	6.3						
>=65 years	104	16	15.4	106	6	5.7						
Sex												
Male	114	16	14.0	108	7	6.5						
Female	55	4	7.3	62	3	4.8						
Baseline FVC percent predicted												
<=70%	95	14	14.7	97	8	8.2						
>70%	74	6	8.1	73	2	2.7						
Baseline HRCT pattern												
UIP-like	116	14	12.1	121	10	8.3						
Other fibrotic patterns	53	6	11.3	49	0	0.0						
Underlying ILD diagnosis												
iNSIP	32	1	3.1	27	3	11.1						
Unclassifiable IIP	46	8	17.4	32	3	9.4						
HP	38	3	7.9	43	0	0.0						
Autoimmune ILD	29	4	13.8	43	2	4.7						
Other ILD	24	4	16.7	25	2	8.0						
Region												
Europe	78	9	11.5	67	2	3.0						
Asia	45	8	17.8	41	6	14.6						
Canada and USA	30	1	3.3	37	1	2.7						
Rest of the World	16	2	12.5	25	1	4.0						

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.1.2.1.5: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (NIN background)
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	169	9	5.3	170	10	5.9	0.8236	1.10 (0.46, 2.65)	1.11 (0.44, 2.81)	0.56 (-4.66, 5.80)	
Age											
<65 years	65	4	6.2	64	3	4.7					
>=65 years	104	5	4.8	106	7	6.6					
Sex											
Male	114	6	5.3	108	6	5.6					
Female	55	3	5.5	62	4	6.5					
Baseline FVC percent predicted											
<=70%	95	5	5.3	97	8	8.2					
>70%	74	4	5.4	73	2	2.7					
Baseline HRCT pattern											
UIP-like	116	7	6.0	121	7	5.8					
Other fibrotic patterns	53	2	3.8	49	3	6.1					
Underlying ILD diagnosis											
iNSIP	32	1	3.1	27	1	3.7					
Unclassifiable IIP	46	1	2.2	32	2	6.3					
HP	38	2	5.3	43	3	7.0					
Autoimmune ILD	29	4	13.8	43	3	7.0					
Other ILD	24	1	4.2	25	1	4.0					
Region											
Europe	78	3	3.8	67	4	6.0					
Asia	45	5	11.1	41	4	9.8					
Canada and USA	30	0	0.0	37	0	0.0					
Rest of the World	16	1	6.3	25	2	8.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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I.2.1.3 Further analysis

I.2.1.3.1 Time to event analyses: treatment policy approach to lung transplant

Table I.2.1.3.1: 1 Cox model for time to first confirmed acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n (e/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (e/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	31 (17/ 14)	18.3	15.86	170	18 (10/ 8)	10.6	9.28	0.53	(0.29, 0.94)	0.0315	
Age												0.8028
<65 years	65	7 (4/ 3)	10.8	8.98	64	3 (3/ 0)	4.7	4.18	0.45	(0.12, 1.74)	0.2472	
>=65 years	104	24 (13/ 11)	23.1	20.42	106	15 (7/ 8)	14.2	12.26	0.54	(0.28, 1.04)	0.0654	
Sex												0.5429
Male	114	26 (14/ 12)	22.8	19.94	108	13 (8/ 5)	12.0	10.80	0.49	(0.25, 0.96)	0.0379	
Female	55	5 (3/ 2)	9.1	7.69	62	5 (2/ 3)	8.1	6.79	0.76	(0.22, 2.65)	0.6699	
Baseline FVC percent predicted												0.2294
<=70%	95	19 (12/ 7)	20.0	17.74	97	8 (7/ 1)	8.2	7.24	0.38	(0.17, 0.88)	0.0242	
>70%	74	12 (5/ 7)	16.2	13.58	73	10 (3/ 7)	13.7	11.97	0.80	(0.34, 1.87)	0.6046	
Baseline HRCT pattern												0.0833
UIP-like	116	20 (12/ 8)	17.2	14.85	121	17 (10/ 7)	14.0	12.17	0.72	(0.37, 1.37)	0.3140	
Other fibrotic patterns	53	11 (5/ 6)	20.8	18.08	49	1 (0/ 1)	2.0	1.84	0.11	(0.01, 0.83)	0.0324	
Underlying ILD diagnosis												0.2854
iNSIP	32	3 (0/ 3)	9.4	8.04	27	6 (4/ 2)	22.2	21.81	2.27	(0.56, 9.20)	0.2511	
Unclassifiable IIP	46	13 (8/ 5)	28.3	25.49	32	4 (2/ 2)	12.5	10.52	0.42	(0.14, 1.29)	0.1301	
HP	38	5 (3/ 2)	13.2	11.07	43	3 (1/ 2)	7.0	6.30	0.40	(0.09, 1.70)	0.2123	
Autoimmune ILD	29	5 (3/ 2)	17.2	14.72	43	4 (2/ 2)	9.3	7.97	0.42	(0.11, 1.59)	0.2027	
Other ILD	24	5 (3/ 2)	20.8	17.85	25	1 (1/ 0)	4.0	3.26	0.24	(0.03, 2.10)	0.1986	
Region												0.7516
Europe	78	13 (7/ 6)	16.7	14.25	67	4 (2/ 2)	6.0	5.33	0.31	(0.10, 0.97)	0.0439	
Asia	45	10 (7/ 3)	22.2	18.82	41	7 (5/ 2)	17.1	14.42	0.58	(0.22, 1.54)	0.2730	
Canada and USA	30	5 (2/ 3)	16.7	14.31	37	4 (3/ 1)	10.8	9.44	0.75	(0.20, 2.80)	0.6646	
Rest of the World	16	3 (1/ 2)	18.8	18.58	25	3 (0/ 3)	12.0	10.70	0.67	(0.13, 3.38)	0.6262	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed acute ILD exacerbations, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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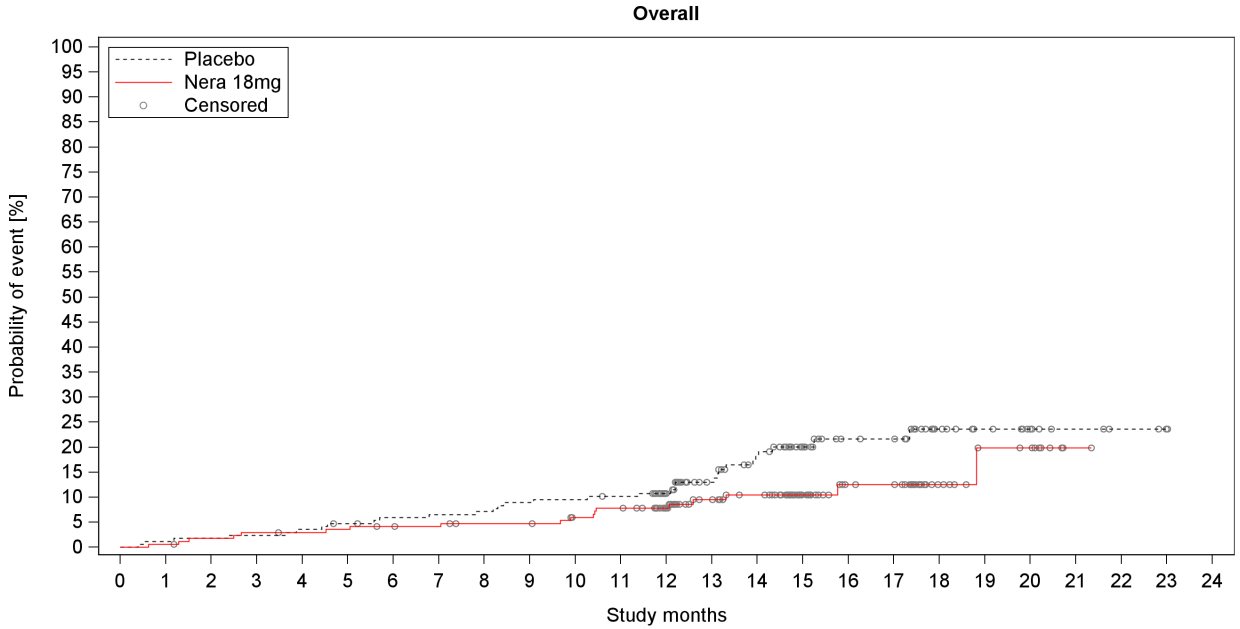

Number at risk (percentage relative to baseline)

Placebo	169	167	166	165	163	160	157	156	155	152	151	149	125	102	91	55	44	43	18	13	9	5	3	1	0
%	100.0	98.8	98.2	97.6	96.4	94.7	92.9	92.3	91.7	89.9	89.3	88.2	74.0	60.4	53.8	32.5	26.0	25.4	10.7	7.7	5.3	3.0	1.8	0.6	0.0
Nera 18mg	170	169	166	164	163	162	160	159	156	156	151	148	130	100	93	52	38	37	17	10	9	1	0	0	0
%	100.0	99.4	97.6	96.5	95.9	95.3	94.1	93.5	91.8	91.8	88.8	87.1	76.5	58.8	54.7	30.6	22.4	21.8	10.0	5.9	5.3	0.6	0.0	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	1	2	2	2	2	2	3	26	46	51	85	95	96	120	125	129	133	135	137	138
%	0.0	0.0	0.0	0.0	0.0	0.6	1.2	1.2	1.2	1.2	1.2	1.8	15.4	27.2	30.2	50.3	56.2	56.8	71.0	74.0	76.3	78.7	79.9	81.1	81.7
Nera 18mg	0	0	1	1	2	2	3	4	6	6	9	9	27	55	61	102	115	116	136	142	143	151	152	152	152
%	0.0	0.0	0.6	0.6	1.2	1.2	1.8	2.4	3.5	3.5	5.3	5.3	15.9	32.4	35.9	60.0	67.6	68.2	80.0	83.5	84.1	88.8	89.4	89.4	89.4

Study: 1305-0023

Figure I.2.1.3.1: 1 Time to first confirmed acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (NIN background)

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Figure I.2.1.3.1: 1

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Table I.2.1.3.1: 2 Cox model for time to first confirmed or suspected acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n (e/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (e/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	35 (22/ 13)	20.7	18.18	170	21 (13/ 8)	12.4	10.88	0.54	(0.31, 0.93)	0.0272	
Age												0.6845
<65 years	65	8 (5/ 3)	12.3	10.29	64	5 (5/ 0)	7.8	7.08	0.66	(0.22, 2.04)	0.4726	
>=65 years	104	27 (17/ 10)	26.0	23.52	106	16 (8/ 8)	15.1	13.08	0.51	(0.27, 0.95)	0.0329	
Sex												0.4288
Male	114	28 (17/ 11)	24.6	21.79	108	14 (9/ 5)	13.0	11.63	0.48	(0.25, 0.92)	0.0259	
Female	55	7 (5/ 2)	12.7	10.93	62	7 (4/ 3)	11.3	9.64	0.79	(0.28, 2.27)	0.6612	
Baseline FVC percent predicted												0.3314
<=70%	95	22 (16/ 6)	23.2	20.81	97	11 (10/ 1)	11.3	10.05	0.44	(0.21, 0.90)	0.0258	
>70%	74	13 (6/ 7)	17.6	14.97	73	10 (3/ 7)	13.7	11.97	0.76	(0.33, 1.75)	0.5129	
Baseline HRCT pattern												0.1898
UIP-like	116	22 (15/ 7)	19.0	16.58	121	18 (11/ 7)	14.9	12.93	0.68	(0.36, 1.27)	0.2240	
Other fibrotic patterns	53	13 (7/ 6)	24.5	21.73	49	3 (2/ 1)	6.1	5.58	0.26	(0.07, 0.93)	0.0378	
Underlying ILD diagnosis												0.2962
iNSIP	32	4 (2/ 2)	12.5	11.19	27	7 (5/ 2)	25.9	25.44	1.81	(0.52, 6.28)	0.3527	
Unclassifiable IIP	46	13 (8/ 5)	28.3	25.49	32	4 (2/ 2)	12.5	10.52	0.43	(0.14, 1.34)	0.1464	
HP	38	6 (4/ 2)	15.8	13.34	43	3 (1/ 2)	7.0	6.30	0.35	(0.08, 1.40)	0.1372	
Autoimmune ILD	29	6 (4/ 2)	20.7	18.08	43	6 (4/ 2)	14.0	12.21	0.51	(0.16, 1.60)	0.2470	
Other ILD	24	6 (4/ 2)	25.0	21.70	25	1 (1/ 0)	4.0	3.26	0.20	(0.02, 1.67)	0.1368	
Region												0.8209
Europe	78	15 (10/ 5)	19.2	16.62	67	5 (3/ 2)	7.5	6.70	0.35	(0.13, 0.98)	0.0446	
Asia	45	10 (7/ 3)	22.2	18.82	41	8 (6/ 2)	19.5	16.69	0.65	(0.25, 1.65)	0.3620	
Canada and USA	30	7 (4/ 3)	23.3	21.20	37	5 (4/ 1)	13.5	11.80	0.62	(0.20, 1.98)	0.4225	
Rest of the World	16	3 (1/ 2)	18.8	18.58	25	3 (0/ 3)	12.0	10.70	0.63	(0.13, 3.19)	0.5786	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb). The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed or suspected acute ILD exacerbations, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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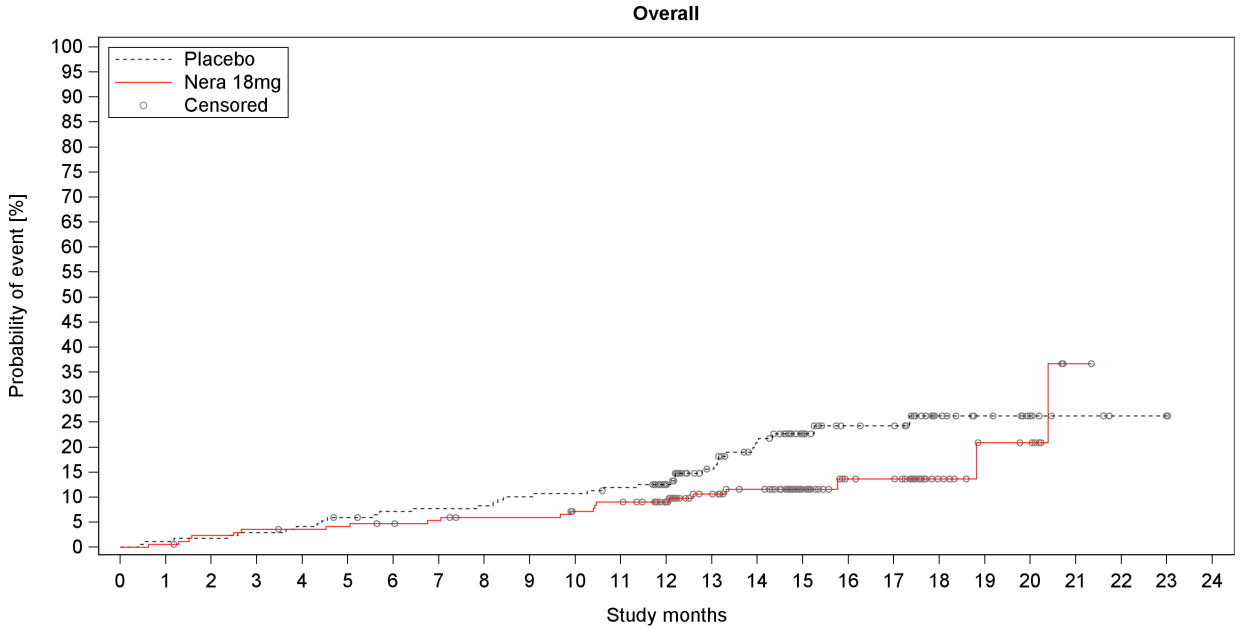

	Number at risk (percentage relative to baseline)																								
Placebo	169	167	166	164	162	158	155	154	153	150	149	146	123	99	88	53	43	42	17	12	8	4	2	1	0
%	100.0	98.8	98.2	97.0	95.9	93.5	91.7	91.1	90.5	88.8	88.2	86.4	72.8	58.6	52.1	31.4	25.4	24.9	10.1	7.1	4.7	2.4	1.2	0.6	0.0
Nera 18mg	170	169	165	163	162	161	159	157	154	154	150	147	130	100	93	52	38	37	17	10	9	1	0	0	0
%	100.0	99.4	97.1	95.9	95.3	94.7	93.5	92.4	90.6	90.6	88.2	86.5	76.5	58.8	54.7	30.6	22.4	21.8	10.0	5.9	5.3	0.6	0.0	0.0	0.0
	Number censored (percentage relative to number at risk at baseline)																								
Placebo	0	0	0	0	0	1	2	2	2	2	2	3	25	45	50	83	92	93	117	122	126	130	132	133	134
%	0.0	0.0	0.0	0.0	0.0	0.6	1.2	1.2	1.2	1.2	1.2	1.8	14.8	26.6	29.6	49.1	54.4	55.0	69.2	72.2	74.6	76.9	78.1	78.7	79.3
Nera 18mg	0	0	1	1	2	2	3	4	6	6	8	8	25	53	59	100	113	114	134	140	141	148	149	149	149
%	0.0	0.0	0.6	0.6	1.2	1.2	1.8	2.4	3.5	3.5	4.7	4.7	14.7	31.2	34.7	58.8	66.5	67.1	78.8	82.4	82.9	87.1	87.6	87.6	87.6

Study: 1305-0023

Figure I.2.1.3.1: 2 Time to first confirmed or suspected acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (NIN background)

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BI Trial No.: x1305p3.hta

Figure I.2.1.3.1: 2

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Table I.2.1.3.1: 3 Cox model for time to death - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	20	11.8	9.92	170	12	7.1	6.07	0.52	(0.25, 1.08)	0.0780	
Age												0.7839
<65 years	65	3	4.6	3.74	64	1	1.6	1.38	0.39	(0.04, 3.75)	0.4124	
>=65 years	104	17	16.3	14.01	106	11	10.4	8.78	0.54	(0.25, 1.16)	0.1146	
Sex												0.3546
Male	114	17	14.9	12.63	108	8	7.4	6.46	0.44	(0.19, 1.02)	0.0548	
Female	55	3	5.5	4.48	62	4	6.5	5.41	0.99	(0.22, 4.46)	0.9868	
Baseline FVC percent predicted												0.2506
<=70%	95	12	12.6	10.79	97	5	5.2	4.43	0.37	(0.13, 1.06)	0.0646	
>70%	74	8	10.8	8.86	73	7	9.6	8.24	0.88	(0.31, 2.49)	0.8128	
Baseline HRCT pattern												0.2320
UIP-like	116	14	12.1	10.10	121	11	9.1	7.67	0.66	(0.30, 1.47)	0.3126	
Other fibrotic patterns	53	6	11.3	9.54	49	1	2.0	1.84	0.16	(0.02, 1.39)	0.0975	
Underlying ILD diagnosis												0.6610
iNSIP	32	3	9.4	8.04	27	5	18.5	17.36	1.51	(0.35, 6.46)	0.5811	
Unclassifiable IIP	46	8	17.4	14.79	32	2	6.3	5.06	0.37	(0.08, 1.76)	0.2095	
HP	38	2	5.3	4.32	43	2	4.7	4.17	0.53	(0.07, 3.92)	0.5345	
Autoimmune ILD	29	4	13.8	11.38	43	3	7.0	5.90	0.35	(0.08, 1.61)	0.1797	
Other ILD	24	3	12.5	10.45	25	0	0.0	0.00	0.00	(NC, NC)	0.9908	
Region												0.8499
Europe	78	7	9.0	7.51	67	3	4.5	3.99	0.38	(0.10, 1.52)	0.1736	
Asia	45	7	15.6	12.54	41	5	12.2	9.91	0.68	(0.21, 2.20)	0.5222	
Canada and USA	30	3	10.0	8.25	37	1	2.7	2.26	0.27	(0.03, 2.63)	0.2595	
Rest of the World	16	3	18.8	18.53	25	3	12.0	10.70	0.69	(0.13, 3.59)	0.6605	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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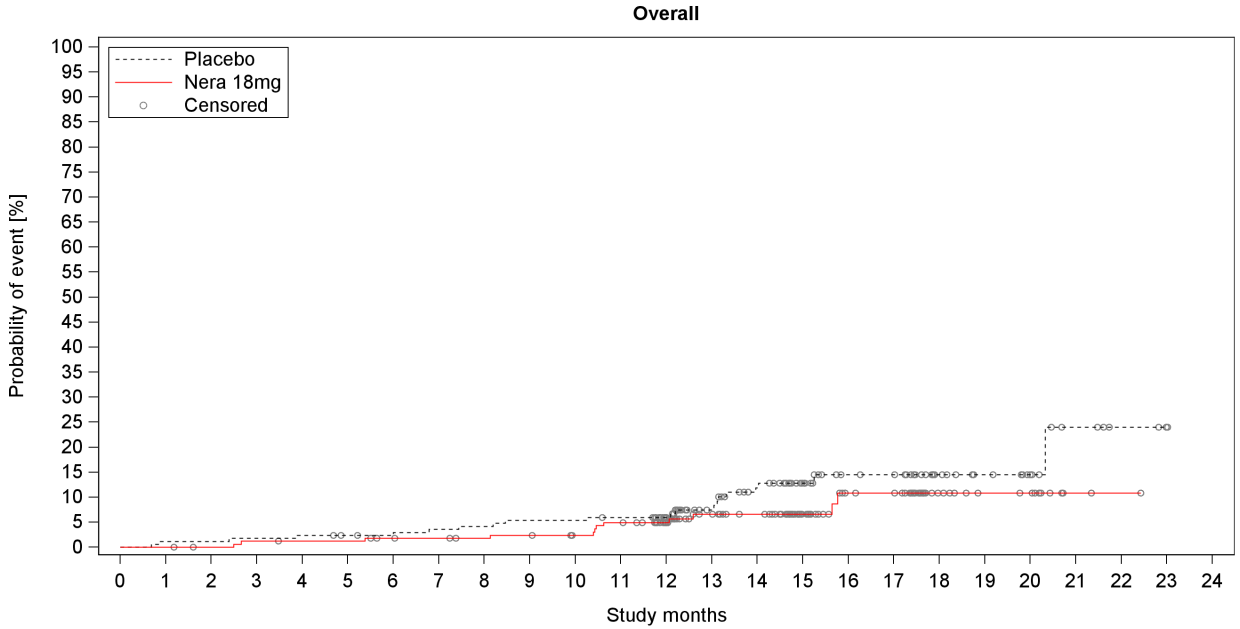

Number at risk (percentage relative to baseline)

Placebo	169	167	167	166	165	163	162	160	159	157	157	155	131	107	96	60	47	45	21	16	12	6	3	1	0
%	100.0	98.8	98.8	98.2	97.6	96.4	95.9	94.7	94.1	92.9	92.9	91.7	77.5	63.3	56.8	35.5	27.8	26.6	12.4	9.5	7.1	3.6	1.8	0.6	0.0
Nera 18mg	170	170	168	166	165	165	162	161	159	158	155	151	133	103	97	55	39	38	17	11	10	2	1	0	0
%	100.0	100.0	98.8	97.6	97.1	97.1	95.3	94.7	93.5	92.9	91.2	88.8	78.2	60.6	57.1	32.4	22.9	22.4	10.0	6.5	5.9	1.2	0.6	0.0	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	0	2	3	3	3	3	3	4	28	50	56	91	103	105	129	134	138	143	146	148	149
%	0.0	0.0	0.0	0.0	0.0	1.2	1.8	1.8	1.8	1.8	1.8	2.4	16.6	29.6	33.1	53.8	60.9	62.1	76.3	79.3	81.7	84.6	86.4	87.6	88.2
Nera 18mg	0	0	2	2	3	3	5	6	8	8	11	11	29	57	63	105	119	120	141	147	148	156	157	158	158
%	0.0	0.0	1.2	1.2	1.8	1.8	2.9	3.5	4.7	4.7	6.5	6.5	17.1	33.5	37.1	61.8	70.0	70.6	82.9	86.5	87.1	91.8	92.4	92.9	92.9

Study: 1305-0023

Figure I.2.1.3.1: 3 Time to death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (NIN background)

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Figure I.2.1.3.1: 3

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Table I.2.1.3.1: 4 Cox model for time to first confirmed acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	17	10.1	8.70	170	10	5.9	5.16	0.54	(0.25, 1.19)	0.1249	
Age												0.6206
<65 years	65	4	6.2	5.13	64	3	4.7	4.18	0.74	(0.16, 3.36)	0.7006	
>=65 years	104	13	12.5	11.06	106	7	6.6	5.74	0.48	(0.19, 1.20)	0.1155	
Sex												0.8563
Male	114	14	12.3	10.73	108	8	7.4	6.67	0.59	(0.24, 1.40)	0.2309	
Female	55	3	5.5	4.61	62	2	3.2	2.72	0.49	(0.08, 2.94)	0.4334	
Baseline FVC percent predicted												0.9131
<=70%	95	12	12.6	11.21	97	7	7.2	6.34	0.53	(0.21, 1.34)	0.1790	
>70%	74	5	6.8	5.66	73	3	4.1	3.61	0.58	(0.14, 2.44)	0.4570	
Baseline HRCT pattern												0.9880
UIP-like	116	12	10.3	8.91	121	10	8.3	7.18	0.73	(0.32, 1.71)	0.4731	
Other fibrotic patterns	53	5	9.4	8.22	49	0	0.0	0.00	0.00	(NC, NC)	0.9878	
Underlying ILD diagnosis												0.9995
iNSIP	32	0	0.0	0.00	27	4	14.8	14.54	>10	(NC, NC)	0.9900	
Unclassifiable IIP	46	8	17.4	15.69	32	2	6.3	5.31	0.33	(0.07, 1.57)	0.1640	
HP	38	3	7.9	6.64	43	1	2.3	2.10	0.25	(0.03, 2.46)	0.2362	
Autoimmune ILD	29	3	10.3	8.83	43	2	4.7	3.99	0.37	(0.06, 2.22)	0.2752	
Other ILD	24	3	12.5	10.71	25	1	4.0	3.26	0.31	(0.03, 3.08)	0.3202	
Region												0.6837
Europe	78	7	9.0	7.67	67	2	3.0	2.68	0.30	(0.06, 1.46)	0.1358	
Asia	45	7	15.6	13.17	41	5	12.2	10.30	0.64	(0.20, 2.03)	0.4464	
Canada and USA	30	2	6.7	5.73	37	3	8.1	7.08	1.32	(0.22, 7.95)	0.7586	
Rest of the World	16	1	6.3	6.19	25	0	0.0	0.00	0.00	(NC, NC)	0.9914	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb). The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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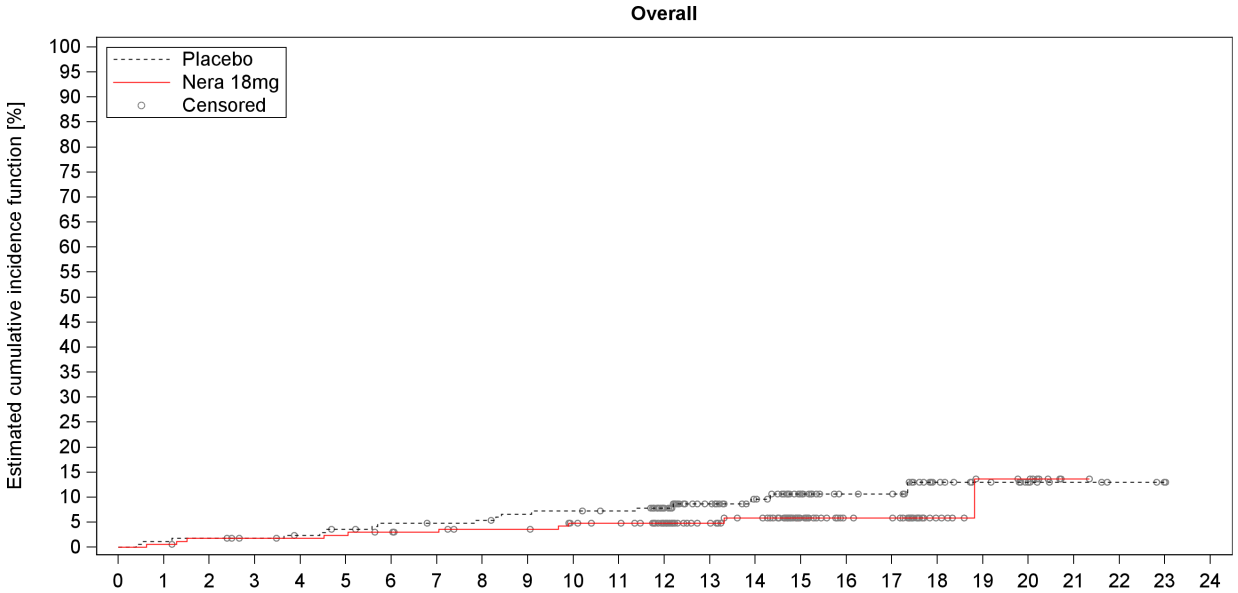

Number at risk (percentage relative to baseline)																									
Placebo	169	167	166	165	163	160	157	156	155	152	151	149	125	102	91	55	44	43	18	13	9	5	3	1	0
%	100.0	98.8	98.2	97.6	96.4	94.7	92.9	92.3	91.7	89.9	89.3	88.2	74.0	60.4	53.8	32.5	26.0	25.4	10.7	7.7	5.3	3.0	1.8	0.6	0.0
Nera 18mg	170	169	166	164	163	162	160	158	155	155	150	148	130	100	93	52	38	37	17	10	9	1	0	0	0
%	100.0	99.4	97.6	96.5	95.9	95.3	94.1	92.9	91.2	91.2	88.2	87.1	76.5	58.8	54.7	30.6	22.4	21.8	10.0	5.9	5.3	0.6	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	0	0	1	2	3	4	5	5	6	6	8	31	53	63	98	109	110	134	139	143	147	149	151	152
%	0.0	0.0	0.0	0.6	1.2	1.8	2.4	3.0	3.0	3.6	3.6	4.7	18.3	31.4	37.3	58.0	64.5	65.1	79.3	82.2	84.6	87.0	88.2	89.3	89.9
Nera 18mg	0	0	1	3	4	4	5	7	9	9	12	14	32	62	68	109	123	124	144	150	151	159	160	160	160
%	0.0	0.0	0.6	1.8	2.4	2.4	2.9	4.1	5.3	5.3	7.1	8.2	18.8	36.5	40.0	64.1	72.4	72.9	84.7	88.2	88.8	93.5	94.1	94.1	94.1

Study: 1305-0023

Figure I.2.1.3.1: 4 Time to first confirmed acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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Table I.2.1.3.1: 5 Cox model for time to first confirmed or suspected acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (NIN background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	169	22	13.0	11.43	170	13	7.6	6.75	0.54	(0.27, 1.08)	0.0829	
Age												0.2512
<65 years	65	5	7.7	6.43	64	5	7.8	7.08	1.00	(0.29, 3.49)	0.9978	
>=65 years	104	17	16.3	14.81	106	8	7.5	6.56	0.41	(0.18, 0.97)	0.0412	
Sex												0.8317
Male	114	17	14.9	13.23	108	9	8.3	7.50	0.53	(0.23, 1.19)	0.1220	
Female	55	5	9.1	7.80	62	4	6.5	5.51	0.62	(0.17, 2.34)	0.4842	
Baseline FVC percent predicted												0.9073
<=70%	95	16	16.8	15.14	97	10	10.3	9.14	0.55	(0.25, 1.22)	0.1394	
>70%	74	6	8.1	6.91	73	3	4.1	3.61	0.50	(0.12, 2.01)	0.3283	
Baseline HRCT pattern												0.4602
UIP-like	116	15	12.9	11.30	121	11	9.1	7.92	0.63	(0.29, 1.38)	0.2481	
Other fibrotic patterns	53	7	13.2	11.70	49	2	4.1	3.72	0.32	(0.07, 1.57)	0.1609	
Underlying ILD diagnosis												0.2310
iNSIP	32	2	6.3	5.59	27	5	18.5	18.17	2.97	(0.57, 15.58)	0.1984	
Unclassifiable IIP	46	8	17.4	15.69	32	2	6.3	5.31	0.35	(0.07, 1.67)	0.1894	
HP	38	4	10.5	8.90	43	1	2.3	2.10	0.19	(0.02, 1.74)	0.1419	
Autoimmune ILD	29	4	13.8	12.06	43	4	9.3	8.15	0.52	(0.13, 2.12)	0.3637	
Other ILD	24	4	16.7	14.47	25	1	4.0	3.26	0.25	(0.03, 2.28)	0.2199	
Region												0.7420
Europe	78	10	12.8	11.08	67	3	4.5	4.04	0.33	(0.09, 1.20)	0.0926	
Asia	45	7	15.6	13.17	41	6	14.6	12.52	0.74	(0.25, 2.23)	0.5960	
Canada and USA	30	4	13.3	12.11	37	4	10.8	9.44	0.87	(0.22, 3.49)	0.8433	
Rest of the World	16	1	6.3	6.19	25	0	0.0	0.00	0.00	(NC, NC)	0.9901	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb). The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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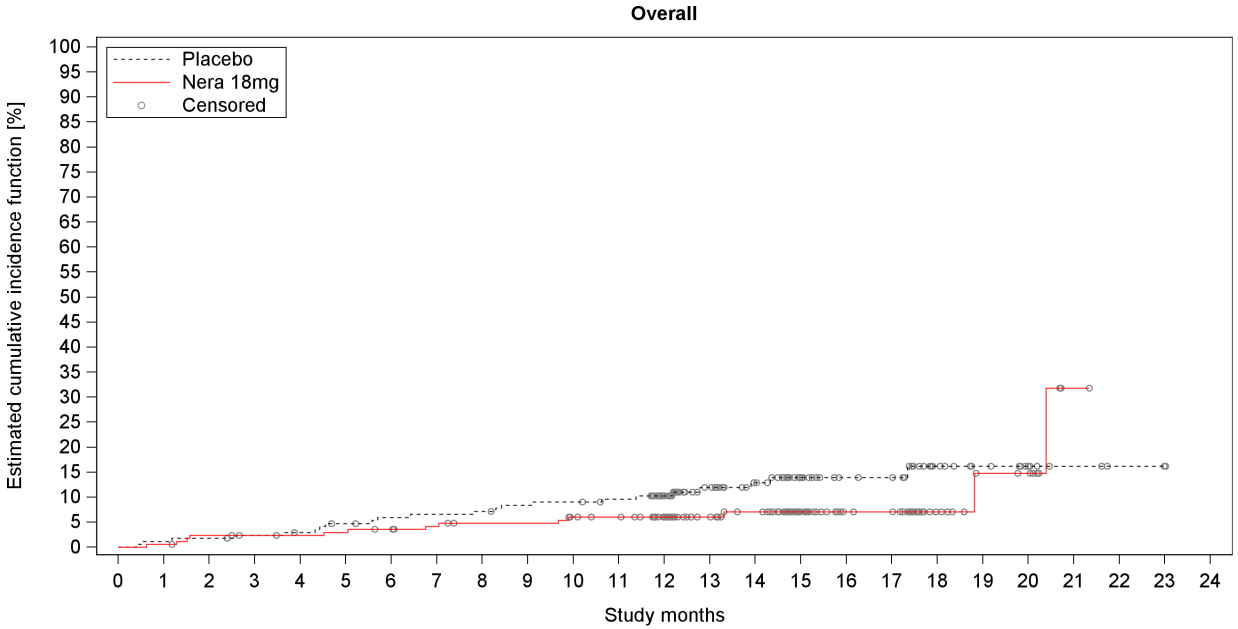

	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Number at risk (percentage relative to baseline)																									
Placebo	169	167	166	164	162	158	155	154	153	150	149	146	123	99	88	53	43	42	17	12	8	4	2	1	0
%	100.0	98.8	98.2	97.0	95.9	93.5	91.7	91.1	90.5	88.8	88.2	86.4	72.8	58.6	52.1	31.4	25.4	24.9	10.1	7.1	4.7	2.4	1.2	0.6	0.0
Nera 18mg	170	169	165	163	162	161	159	156	153	153	149	147	130	100	93	52	38	37	17	10	9	1	0	0	0
%	100.0	99.4	97.1	95.9	95.3	94.7	93.5	91.8	90.0	90.0	87.6	86.5	76.5	58.8	54.7	30.6	22.4	21.8	10.0	5.9	5.3	0.6	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																									
Placebo	0	0	0	1	2	3	4	4	4	5	5	7	29	51	61	95	105	106	130	135	139	143	145	146	147
%	0.0	0.0	0.0	0.6	1.2	1.8	2.4	2.4	2.4	3.0	3.0	4.1	17.2	30.2	36.1	56.2	62.1	62.7	76.9	79.9	82.2	84.6	85.8	86.4	87.0
Nera 18mg	0	0	1	3	4	4	5	7	9	9	11	13	30	60	66	107	121	122	142	148	149	156	157	157	157
%	0.0	0.0	0.6	1.8	2.4	2.4	2.9	4.1	5.3	5.3	6.5	7.6	17.6	35.3	38.8	62.9	71.2	71.8	83.5	87.1	87.6	91.8	92.4	92.4	92.4

Study: 1305-0023

Figure I.2.1.3.1: 5 Time to first confirmed or suspected acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (NIN background)

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I.2.2 Population with non-AF background

I.2.2.1 Efficacy Analysis

I.2.2.1.1 Time to event analyses

I.2.2.1.1.1 Analyses of composite endpoints

I.2.2.1.1.1.1 Time to first confirmed acute ILD exacerbation or death

Table I.2.2.1.1.1.1: 1 Cox model for time to first confirmed acute ILD exacerbation or death over the whole trial (DBL1) - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n (e/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (e/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	222	42 (20/ 22)	18.9	16.42	220	22 (12/ 10)	10.0	8.42	0.60	(0.36, 1.02)	0.0589	
Age												0.3613
<65 years	83	11 (6/ 5)	13.3	10.84	88	8 (5/ 3)	9.1	7.42	0.85	(0.34, 2.12)	0.7224	
>=65 years	139	31 (14/ 17)	22.3	20.08	132	14 (7/ 7)	10.6	9.11	0.50	(0.27, 0.95)	0.0354	
Sex												0.4972
Male	116	26 (13/ 13)	22.4	19.99	111	11 (5/ 6)	9.9	8.52	0.51	(0.25, 1.05)	0.0689	
Female	106	16 (7/ 9)	15.1	12.72	109	11 (7/ 4)	10.1	8.31	0.74	(0.34, 1.60)	0.4429	
Baseline FVC percent predicted												0.2543
<=70%	118	33 (16/ 17)	28.0	24.64	96	13 (8/ 5)	13.5	11.61	0.49	(0.26, 0.94)	0.0318	
>70%	104	9 (4/ 5)	8.7	7.38	124	9 (4/ 5)	7.3	6.02	0.96	(0.37, 2.50)	0.9395	
Baseline HRCT pattern												0.6693
UIP-like	158	30 (15/ 15)	19.0	16.68	154	15 (7/ 8)	9.7	8.18	0.56	(0.30, 1.05)	0.0707	
Other fibrotic patterns	64	12 (5/ 7)	18.8	15.78	66	7 (5/ 2)	10.6	8.96	0.72	(0.28, 1.86)	0.4988	
Underlying ILD diagnosis												0.1917
iNSIP	40	6 (3/ 3)	15.0	12.13	55	7 (3/ 4)	12.7	10.71	1.04	(0.35, 3.13)	0.9401	
Unclassifiable IIP	36	4 (1/ 3)	11.1	9.53	40	4 (4/ 0)	10.0	8.61	1.14	(0.28, 4.61)	0.8539	
HP	39	11 (7/ 4)	28.2	29.00	30	2 (0/ 2)	6.7	5.86	0.25	(0.05, 1.15)	0.0743	
Autoimmune ILD	71	14 (6/ 8)	19.7	16.49	70	4 (1/ 3)	5.7	4.62	0.29	(0.10, 0.90)	0.0314	
Other ILD	36	7 (3/ 4)	19.4	16.82	25	5 (4/ 1)	20.0	17.36	1.29	(0.41, 4.07)	0.6697	
Region												0.4534
Europe	40	7 (2/ 5)	17.5	15.68	53	8 (4/ 4)	15.1	13.98	1.01	(0.36, 2.80)	0.9826	
Asia	106	16 (11/ 5)	15.1	12.16	107	11 (6/ 5)	10.3	8.23	0.78	(0.36, 1.69)	0.5262	
Canada and USA	30	7 (3/ 4)	23.3	21.59	17	0 (0/ 0)	0.0	0.00	0.00	(NC, NC)	0.9849	
Rest of the World	46	12 (4/ 8)	26.1	25.39	43	3 (2/ 1)	7.0	6.02	0.28	(0.08, 0.99)	0.0481	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed acute ILD exacerbations, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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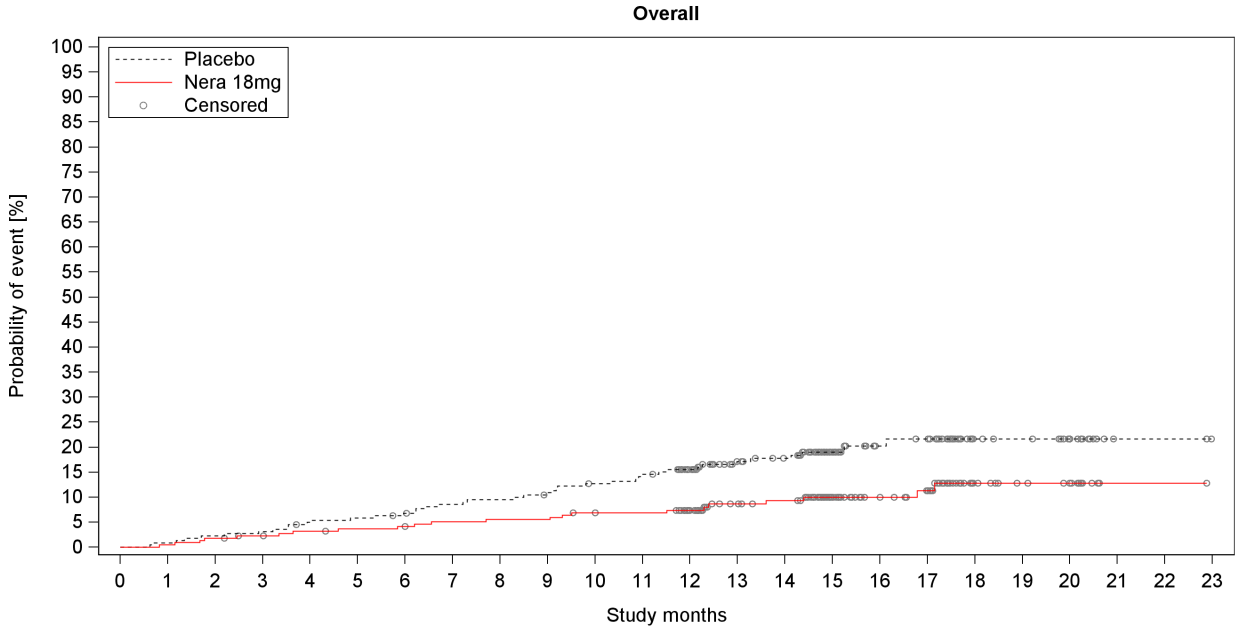

Number at risk (percentage relative to baseline)

Placebo	222	220	217	215	210	208	205	200	198	194	189	185	167	139	133	75	58	56	26	24	18	2	2	0
%	100.0	99.1	97.7	96.8	94.6	93.7	92.3	90.1	89.2	87.4	85.1	83.3	75.2	62.6	59.9	33.8	26.1	25.2	11.7	10.8	8.1	0.9	0.9	0.0
Nera 18mg	220	219	216	213	210	208	207	204	203	203	199	198	173	142	137	85	71	65	26	20	18	1	1	0
%	100.0	99.5	98.2	96.8	95.5	94.5	94.1	92.7	92.3	92.3	90.5	90.0	78.6	64.5	62.3	38.6	32.3	29.5	11.8	9.1	8.2	0.5	0.5	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	1	1	2	3	3	4	5	5	21	46	51	107	123	124	154	156	162	178	178	180
%	0.0	0.0	0.0	0.0	0.5	0.5	0.9	1.4	1.4	1.8	2.3	2.3	9.5	20.7	23.0	48.2	55.4	55.9	69.4	70.3	73.0	80.2	80.2	81.1
Nera 18mg	0	0	0	2	3	4	4	5	5	5	6	7	31	60	64	115	129	134	172	178	180	197	197	198
%	0.0	0.0	0.0	0.9	1.4	1.8	1.8	2.3	2.3	2.3	2.7	3.2	14.1	27.3	29.1	52.3	58.6	60.9	78.2	80.9	81.8	89.5	89.5	90.0

Study: 1305-0023

Figure I.2.2.1.1.1.1: 1 Time to first confirmed acute ILD exacerbation or death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (non-AF background)

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BI Trial No.: x1305p3.hta

Figure I.2.2.1.1.1.1: 1

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I.2.2.1.1.1.2 Time to first confirmed or suspected acute ILD exacerbation or death

Table I.2.2.1.1.1.2: 1 Cox model for time to first confirmed or suspected acute ILD exacerbation or death over the whole trial (DBL1) - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n (e/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (e/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	222	48 (30/ 18)	21.6	19.22	220	26 (17/ 9)	11.8	10.07	0.60	(0.37, 0.97)	0.0385	
Age												0.3288
<65 years	83	15 (12/ 3)	18.1	15.30	88	11 (9/ 2)	12.5	10.38	0.82	(0.37, 1.79)	0.6127	
>=65 years	139	33 (18/ 15)	23.7	21.74	132	15 (8/ 7)	11.4	9.84	0.50	(0.27, 0.92)	0.0264	
Sex												0.6923
Male	116	29 (19/ 10)	25.0	22.84	111	14 (9/ 5)	12.6	11.03	0.55	(0.29, 1.05)	0.0720	
Female	106	19 (11/ 8)	17.9	15.47	109	12 (8/ 4)	11.0	9.13	0.67	(0.33, 1.39)	0.2810	
Baseline FVC percent predicted												0.3523
<=70%	118	36 (21/ 15)	30.5	27.56	96	15 (11/ 4)	15.6	13.62	0.51	(0.28, 0.93)	0.0289	
>70%	104	12 (9/ 3)	11.5	10.07	124	11 (6/ 5)	8.9	7.42	0.83	(0.36, 1.92)	0.6670	
Baseline HRCT pattern												0.7277
UIP-like	158	33 (21/ 12)	20.9	18.63	154	17 (10/ 7)	11.0	9.34	0.57	(0.31, 1.02)	0.0588	
Other fibrotic patterns	64	15 (9/ 6)	23.4	20.65	66	9 (7/ 2)	13.6	11.79	0.68	(0.29, 1.57)	0.3672	
Underlying ILD diagnosis												0.4907
iNSIP	40	8 (7/ 1)	20.0	16.94	55	8 (4/ 4)	14.5	12.28	0.77	(0.29, 2.06)	0.6057	
Unclassifiable IIP	36	4 (1/ 3)	11.1	9.53	40	4 (4/ 0)	10.0	8.61	1.08	(0.27, 4.35)	0.9143	
HP	39	12 (9/ 3)	30.8	32.41	30	3 (1/ 2)	10.0	8.97	0.33	(0.09, 1.20)	0.0921	
Autoimmune ILD	71	16 (9/ 7)	22.5	19.34	70	6 (3/ 3)	8.6	7.10	0.40	(0.16, 1.03)	0.0579	
Other ILD	36	8 (4/ 4)	22.2	19.58	25	5 (5/ 0)	20.0	17.37	1.07	(0.35, 3.28)	0.9087	
Region												0.5178
Europe	40	8 (6/ 2)	20.0	18.73	53	10 (6/ 4)	18.9	17.94	1.01	(0.40, 2.56)	0.9888	
Asia	106	17 (12/ 5)	16.0	13.05	107	11 (7/ 4)	10.3	8.23	0.72	(0.34, 1.55)	0.4067	
Canada and USA	30	8 (4/ 4)	26.7	25.27	17	0 (0/ 0)	0.0	0.00	0.00	(NC, NC)	0.9836	
Rest of the World	46	15 (8/ 7)	32.6	33.21	43	5 (4/ 1)	11.6	10.37	0.35	(0.13, 0.99)	0.0467	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed or suspected acute ILD exacerbations, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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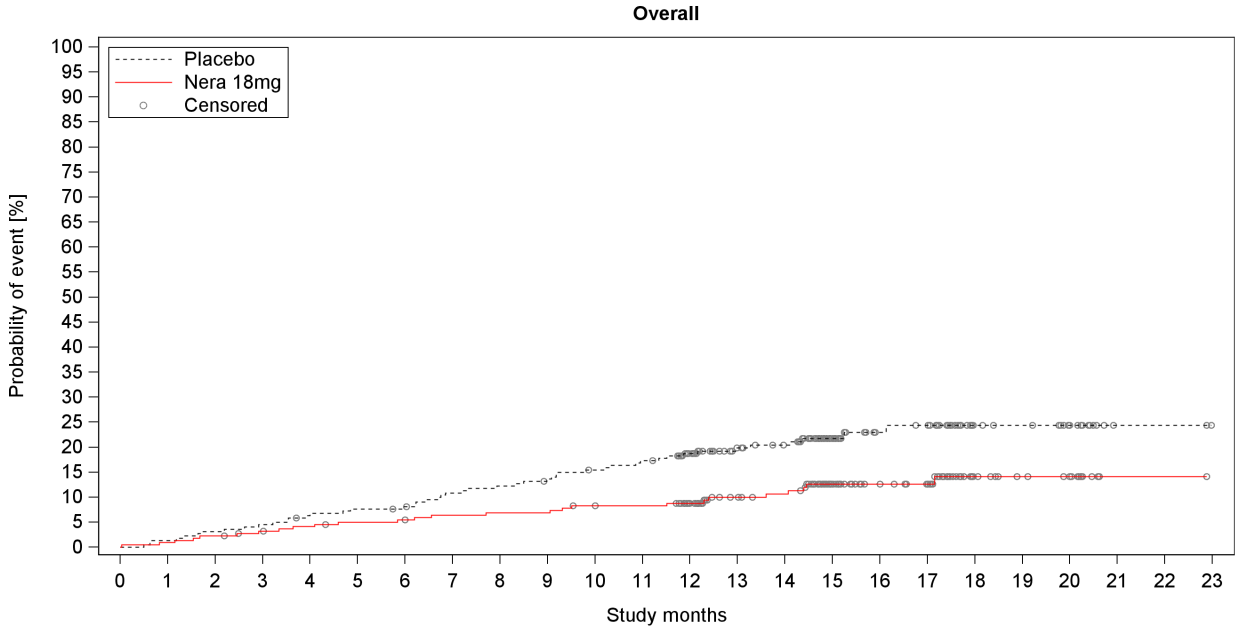

Number at risk (percentage relative to baseline)

Placebo	222	219	215	212	207	204	202	195	192	188	183	179	161	134	128	71	55	53	25	23	17	2	2	0
%	100.0	98.6	96.8	95.5	93.2	91.9	91.0	87.8	86.5	84.7	82.4	80.6	72.5	60.4	57.7	32.0	24.8	23.9	11.3	10.4	7.7	0.9	0.9	0.0
Nera 18mg	220	218	215	211	208	205	204	201	200	200	196	195	171	140	135	84	70	65	26	20	18	1	1	0
%	100.0	99.1	97.7	95.9	94.5	93.2	92.7	91.4	90.9	90.9	89.1	88.6	77.7	63.6	61.4	38.2	31.8	29.5	11.8	9.1	8.2	0.5	0.5	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	1	1	2	3	3	4	5	5	20	45	50	105	120	121	149	151	157	172	172	174
%	0.0	0.0	0.0	0.0	0.5	0.5	0.9	1.4	1.4	1.8	2.3	2.3	9.0	20.3	22.5	47.3	54.1	54.5	67.1	68.0	70.7	77.5	77.5	78.4
Nera 18mg	0	0	0	2	3	4	4	5	5	5	6	7	30	59	63	111	125	130	168	174	176	193	193	194
%	0.0	0.0	0.0	0.9	1.4	1.8	1.8	2.3	2.3	2.3	2.7	3.2	13.6	26.8	28.6	50.5	56.8	59.1	76.4	79.1	80.0	87.7	87.7	88.2

Study: 1305-0023

Figure I.2.2.1.1.2: 1 Time to first confirmed or suspected acute ILD exacerbation or death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (non-AF background)

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BI Trial No.: x1305p3.hta

Figure I.2.2.1.1.2: 1

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I.2.2.1.1.2 Analyses of single endpoints

I.2.2.1.1.2.1 Time to death

Table I.2.2.1.1.2.1: 1 Cox model for time to death over the whole trial (DBL1) - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	222	30	13.5	11.26	220	11	5.0	4.09	0.43	(0.21,	0.86)	0.0171	
Age													0.2562
<65 years	83	6	7.2	5.74	88	4	4.5	3.64	0.80	(0.22,	2.86)	0.7321	
>=65 years	139	24	17.3	14.83	132	7	5.3	4.41	0.33	(0.14,	0.77)	0.0108	
Sex													0.7479
Male	116	19	16.4	13.90	111	6	5.4	4.56	0.39	(0.15,	0.99)	0.0484	
Female	106	11	10.4	8.48	109	5	4.6	3.64	0.49	(0.17,	1.42)	0.1917	
Baseline FVC percent predicted													0.2855
<=70%	118	24	20.3	16.90	96	6	6.3	5.14	0.33	(0.13,	0.80)	0.0146	
>70%	104	6	5.8	4.83	124	5	4.0	3.29	0.73	(0.22,	2.41)	0.6099	
Baseline HRCT pattern													0.9310
UIP-like	158	22	13.9	11.69	154	8	5.2	4.26	0.42	(0.19,	0.95)	0.0371	
Other fibrotic patterns	64	8	12.5	10.23	66	3	4.5	3.71	0.45	(0.12,	1.71)	0.2405	
Underlying ILD diagnosis													0.5837
iNSIP	40	3	7.5	5.82	55	4	7.3	6.01	1.39	(0.31,	6.27)	0.6694	
Unclassifiable IIP	36	3	8.3	7.02	40	1	2.5	2.04	0.37	(0.04,	3.56)	0.3875	
HP	39	8	20.5	19.60	30	2	6.7	5.86	0.40	(0.08,	1.92)	0.2547	
Autoimmune ILD	71	10	14.1	11.31	70	3	4.3	3.44	0.28	(0.08,	1.05)	0.0596	
Other ILD	36	6	16.7	14.02	25	1	4.0	3.13	0.28	(0.03,	2.37)	0.2448	
Region													0.4273
Europe	40	6	15.0	12.95	53	5	9.4	8.45	0.76	(0.23,	2.52)	0.6584	
Asia	106	8	7.5	5.79	107	5	4.7	3.63	0.72	(0.23,	2.22)	0.5699	
Canada and USA	30	7	23.3	21.29	17	0	0.0	0.00	0.00	(NC,	NC)	0.9840	
Rest of the World	46	9	19.6	18.39	43	1	2.3	1.95	0.11	(0.01,	0.89)	0.0383	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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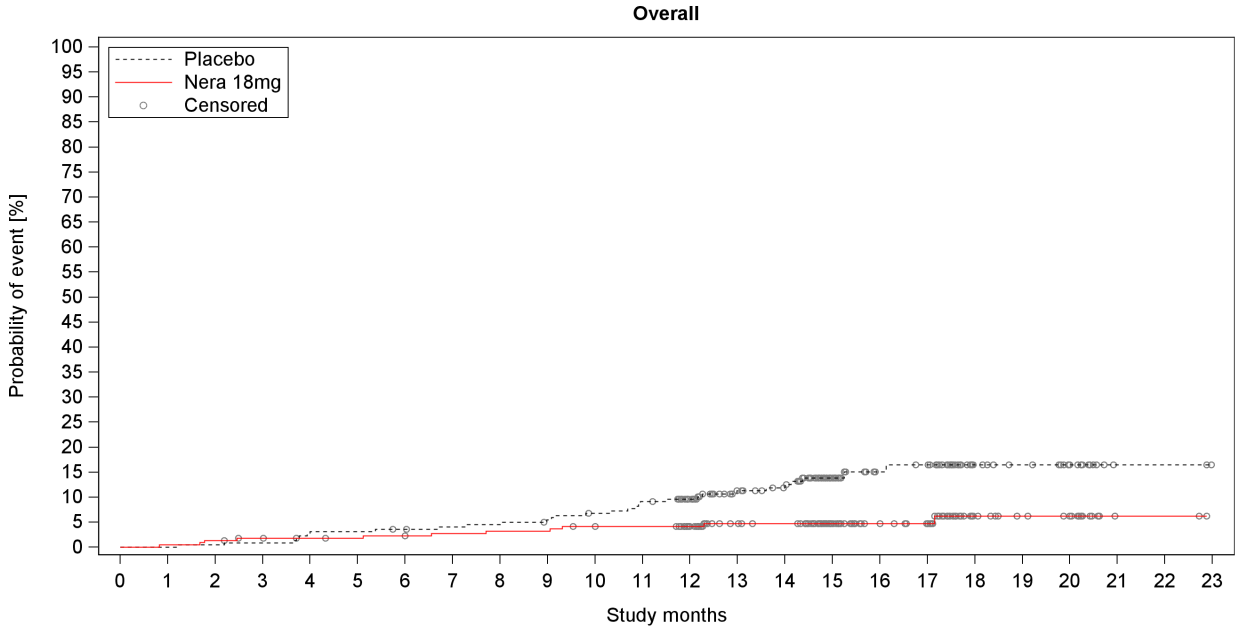

Number at risk (percentage relative to baseline)

Placebo	222	222	221	220	215	214	212	210	209	206	202	197	180	147	140	78	61	59	28	24	18	2	2	0
%	100.0	100.0	99.5	99.1	96.8	96.4	95.5	94.6	94.1	92.8	91.0	88.7	81.1	66.2	63.1	35.1	27.5	26.6	12.6	10.8	8.1	0.9	0.9	0.0
Nera 18mg	220	219	217	214	213	212	211	209	208	208	205	204	179	148	144	91	76	71	29	23	21	2	2	0
%	100.0	99.5	98.6	97.3	96.8	96.4	95.9	95.0	94.5	94.5	93.2	92.7	81.4	67.3	65.5	41.4	34.5	32.3	13.2	10.5	9.5	0.9	0.9	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	1	1	2	3	3	4	5	5	21	51	57	116	132	133	164	168	174	190	190	192
%	0.0	0.0	0.0	0.0	0.5	0.5	0.9	1.4	1.4	1.8	2.3	2.3	9.5	23.0	25.7	52.3	59.5	59.9	73.9	75.7	78.4	85.6	85.6	86.5
Nera 18mg	0	0	0	2	3	4	4	5	5	5	6	7	32	62	66	119	134	139	180	186	188	207	207	209
%	0.0	0.0	0.0	0.9	1.4	1.8	1.8	2.3	2.3	2.3	2.7	3.2	14.5	28.2	30.0	54.1	60.9	63.2	81.8	84.5	85.5	94.1	94.1	95.0

Study: 1305-0023

Figure I.2.2.1.1.2.1: 1 Time to death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (non-AF background)

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I.2.2.1.1.2.2 Time to first confirmed acute ILD exacerbation

Table I.2.2.1.1.2.2: 1 Cox model for time to first confirmed acute ILD exacerbation over the whole trial (DBL1) - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	222	20	9.0	7.82	220	12	5.5	4.59	0.72	(0.35,	1.48)	0.3663	
Age													0.4762
<65 years	83	6	7.2	5.91	88	5	5.7	4.64	1.00	(0.30,	3.34)	0.9957	
>=65 years	139	14	10.1	9.07	132	7	5.3	4.56	0.58	(0.23,	1.45)	0.2438	
Sex													0.3252
Male	116	13	11.2	9.99	111	5	4.5	3.88	0.50	(0.17,	1.43)	0.1964	
Female	106	7	6.6	5.57	109	7	6.4	5.29	1.05	(0.37,	3.01)	0.9224	
Baseline FVC percent predicted													0.5168
<=70%	118	16	13.6	11.95	96	8	8.3	7.15	0.63	(0.27,	1.47)	0.2861	
>70%	104	4	3.8	3.28	124	4	3.2	2.68	1.11	(0.25,	4.98)	0.8889	
Baseline HRCT pattern													0.3230
UIP-like	158	15	9.5	8.34	154	7	4.5	3.82	0.56	(0.22,	1.37)	0.2026	
Other fibrotic patterns	64	5	7.8	6.58	66	5	7.6	6.40	1.25	(0.33,	4.68)	0.7428	
Underlying ILD diagnosis													
iNSIP	40	3	7.5		55	3	5.5						
Unclassifiable IIP	36	1	2.8		40	4	10.0						
HP	39	7	17.9		30	0	0.0						
Autoimmune ILD	71	6	8.5		70	1	1.4						
Other ILD	36	3	8.3		25	4	16.0						
Region													0.8188
Europe	40	2	5.0	4.48	53	4	7.5	6.99	1.67	(0.30,	9.18)	0.5541	
Asia	106	11	10.4	8.36	107	6	5.6	4.49	0.65	(0.24,	1.77)	0.3982	
Canada and USA	30	3	10.0	9.25	17	0	0.0	0.00	0.00	(NC,	NC)	0.9887	
Rest of the World	46	4	8.7	8.46	43	2	4.7	4.02	0.67	(0.11,	4.01)	0.6590	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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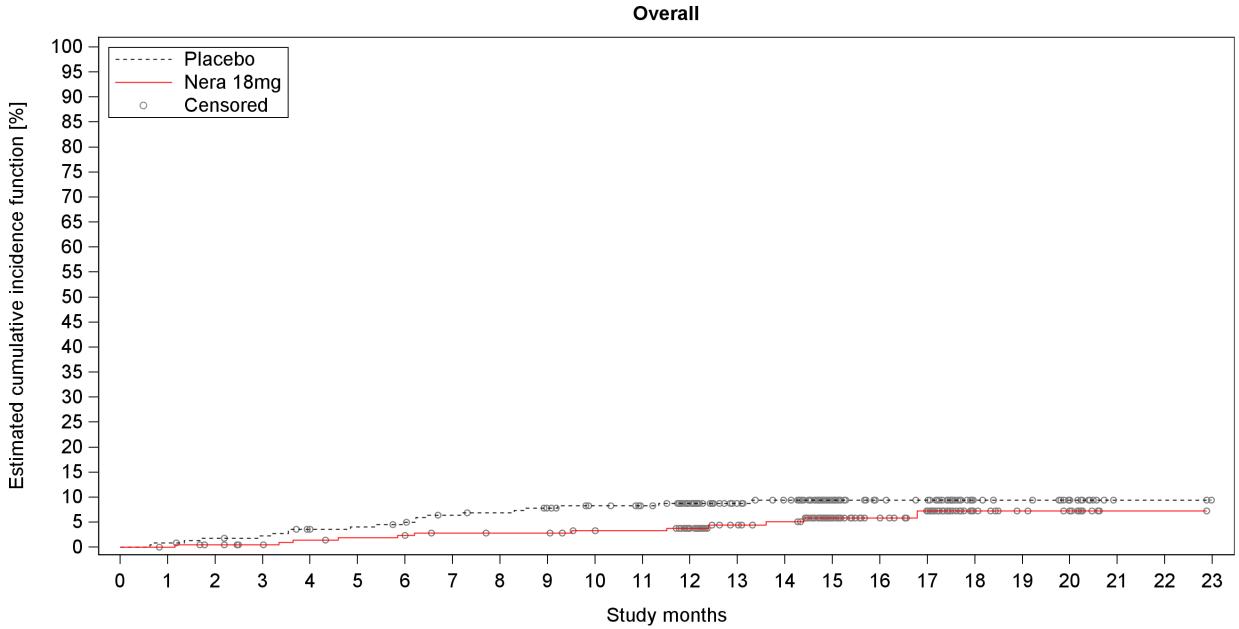

Number at risk (percentage relative to baseline)																								
Placebo	222	220	217	215	210	208	205	200	198	194	189	185	167	139	133	75	58	56	26	24	18	2	2	0
%	100.0	99.1	97.7	96.8	94.6	93.7	92.3	90.1	89.2	87.4	85.1	83.3	75.2	62.6	59.9	33.8	26.1	25.2	11.7	10.8	8.1	0.9	0.9	0.0
Nera 18mg	220	219	216	213	210	208	207	204	203	203	199	198	173	142	137	85	71	64	26	20	18	1	1	0
%	100.0	99.5	98.2	96.8	95.5	94.5	94.1	92.7	92.3	92.3	90.5	90.0	78.6	64.5	62.3	38.6	32.3	29.1	11.8	9.1	8.2	0.5	0.5	0.0
Number censored (percentage relative to number at risk at baseline)																								
Placebo	0	0	1	2	4	5	6	8	9	11	15	19	36	64	69	127	144	146	176	178	184	200	200	202
%	0.0	0.0	0.5	0.9	1.8	2.3	2.7	3.6	4.1	5.0	6.8	8.6	16.2	28.8	31.1	57.2	64.9	65.8	79.3	80.2	82.9	90.1	90.1	91.0
Nera 18mg	0	1	3	6	7	8	8	10	11	11	14	15	39	69	73	124	138	144	182	188	190	207	207	208
%	0.0	0.5	1.4	2.7	3.2	3.6	3.6	4.5	5.0	5.0	6.4	6.8	17.7	31.4	33.2	56.4	62.7	65.5	82.7	85.5	86.4	94.1	94.1	94.5

Study: 1305-0023

Figure I.2.2.1.1.2.2: 1 Time to first confirmed acute ILD exacerbation over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (non-AF background)

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Figure I.2.2.1.1.2.2: 1

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I.2.2.1.1.2.3 Time to first confirmed or suspected acute ILD exacerbation

Table I.2.2.1.1.2.3: 1 Cox model for time to first confirmed or suspected acute ILD exacerbation over the whole trial (DBL1) - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	222	30	13.5	12.01	220	17	7.7	6.58	0.63	(0.35, 1.15)	0.1348	
Age												0.4220
<65 years	83	12	14.5	12.24	88	9	10.2	8.50	0.82	(0.34, 1.96)	0.6586	
>=65 years	139	18	12.9	11.86	132	8	6.1	5.25	0.50	(0.22, 1.16)	0.1070	
Sex												0.6016
Male	116	19	16.4	14.97	111	9	8.1	7.10	0.55	(0.25, 1.23)	0.1466	
Female	106	11	10.4	8.95	109	8	7.3	6.09	0.76	(0.31, 1.89)	0.5567	
Baseline FVC percent predicted												0.9354
<=70%	118	21	17.8	16.08	96	11	11.5	9.99	0.64	(0.31, 1.33)	0.2343	
>70%	104	9	8.7	7.55	124	6	4.8	4.05	0.61	(0.21, 1.76)	0.3582	
Baseline HRCT pattern												0.4430
UIP-like	158	21	13.3	11.85	154	10	6.5	5.50	0.53	(0.25, 1.14)	0.1026	
Other fibrotic patterns	64	9	14.1	12.39	66	7	10.6	9.17	0.87	(0.32, 2.42)	0.7955	
Underlying ILD diagnosis												0.0726
iNSIP	40	7	17.5	14.82	55	4	7.3	6.14	0.41	(0.12, 1.40)	0.1551	
Unclassifiable IIP	36	1	2.8	2.38	40	4	10.0	8.61	3.99	(0.44, 35.90)	0.2167	
HP	39	9	23.1	24.30	30	1	3.3	2.99	0.14	(0.02, 1.14)	0.0666	
Autoimmune ILD	71	9	12.7	10.88	70	3	4.3	3.55	0.39	(0.11, 1.46)	0.1629	
Other ILD	36	4	11.1	9.79	25	5	20.0	17.37	2.01	(0.54, 7.52)	0.2985	
Region												0.9864
Europe	40	6	15.0	14.05	53	6	11.3	10.76	0.77	(0.25, 2.38)	0.6436	
Asia	106	12	11.3	9.21	107	7	6.5	5.24	0.67	(0.26, 1.72)	0.4058	
Canada and USA	30	4	13.3	12.63	17	0	0.0	0.00	0.00	(NC, NC)	0.9866	
Rest of the World	46	8	17.4	17.71	43	4	9.3	8.31	0.56	(0.16, 1.90)	0.3490	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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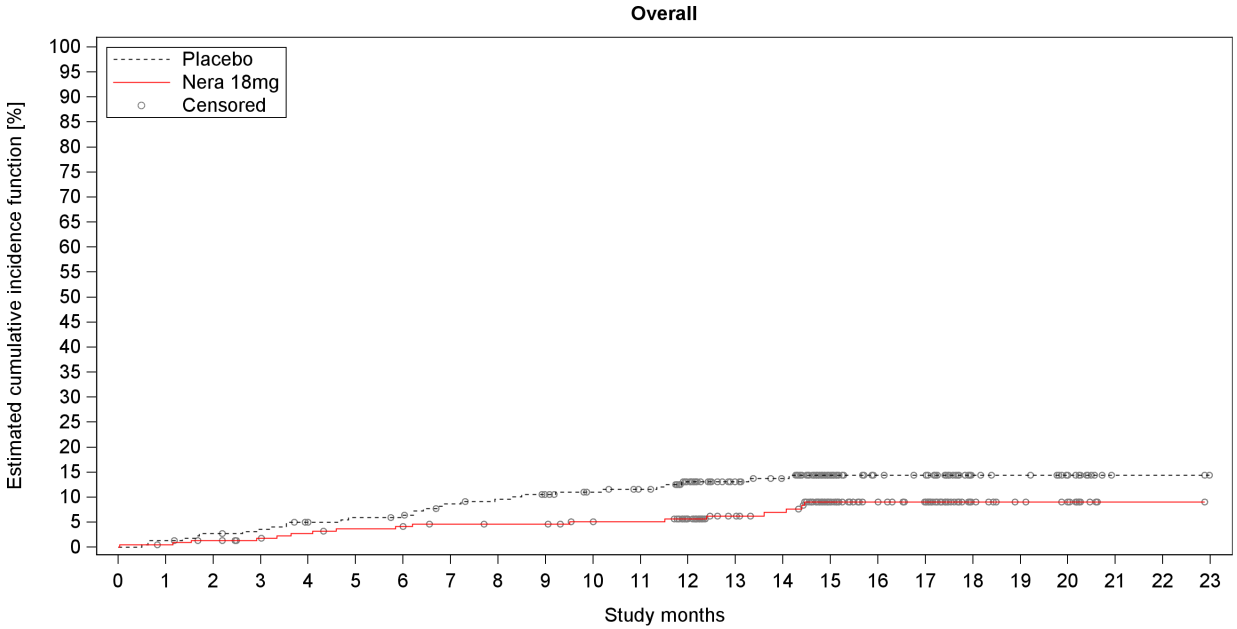

Number at risk (percentage relative to baseline)																								
Placebo	222	219	215	212	207	204	202	195	192	188	183	179	161	134	128	71	55	53	25	23	17	2	2	0
%	100.0	98.6	96.8	95.5	93.2	91.9	91.0	87.8	86.5	84.7	82.4	80.6	72.5	60.4	57.7	32.0	24.8	23.9	11.3	10.4	7.7	0.9	0.9	0.0
Nera 18mg	220	218	215	211	208	205	204	201	200	200	196	195	171	140	135	84	70	64	26	20	18	1	1	0
%	100.0	99.1	97.7	95.9	94.5	93.2	92.7	91.4	90.9	90.9	89.1	88.6	77.7	63.6	61.4	38.2	31.8	29.1	11.8	9.1	8.2	0.5	0.5	0.0
Number censored (percentage relative to number at risk at baseline)																								
Placebo	0	0	1	2	4	5	6	8	9	11	15	18	33	60	65	121	137	139	167	169	175	190	190	192
%	0.0	0.0	0.5	0.9	1.8	2.3	2.7	3.6	4.1	5.0	6.8	8.1	14.9	27.0	29.3	54.5	61.7	62.6	75.2	76.1	78.8	85.6	85.6	86.5
Nera 18mg	0	1	2	5	6	7	7	9	10	10	13	14	37	67	71	119	133	139	177	183	185	202	202	203
%	0.0	0.5	0.9	2.3	2.7	3.2	3.2	4.1	4.5	4.5	5.9	6.4	16.8	30.5	32.3	54.1	60.5	63.2	80.5	83.2	84.1	91.8	91.8	92.3

Study: 1305-0023

Figure I.2.2.1.1.2.3: 1 Time to first confirmed or suspected acute ILD exacerbation over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (non-AF background)

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Figure I.2.2.1.1.2.3: 1

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I.2.2.2 Safety analysis

I.2.2.2.1 Safety analysis over the whole trial

I.2.2.2.1.1 Adverse events overall over the whole trial

Table I.2.2.2.1.1: 1 Proportion of patients with any adverse events over the whole trial (DBL1) - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	208	93.7	220	205	93.2	0.8280	0.99 (0.95, 1.04)	0.92 (0.43, 1.95)	-0.51 (-5.34, 4.28)	
Age											0.0200
<65 years	83	79	95.2	88	77	87.5	0.0760	0.92 (0.84, 1.01)	0.35 (0.11, 1.16)	-7.68 (-16.68, 1.09)	
>=65 years	139	129	92.8	132	128	97.0	0.1216	1.04 (0.99, 1.10)	2.48 (0.76, 8.11)	4.16 (-1.38, 10.01)	
Sex											0.3850
Male	116	109	94.0	111	106	95.5	0.6066	1.02 (0.96, 1.08)	1.36 (0.42, 4.42)	1.53 (-4.87, 7.96)	
Female	106	99	93.4	109	99	90.8	0.4850	0.97 (0.90, 1.05)	0.70 (0.26, 1.91)	-2.57 (-10.24, 5.04)	
Baseline FVC percent predicted											0.2710
<=70%	118	111	94.1	96	87	90.6	0.3409	0.96 (0.89, 1.04)	0.61 (0.22, 1.70)	-3.44 (-11.52, 3.82)	
>70%	104	97	93.3	124	118	95.2	0.5394	1.02 (0.96, 1.09)	1.42 (0.46, 4.36)	1.89 (-4.44, 8.91)	
Baseline HRCT pattern											0.8431
UIP-like	158	148	93.7	154	143	92.9	0.7743	0.99 (0.93, 1.05)	0.88 (0.36, 2.13)	-0.81 (-6.74, 5.01)	
Other fibrotic patterns	64	60	93.8	66	62	93.9	0.9642	1.00 (0.92, 1.09)	1.03 (0.25, 4.32)	0.19 (-9.13, 9.68)	
Underlying ILD diagnosis											0.2842
iNSIP	40	38	95.0	55	49	89.1	0.3058	0.94 (0.83, 1.05)	0.43 (0.08, 2.25)	-5.91 (-17.41, 6.98)	
Unclassifiable IIP	36	33	91.7	40	38	95.0	0.5584	1.04 (0.92, 1.17)	1.73 (0.27, 10.97)	3.33 (-9.40, 17.30)	
HP	39	38	97.4	30	28	93.3	0.4074	0.96 (0.86, 1.07)	0.37 (0.03, 4.27)	-4.10 (-18.91, 7.56)	
Autoimmune ILD	71	66	93.0	70	65	92.9	0.9814	1.00 (0.91, 1.09)	0.98 (0.27, 3.56)	-0.10 (-9.50, 9.23)	
Other ILD	36	33	91.7	25	25	100.0	0.1388	1.09 (0.99, 1.20)	NC (NC, NC)	8.33 (-6.06, 21.83)	
Region											0.9707
Europe	40	39	97.5	53	51	96.2	0.7307	0.99 (0.92, 1.06)	0.65 (0.06, 7.47)	-1.27 (-10.49, 9.46)	
Asia	106	100	94.3	107	101	94.4	0.9866	1.00 (0.94, 1.07)	1.01 (0.32, 3.24)	0.05 (-6.75, 6.89)	
Canada and USA	30	28	93.3	17	16	94.1	0.9158	1.01 (0.87, 1.17)	1.14 (0.10, 13.62)	0.78 (-20.86, 16.22)	
Rest of the World	46	41	89.1	43	37	86.0	0.6587	0.97 (0.83, 1.13)	0.75 (0.21, 2.67)	-3.08 (-17.74, 11.16)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.2.1.1: 2 Proportion of patients with any adverse events (excluding disease-related events) over the whole trial (DBL1) - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	205	92.3	220	205	93.2	0.7335	1.01 (0.96, 1.06)	1.13 (0.55, 2.33)	0.84 (-4.16, 5.85)	
Age											0.0595
<65 years	83	77	92.8	88	77	87.5	0.2496	0.94 (0.85, 1.04)	0.55 (0.19, 1.55)	-5.27 (-14.62, 4.08)	
>=65 years	139	128	92.1	132	128	97.0	0.0789	1.05 (0.99, 1.12)	2.75 (0.85, 8.86)	4.88 (-0.78, 10.88)	
Sex											0.5392
Male	116	108	93.1	111	106	95.5	0.4381	1.03 (0.96, 1.09)	1.57 (0.50, 4.95)	2.39 (-4.15, 9.03)	
Female	106	97	91.5	109	99	90.8	0.8598	0.99 (0.91, 1.08)	0.92 (0.36, 2.36)	-0.68 (-8.63, 7.32)	
Baseline FVC percent predicted											0.2079
<=70%	118	110	93.2	96	87	90.6	0.4850	0.97 (0.90, 1.05)	0.70 (0.26, 1.90)	-2.60 (-10.78, 4.85)	
>70%	104	95	91.3	124	118	95.2	0.2471	1.04 (0.97, 1.12)	1.86 (0.64, 5.42)	3.82 (-2.86, 11.26)	
Baseline HRCT pattern											0.5261
UIP-like	158	147	93.0	154	143	92.9	0.9503	1.00 (0.94, 1.06)	0.97 (0.41, 2.31)	-0.18 (-6.19, 5.77)	
Other fibrotic patterns	64	58	90.6	66	62	93.9	0.4783	1.04 (0.94, 1.15)	1.60 (0.43, 5.97)	3.31 (-6.56, 13.60)	
Underlying ILD diagnosis											0.2350
iNSIP	40	38	95.0	55	49	89.1	0.3058	0.94 (0.83, 1.05)	0.43 (0.08, 2.25)	-5.91 (-17.41, 6.98)	
Unclassifiable IIP	36	32	88.9	40	38	95.0	0.3239	1.07 (0.93, 1.22)	2.38 (0.41, 13.82)	6.11 (-7.20, 20.77)	
HP	39	38	97.4	30	28	93.3	0.4074	0.96 (0.86, 1.07)	0.37 (0.03, 4.27)	-4.10 (-18.91, 7.56)	
Autoimmune ILD	71	64	90.1	70	65	92.9	0.5633	1.03 (0.93, 1.14)	1.42 (0.43, 4.71)	2.72 (-7.16, 12.70)	
Other ILD	36	33	91.7	25	25	100.0	0.1388	1.09 (0.99, 1.20)	NC (NC, NC)	8.33 (-6.06, 21.83)	
Region											0.9281
Europe	40	39	97.5	53	51	96.2	0.7307	0.99 (0.92, 1.06)	0.65 (0.06, 7.47)	-1.27 (-10.49, 9.46)	
Asia	106	98	92.5	107	101	94.4	0.5679	1.02 (0.95, 1.10)	1.37 (0.46, 4.11)	1.94 (-5.17, 9.23)	
Canada and USA	30	28	93.3	17	16	94.1	0.9158	1.01 (0.87, 1.17)	1.14 (0.10, 13.62)	0.78 (-20.86, 16.22)	
Rest of the World	46	40	87.0	43	37	86.0	0.9000	0.99 (0.84, 1.17)	0.93 (0.27, 3.12)	-0.91 (-15.91, 13.72)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.2.1.1: 3 Proportion of patients with serious adverse events over the whole trial (DBL1) - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	103	46.4	220	86	39.1	0.1206	0.84 (0.68, 1.05)	0.74 (0.51, 1.08)	-7.31 (-16.34, 1.91)	
Age											0.3489
<65 years	83	35	42.2	88	27	30.7	0.1184	0.73 (0.49, 1.09)	0.61 (0.32, 1.14)	-11.49 (-25.28, 2.88)	
>=65 years	139	68	48.9	132	59	44.7	0.4861	0.91 (0.71, 1.18)	0.84 (0.52, 1.36)	-4.22 (-15.85, 7.57)	
Sex											0.8247
Male	116	57	49.1	111	45	40.5	0.1930	0.83 (0.62, 1.10)	0.71 (0.42, 1.19)	-8.60 (-21.08, 4.29)	
Female	106	46	43.4	109	41	37.6	0.3879	0.87 (0.63, 1.20)	0.79 (0.46, 1.36)	-5.78 (-18.55, 7.24)	
Baseline FVC percent predicted											0.2977
<=70%	118	67	56.8	96	43	44.8	0.0810	0.79 (0.60, 1.04)	0.62 (0.36, 1.06)	-11.99 (-24.83, 1.44)	
>70%	104	36	34.6	124	43	34.7	0.9922	1.00 (0.70, 1.43)	1.00 (0.58, 1.73)	0.06 (-12.27, 12.21)	
Baseline HRCT pattern											0.0370
UIP-like	158	68	43.0	154	65	42.2	0.8821	0.98 (0.76, 1.27)	0.97 (0.62, 1.51)	-0.83 (-11.66, 10.04)	
Other fibrotic patterns	64	35	54.7	66	21	31.8	0.0085	0.58 (0.38, 0.88)	0.39 (0.19, 0.79)	-22.87 (-38.15, -5.84)	
Underlying ILD diagnosis											0.6975
iNSIP	40	18	45.0	55	21	38.2	0.5048	0.85 (0.52, 1.37)	0.75 (0.33, 1.73)	-6.82 (-25.96, 12.64)	
Unclassifiable IIP	36	18	50.0	40	18	45.0	0.6629	0.90 (0.56, 1.44)	0.82 (0.33, 2.02)	-5.00 (-26.10, 16.71)	
HP	39	18	46.2	30	8	26.7	0.0977	0.58 (0.29, 1.14)	0.42 (0.15, 1.18)	-19.49 (-39.22, 3.51)	
Autoimmune ILD	71	28	39.4	70	28	40.0	0.9455	1.01 (0.68, 1.52)	1.02 (0.52, 2.01)	0.56 (-15.22, 16.32)	
Other ILD	36	21	58.3	25	11	44.0	0.2703	0.75 (0.45, 1.27)	0.56 (0.20, 1.57)	-14.33 (-36.95, 10.54)	
Region											0.3767
Europe	40	18	45.0	53	25	47.2	0.8354	1.05 (0.67, 1.64)	1.09 (0.48, 2.49)	2.17 (-17.67, 21.61)	
Asia	106	52	49.1	107	46	43.0	0.3745	0.88 (0.65, 1.17)	0.78 (0.46, 1.34)	-6.07 (-19.05, 7.21)	
Canada and USA	30	14	46.7	17	4	23.5	0.1169	0.50 (0.20, 1.29)	0.35 (0.09, 1.33)	-23.14 (-45.29, 5.73)	
Rest of the World	46	19	41.3	43	11	25.6	0.1169	0.62 (0.33, 1.15)	0.49 (0.20, 1.20)	-15.72 (-33.60, 3.88)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.2.1.1: 4 Proportion of patients with serious adverse events (excluding disease-related events) over the whole trial (DBL1) - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	98	44.1	220	84	38.2	0.2028	0.86 (0.69, 1.08)	0.78 (0.53, 1.14)	-5.96 (-14.98, 3.19)	
Age											0.4557
<65 years	83	32	38.6	88	26	29.5	0.2136	0.77 (0.50, 1.17)	0.67 (0.35, 1.26)	-9.01 (-22.73, 5.12)	
>=65 years	139	66	47.5	132	58	43.9	0.5585	0.93 (0.71, 1.20)	0.87 (0.54, 1.40)	-3.54 (-15.16, 8.23)	
Sex											0.8702
Male	116	54	46.6	111	44	39.6	0.2933	0.85 (0.63, 1.15)	0.75 (0.45, 1.28)	-6.91 (-19.40, 5.91)	
Female	106	44	41.5	109	40	36.7	0.4697	0.88 (0.63, 1.24)	0.82 (0.47, 1.41)	-4.81 (-17.54, 8.12)	
Baseline FVC percent predicted											0.2826
<=70%	118	63	53.4	96	41	42.7	0.1200	0.80 (0.60, 1.07)	0.65 (0.38, 1.12)	-10.68 (-23.54, 2.74)	
>70%	104	35	33.7	124	43	34.7	0.8711	1.03 (0.72, 1.48)	1.05 (0.60, 1.81)	1.02 (-11.29, 13.10)	
Baseline HRCT pattern											0.0624
UIP-like	158	65	41.1	154	63	40.9	0.9670	0.99 (0.76, 1.30)	0.99 (0.63, 1.56)	-0.23 (-11.01, 10.57)	
Other fibrotic patterns	64	33	51.6	66	21	31.8	0.0224	0.62 (0.40, 0.94)	0.44 (0.21, 0.89)	-19.74 (-35.19, -2.81)	
Underlying ILD diagnosis											0.6186
iNSIP	40	17	42.5	55	20	36.4	0.5448	0.86 (0.52, 1.41)	0.77 (0.34, 1.78)	-6.14 (-25.24, 13.11)	
Unclassifiable IIP	36	17	47.2	40	17	42.5	0.6793	0.90 (0.55, 1.48)	0.83 (0.33, 2.04)	-4.72 (-25.81, 16.87)	
HP	39	18	46.2	30	8	26.7	0.0977	0.58 (0.29, 1.14)	0.42 (0.15, 1.18)	-19.49 (-39.22, 3.51)	
Autoimmune ILD	71	26	36.6	70	28	40.0	0.6797	1.09 (0.72, 1.66)	1.15 (0.58, 2.28)	3.38 (-12.39, 18.94)	
Other ILD	36	20	55.6	25	11	44.0	0.3746	0.79 (0.47, 1.35)	0.63 (0.22, 1.76)	-11.56 (-34.42, 13.22)	
Region											0.4055
Europe	40	17	42.5	53	24	45.3	0.7890	1.07 (0.67, 1.70)	1.12 (0.49, 2.56)	2.78 (-17.06, 22.06)	
Asia	106	49	46.2	107	45	42.1	0.5400	0.91 (0.67, 1.23)	0.84 (0.49, 1.45)	-4.17 (-17.17, 9.03)	
Canada and USA	30	14	46.7	17	4	23.5	0.1169	0.50 (0.20, 1.29)	0.35 (0.09, 1.33)	-23.14 (-45.29, 5.73)	
Rest of the World	46	18	39.1	43	11	25.6	0.1729	0.65 (0.35, 1.22)	0.53 (0.22, 1.32)	-13.55 (-31.47, 5.87)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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I.2.2.2.1.2 Adverse events by intensity over the whole trial

Table I.2.2.2.1.2: 1 Proportion of patients with any adverse events with CTCAE grade >=3 over the whole trial (DBL1) - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	93	41.9	220	74	33.6	0.0735	0.80 (0.63, 1.02)	0.70 (0.48, 1.03)	-8.26 (-17.10, 0.78)	
Age											0.7349
<65 years	83	31	37.3	88	25	28.4	0.2131	0.76 (0.49, 1.17)	0.67 (0.35, 1.27)	-8.94 (-22.56, 5.07)	
>=65 years	139	62	44.6	132	49	37.1	0.2105	0.83 (0.62, 1.11)	0.73 (0.45, 1.19)	-7.48 (-18.85, 4.19)	
Sex											0.2697
Male	116	52	44.8	111	35	31.5	0.0394	0.70 (0.50, 0.99)	0.57 (0.33, 0.97)	-13.30 (-25.33, -0.65)	
Female	106	41	38.7	109	39	35.8	0.6601	0.93 (0.65, 1.31)	0.88 (0.51, 1.54)	-2.90 (-15.57, 9.88)	
Baseline FVC percent predicted											0.4302
<=70%	118	62	52.5	96	39	40.6	0.0824	0.77 (0.57, 1.04)	0.62 (0.36, 1.07)	-11.92 (-24.70, 1.50)	
>70%	104	31	29.8	124	35	28.2	0.7931	0.95 (0.63, 1.42)	0.93 (0.52, 1.64)	-1.58 (-13.39, 10.04)	
Baseline HRCT pattern											0.6394
UIP-like	158	64	40.5	154	52	33.8	0.2181	0.83 (0.62, 1.12)	0.75 (0.47, 1.19)	-6.74 (-17.21, 3.96)	
Other fibrotic patterns	64	29	45.3	66	22	33.3	0.1620	0.74 (0.48, 1.14)	0.60 (0.30, 1.23)	-11.98 (-27.80, 4.71)	
Underlying ILD diagnosis											0.4660
iNSIP	40	15	37.5	55	17	30.9	0.5022	0.82 (0.47, 1.45)	0.75 (0.32, 1.76)	-6.59 (-25.36, 12.07)	
Unclassifiable IIP	36	17	47.2	40	11	27.5	0.0751	0.58 (0.32, 1.07)	0.42 (0.16, 1.10)	-19.72 (-39.18, 1.89)	
HP	39	16	41.0	30	7	23.3	0.1222	0.57 (0.27, 1.20)	0.44 (0.15, 1.26)	-17.69 (-37.06, 4.76)	
Autoimmune ILD	71	27	38.0	70	28	40.0	0.8103	1.05 (0.70, 1.59)	1.09 (0.55, 2.14)	1.97 (-13.81, 17.63)	
Other ILD	36	18	50.0	25	11	44.0	0.6444	0.88 (0.51, 1.52)	0.79 (0.28, 2.19)	-6.00 (-29.27, 18.48)	
Region											0.4451
Europe	40	16	40.0	53	22	41.5	0.8834	1.04 (0.63, 1.70)	1.06 (0.46, 2.46)	1.51 (-18.17, 20.64)	
Asia	106	47	44.3	107	39	36.4	0.2406	0.82 (0.59, 1.14)	0.72 (0.42, 1.25)	-7.89 (-20.63, 5.22)	
Canada and USA	30	13	43.3	17	4	23.5	0.1746	0.54 (0.21, 1.40)	0.40 (0.11, 1.53)	-19.80 (-42.17, 8.79)	
Rest of the World	46	17	37.0	43	9	20.9	0.0966	0.57 (0.28, 1.13)	0.45 (0.18, 1.16)	-16.03 (-33.32, 2.90)	

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.2.1.2: 2 Proportion of patients with any adverse events (excluding disease-related events) with CTCAE grade >=3 over the whole trial (DBL1) - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	87	39.2	220	71	32.3	0.1293	0.82 (0.64, 1.06)	0.74 (0.50, 1.09)	-6.92 (-15.69, 2.01)	
Age											0.7202
<65 years	83	28	33.7	88	23	26.1	0.2777	0.77 (0.49, 1.23)	0.70 (0.36, 1.34)	-7.60 (-20.98, 6.05)	
>=65 years	139	59	42.4	132	48	36.4	0.3059	0.86 (0.64, 1.15)	0.77 (0.48, 1.26)	-6.08 (-17.42, 5.51)	
Sex											0.3722
Male	116	47	40.5	111	33	29.7	0.0890	0.73 (0.51, 1.05)	0.62 (0.36, 1.08)	-10.79 (-22.71, 1.63)	
Female	106	40	37.7	109	38	34.9	0.6613	0.92 (0.65, 1.32)	0.88 (0.51, 1.54)	-2.87 (-15.49, 9.84)	
Baseline FVC percent predicted											0.2133
<=70%	118	59	50.0	96	36	37.5	0.0672	0.75 (0.55, 1.03)	0.60 (0.35, 1.04)	-12.50 (-25.16, 0.86)	
>70%	104	28	26.9	124	35	28.2	0.8266	1.05 (0.69, 1.60)	1.07 (0.60, 1.91)	1.30 (-10.39, 12.69)	
Baseline HRCT pattern											0.6828
UIP-like	158	59	37.3	154	49	31.8	0.3052	0.85 (0.63, 1.16)	0.78 (0.49, 1.25)	-5.52 (-15.87, 5.01)	
Other fibrotic patterns	64	28	43.8	66	22	33.3	0.2223	0.76 (0.49, 1.18)	0.64 (0.32, 1.31)	-10.42 (-26.28, 6.18)	
Underlying ILD diagnosis											0.3938
iNSIP	40	14	35.0	55	16	29.1	0.5407	0.83 (0.46, 1.50)	0.76 (0.32, 1.82)	-5.91 (-24.53, 12.42)	
Unclassifiable IIP	36	16	44.4	40	10	25.0	0.0744	0.56 (0.29, 1.08)	0.42 (0.16, 1.10)	-19.44 (-38.73, 1.84)	
HP	39	15	38.5	30	7	23.3	0.1813	0.61 (0.28, 1.30)	0.49 (0.17, 1.41)	-15.13 (-34.56, 7.09)	
Autoimmune ILD	71	25	35.2	70	28	40.0	0.5572	1.14 (0.74, 1.74)	1.23 (0.62, 2.43)	4.79 (-10.97, 20.24)	
Other ILD	36	17	47.2	25	10	40.0	0.5765	0.85 (0.47, 1.53)	0.75 (0.27, 2.09)	-7.22 (-30.12, 17.34)	
Region											0.4149
Europe	40	14	35.0	53	21	39.6	0.6487	1.13 (0.66, 1.94)	1.22 (0.52, 2.86)	4.62 (-15.00, 23.22)	
Asia	106	44	41.5	107	37	34.6	0.2976	0.83 (0.59, 1.18)	0.74 (0.43, 1.30)	-6.93 (-19.58, 6.03)	
Canada and USA	30	13	43.3	17	4	23.5	0.1746	0.54 (0.21, 1.40)	0.40 (0.11, 1.53)	-19.80 (-42.17, 8.79)	
Rest of the World	46	16	34.8	43	9	20.9	0.1462	0.60 (0.30, 1.22)	0.50 (0.19, 1.29)	-13.85 (-31.15, 4.86)	

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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I.2.2.2.1.3 Adverse events leading to treatment discontinuation over the whole trial

Table I.2.2.2.1.3: 1 Proportion of patients with any adverse events leading to treatment discontinuation over the whole trial (DBL1) - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	29	13.1	220	21	9.5	0.2431	0.73 (0.43, 1.24)	0.70 (0.39, 1.27)	-3.52 (-9.52, 2.46)	
Age											0.3609
<65 years	83	11	13.3	88	6	6.8	0.1599	0.51 (0.20, 1.33)	0.48 (0.17, 1.36)	-6.43 (-16.09, 2.80)	
>=65 years	139	18	12.9	132	15	11.4	0.6898	0.88 (0.46, 1.67)	0.86 (0.41, 1.79)	-1.59 (-9.49, 6.41)	
Sex											0.4951
Male	116	17	14.7	111	10	9.0	0.1890	0.61 (0.29, 1.28)	0.58 (0.25, 1.32)	-5.65 (-14.22, 2.96)	
Female	106	12	11.3	109	11	10.1	0.7707	0.89 (0.41, 1.93)	0.88 (0.37, 2.09)	-1.23 (-9.85, 7.28)	
Baseline FVC percent predicted											0.0467
<=70%	118	19	16.1	96	6	6.3	0.0256	0.39 (0.16, 0.93)	0.35 (0.13, 0.91)	-9.85 (-18.23, -1.14)	
>70%	104	10	9.6	124	15	12.1	0.5503	1.26 (0.59, 2.68)	1.29 (0.55, 3.02)	2.48 (-6.07, 10.62)	
Baseline HRCT pattern											0.9071
UIP-like	158	22	13.9	154	16	10.4	0.3399	0.75 (0.41, 1.37)	0.72 (0.36, 1.42)	-3.53 (-10.90, 3.85)	
Other fibrotic patterns	64	7	10.9	66	5	7.6	0.5080	0.69 (0.23, 2.07)	0.67 (0.20, 2.22)	-3.36 (-14.21, 7.17)	
Underlying ILD diagnosis											0.7765
iNSIP	40	3	7.5	55	6	10.9	0.5753	1.45 (0.39, 5.47)	1.51 (0.35, 6.44)	3.41 (-10.25, 15.38)	
Unclassifiable IIP	36	2	5.6	40	2	5.0	0.9138	0.90 (0.13, 6.06)	0.89 (0.12, 6.70)	-0.56 (-13.65, 11.63)	
HP	39	6	15.4	30	2	6.7	0.2622	0.43 (0.09, 2.00)	0.39 (0.07, 2.10)	-8.72 (-23.85, 8.05)	
Autoimmune ILD	71	10	14.1	70	6	8.6	0.3021	0.61 (0.23, 1.58)	0.57 (0.20, 1.67)	-5.51 (-16.46, 5.36)	
Other ILD	36	8	22.2	25	5	20.0	0.8349	0.90 (0.33, 2.43)	0.88 (0.25, 3.07)	-2.22 (-21.61, 19.60)	
Region											0.8727
Europe	40	5	12.5	53	7	13.2	0.9197	1.06 (0.36, 3.09)	1.07 (0.31, 3.64)	0.71 (-14.45, 14.30)	
Asia	106	9	8.5	107	7	6.5	0.5896	0.77 (0.30, 1.99)	0.75 (0.27, 2.11)	-1.95 (-9.58, 5.53)	
Canada and USA	30	6	20.0	17	2	11.8	0.4704	0.59 (0.13, 2.60)	0.53 (0.09, 2.99)	-8.24 (-27.51, 16.66)	
Rest of the World	46	9	19.6	43	5	11.6	0.3041	0.59 (0.22, 1.63)	0.54 (0.17, 1.77)	-7.94 (-23.04, 7.70)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.2.1.3: 2 Proportion of patients with any adverse events leading to treatment discontinuation (excluding disease-related events) over the whole trial (DBL1) - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	25	11.3	220	21	9.5	0.5547	0.85 (0.49, 1.47)	0.83 (0.45, 1.53)	-1.72 (-7.52, 4.08)	
Age											0.4576
<65 years	83	9	10.8	88	6	6.8	0.3524	0.63 (0.23, 1.69)	0.60 (0.20, 1.77)	-4.03 (-13.28, 4.82)	
>=65 years	139	16	11.5	132	15	11.4	0.9697	0.99 (0.51, 1.92)	0.99 (0.47, 2.08)	-0.15 (-7.86, 7.68)	
Sex											0.6385
Male	116	14	12.1	111	10	9.0	0.4536	0.75 (0.35, 1.61)	0.72 (0.31, 1.70)	-3.06 (-11.29, 5.22)	
Female	106	11	10.4	109	11	10.1	0.9449	0.97 (0.44, 2.15)	0.97 (0.40, 2.34)	-0.29 (-8.75, 8.09)	
Baseline FVC percent predicted											0.0683
<=70%	118	16	13.6	96	6	6.3	0.0799	0.46 (0.19, 1.13)	0.43 (0.16, 1.13)	-7.31 (-15.38, 1.09)	
>70%	104	9	8.7	124	15	12.1	0.3988	1.40 (0.64, 3.06)	1.45 (0.61, 3.47)	3.44 (-4.93, 11.44)	
Baseline HRCT pattern											0.6702
UIP-like	158	18	11.4	154	16	10.4	0.7763	0.91 (0.48, 1.72)	0.90 (0.44, 1.84)	-1.00 (-8.07, 6.10)	
Other fibrotic patterns	64	7	10.9	66	5	7.6	0.5080	0.69 (0.23, 2.07)	0.67 (0.20, 2.22)	-3.36 (-14.21, 7.17)	
Underlying ILD diagnosis											0.4823
iNSIP	40	1	2.5	55	6	10.9	0.1214	4.36 (0.55, 34.84)	4.78 (0.55, 41.34)	8.41 (-3.49, 19.52)	
Unclassifiable IIP	36	2	5.6	40	2	5.0	0.9138	0.90 (0.13, 6.06)	0.89 (0.12, 6.70)	-0.56 (-13.65, 11.63)	
HP	39	6	15.4	30	2	6.7	0.2622	0.43 (0.09, 2.00)	0.39 (0.07, 2.10)	-8.72 (-23.85, 8.05)	
Autoimmune ILD	71	9	12.7	70	6	8.6	0.4293	0.68 (0.25, 1.80)	0.65 (0.22, 1.92)	-4.10 (-14.83, 6.55)	
Other ILD	36	7	19.4	25	5	20.0	0.9572	1.03 (0.37, 2.88)	1.04 (0.29, 3.73)	0.56 (-18.60, 22.00)	
Region											0.8482
Europe	40	4	10.0	53	7	13.2	0.6353	1.32 (0.41, 4.20)	1.37 (0.37, 5.04)	3.21 (-11.45, 16.32)	
Asia	106	9	8.5	107	7	6.5	0.5896	0.77 (0.30, 1.99)	0.75 (0.27, 2.11)	-1.95 (-9.58, 5.53)	
Canada and USA	30	4	13.3	17	2	11.8	0.8769	0.88 (0.18, 4.33)	0.87 (0.14, 5.31)	-1.57 (-19.98, 22.39)	
Rest of the World	46	8	17.4	43	5	11.6	0.4417	0.67 (0.24, 1.89)	0.63 (0.19, 2.08)	-5.76 (-20.62, 9.54)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.2.1.3: 3 Descriptive statistics of patients with any adverse events leading to treatment discontinuation over the whole trial by SOC and PT (DBL1) - 18mg - TS (non-AF background)

Primary System Organ Class Preferred Term	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %
Overall	222	29	13.1	220	21	9.5
Infections and infestations		8	3.6		3	1.4
Pneumonia		3	1.4		1	0.5
Infection		2	0.9		0	0.0
Bronchopulmonary aspergillosis		1	0.5		0	0.0
COVID-19		1	0.5		0	0.0
Influenza		0	0.0		1	0.5
Meningitis viral		1	0.5		0	0.0
Pneumocystis jirovecii pneumonia		0	0.0		1	0.5
Pulmonary tuberculosis		1	0.5		0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		4	1.8		7	3.2
Squamous cell carcinoma of skin		0	0.0		3	1.4
Brain neoplasm malignant		1	0.5		0	0.0
Colon cancer		1	0.5		0	0.0
Colorectal cancer		0	0.0		1	0.5
Non-small cell lung cancer		0	0.0		1	0.5
Papillary thyroid cancer		1	0.5		0	0.0
Small cell lung cancer		0	0.0		1	0.5
Squamous cell carcinoma of lung		1	0.5		0	0.0
Squamous cell carcinoma of the cervix		0	0.0		1	0.5
General disorders and administration site conditions		6	2.7		1	0.5
Condition aggravated		6	2.7		0	0.0
Peripheral swelling		0	0.0		1	0.5
Psychiatric disorders		3	1.4		3	1.4
Depression		2	0.9		1	0.5
Suicidal ideation		0	0.0		2	0.9
Insomnia		0	0.0		1	0.5
Negative thoughts		1	0.5		0	0.0
Respiratory, thoracic and mediastinal disorders		6	2.7		0	0.0
Dyspnoea		3	1.4		0	0.0
Cough		1	0.5		0	0.0
Interstitial lung disease		1	0.5		0	0.0
Pneumothorax		1	0.5		0	0.0
Gastrointestinal disorders		1	0.5		3	1.4
Diarrhoea		0	0.0		3	1.4

Study: 1305-0023. MedDRA version: 27.1
N is the number of patients, n the number of patients with at least one event.
Percentages are calculated using total number of patients per treatment as the denominator.

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Table I.2.2.2.1.3: 3 Descriptive statistics of patients with any adverse events leading to treatment discontinuation over the whole trial by SOC and PT (DBL1) - 18mg - TS (non-AF background)

Primary System Organ Class Preferred Term	Placebo N	 n	 %	Nera 18mg N	 n	 %
Abdominal pain upper		1	0.5		0	0.0
Investigations		1	0.5		2	0.9
Alanine aminotransferase increased		1	0.5		0	0.0
Aspartate aminotransferase increased		1	0.5		0	0.0
Blood creatine phosphokinase increased		1	0.5		0	0.0
Interferon gamma release assay positive		0	0.0		1	0.5
Weight decreased		0	0.0		1	0.5
Cardiac disorders		1	0.5		1	0.5
Angina unstable		0	0.0		1	0.5
Cardiac failure		1	0.5		0	0.0
Metabolism and nutrition disorders		1	0.5		1	0.5
Decreased appetite		1	0.5		1	0.5
Musculoskeletal and connective tissue disorders		1	0.5		1	0.5
Muscular weakness		1	0.5		0	0.0
Pain in extremity		0	0.0		1	0.5
Nervous system disorders		2	0.9		0	0.0
Dizziness		2	0.9		0	0.0
Vascular disorders		0	0.0		1	0.5
Hypertension		0	0.0		1	0.5

Study: 1305-0023. MedDRA version: 27.1
N is the number of patients, n the number of patients with at least one event.
Percentages are calculated using total number of patients per treatment as the denominator.

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I.2.2.2.1.4 Adverse events on SOC level over the whole trial

Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Cardiac disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	18	8.1	220	28	12.7	0.1118	1.57 (0.89, 2.75)	1.65 (0.89, 3.08)	4.62 (-1.13, 10.45)	
Age											
<65 years	83	6	7.2	88	7	8.0					
>=65 years	139	12	8.6	132	21	15.9					
Sex											
Male	116	10	8.6	111	18	16.2					
Female	106	8	7.5	109	10	9.2					
Baseline FVC percent predicted											
<=70%	118	8	6.8	96	14	14.6					
>70%	104	10	9.6	124	14	11.3					
Baseline HRCT pattern											
UIP-like	158	11	7.0	154	21	13.6					
Other fibrotic patterns	64	7	10.9	66	7	10.6					
Underlying ILD diagnosis											
iNSIP	40	1	2.5	55	5	9.1					
Unclassifiable IIP	36	5	13.9	40	4	10.0					
HP	39	4	10.3	30	4	13.3					
Autoimmune ILD	71	6	8.5	70	11	15.7					
Other ILD	36	2	5.6	25	4	16.0					
Region											
Europe	40	8	20.0	53	9	17.0					
Asia	106	6	5.7	107	13	12.1					
Canada and USA	30	3	10.0	17	2	11.8					
Rest of the World	46	1	2.2	43	4	9.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Ear and labyrinth disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	1	0.5	220	10	4.5	0.0057	>10 (1.30, 78.16)	>10 (1.34, 82.92)	4.10 (1.19, 7.73)	
Age											
<65 years	83	1	1.2	88	4	4.5					
>=65 years	139	0	0.0	132	6	4.5					
Sex											
Male	116	1	0.9	111	3	2.7					
Female	106	0	0.0	109	7	6.4					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	3	3.1					
>70%	104	1	1.0	124	7	5.6					
Baseline HRCT pattern											
UIP-like	158	1	0.6	154	6	3.9					
Other fibrotic patterns	64	0	0.0	66	4	6.1					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	2	3.6					
Unclassifiable IIP	36	0	0.0	40	4	10.0					
HP	39	1	2.6	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	1	1.4					
Other ILD	36	0	0.0	25	3	12.0					
Region											
Europe	40	0	0.0	53	5	9.4					
Asia	106	0	0.0	107	2	1.9					
Canada and USA	30	0	0.0	17	1	5.9					
Rest of the World	46	1	2.2	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Eye disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	10	4.5	220	13	5.9	0.5062	1.31 (0.59, 2.93)	1.33 (0.57, 3.10)	1.40 (-2.92, 5.84)	
Age											
<65 years	83	3	3.6	88	5	5.7					
>=65 years	139	7	5.0	132	8	6.1					
Sex											
Male	116	6	5.2	111	5	4.5					
Female	106	4	3.8	109	8	7.3					
Baseline FVC percent predicted											
<=70%	118	3	2.5	96	5	5.2					
>70%	104	7	6.7	124	8	6.5					
Baseline HRCT pattern											
UIP-like	158	8	5.1	154	8	5.2					
Other fibrotic patterns	64	2	3.1	66	5	7.6					
Underlying ILD diagnosis											
iNSIP	40	4	10.0	55	2	3.6					
Unclassifiable IIP	36	2	5.6	40	4	10.0					
HP	39	1	2.6	30	1	3.3					
Autoimmune ILD	71	1	1.4	70	4	5.7					
Other ILD	36	2	5.6	25	2	8.0					
Region											
Europe	40	3	7.5	53	5	9.4					
Asia	106	5	4.7	107	6	5.6					
Canada and USA	30	1	3.3	17	1	5.9					
Rest of the World	46	1	2.2	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Gastrointestinal disorders

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
								Risk	Odds	Risk		Interaction
Category	N	n	%	N	n	%	p-value*	ratio (95% CI)	ratio (95% CI)	diff.	(95% CI)	p-value**
Overall	222	80	36.0	220	99	45.0	0.0549	1.25 (0.99, 1.57)	1.45 (0.99, 2.13)	8.96	(-0.18, 17.91)	
Age												
<65 years	83	33	39.8	88	30	34.1						
>=65 years	139	47	33.8	132	69	52.3						
Sex												
Male	116	38	32.8	111	47	42.3						
Female	106	42	39.6	109	52	47.7						
Baseline FVC percent predicted												
<=70%	118	47	39.8	96	42	43.8						
>70%	104	33	31.7	124	57	46.0						
Baseline HRCT pattern												
UIP-like	158	54	34.2	154	74	48.1						
Other fibrotic patterns	64	26	40.6	66	25	37.9						
Underlying ILD diagnosis												
iNSIP	40	10	25.0	55	18	32.7						
Unclassifiable IIP	36	14	38.9	40	21	52.5						
HP	39	16	41.0	30	13	43.3						
Autoimmune ILD	71	26	36.6	70	33	47.1						
Other ILD	36	14	38.9	25	14	56.0						
Region												
Europe	40	13	32.5	53	24	45.3						
Asia	106	40	37.7	107	48	44.9						
Canada and USA	30	14	46.7	17	9	52.9						
Rest of the World	46	13	28.3	43	18	41.9						

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo							
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)			Odds ratio (95% CI)		Risk diff.	(95% CI)	Interaction p-value**
Overall	222	84	37.8	220	62	28.2	0.0309	0.74 (0.57,	0.98)	0.64 (0.43,	0.96)	-9.66	(-18.22, -0.89)	
Age														0.8576
<65 years	83	34	41.0	88	26	29.5	0.1179	0.72 (0.48,	1.09)	0.60 (0.32,	1.14)	-11.42	(-25.13, 2.85)	
>=65 years	139	50	36.0	132	36	27.3	0.1241	0.76 (0.53,	1.08)	0.67 (0.40,	1.12)	-8.70	(-19.44, 2.39)	
Sex														0.3697
Male	116	46	39.7	111	29	26.1	0.0303	0.66 (0.45,	0.97)	0.54 (0.31,	0.95)	-13.53	(-25.18, -1.29)	
Female	106	38	35.8	109	33	30.3	0.3849	0.84 (0.58,	1.24)	0.78 (0.44,	1.37)	-5.57	(-17.87, 6.92)	
Baseline FVC percent predicted														0.0934
<=70%	118	47	39.8	96	36	37.5	0.7279	0.94 (0.67,	1.32)	0.91 (0.52,	1.58)	-2.33	(-15.09, 10.71)	
>70%	104	37	35.6	124	26	21.0	0.0140	0.59 (0.38,	0.90)	0.48 (0.27,	0.87)	-14.61	(-26.03, -2.92)	
Baseline HRCT pattern														0.5256
UIP-like	158	56	35.4	154	38	24.7	0.0382	0.70 (0.49,	0.99)	0.60 (0.37,	0.97)	-10.77	(-20.63, -0.58)	
Other fibrotic patterns	64	28	43.8	66	24	36.4	0.3901	0.83 (0.54,	1.27)	0.73 (0.36,	1.49)	-7.39	(-23.49, 9.25)	
Underlying ILD diagnosis														0.2614
iNSIP	40	10	25.0	55	17	30.9	0.5284	1.24 (0.63,	2.41)	1.34 (0.54,	3.35)	5.91	(-12.63, 22.91)	
Unclassifiable IIP	36	15	41.7	40	9	22.5	0.0727	0.54 (0.27,	1.08)	0.41 (0.15,	1.10)	-19.17	(-38.25, 1.72)	
HP	39	20	51.3	30	8	26.7	0.0390	0.52 (0.27,	1.01)	0.35 (0.12,	0.96)	-24.62	(-44.02, -1.30)	
Autoimmune ILD	71	27	38.0	70	19	27.1	0.1681	0.71 (0.44,	1.16)	0.61 (0.30,	1.24)	-10.89	(-25.61, 4.55)	
Other ILD	36	12	33.3	25	9	36.0	0.8293	1.08 (0.54,	2.17)	1.13 (0.39,	3.28)	2.67	(-20.02, 26.15)	
Region														0.9395
Europe	40	15	37.5	53	17	32.1	0.5856	0.86 (0.49,	1.50)	0.79 (0.33,	1.86)	-5.42	(-24.39, 13.44)	
Asia	106	40	37.7	107	30	28.0	0.1319	0.74 (0.50,	1.10)	0.64 (0.36,	1.14)	-9.70	(-21.89, 2.90)	
Canada and USA	30	14	46.7	17	5	29.4	0.2468	0.63 (0.27,	1.45)	0.48 (0.13,	1.69)	-17.25	(-40.83, 11.60)	
Rest of the World	46	15	32.6	43	10	23.3	0.3266	0.71 (0.36,	1.41)	0.63 (0.25,	1.60)	-9.35	(-26.96, 9.30)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	153	68.9	220	144	65.5	0.4380	0.95 (0.83, 1.08)	0.85 (0.57, 1.27)	-3.46 (-12.12, 5.26)	
Age											
<65 years	83	60	72.3	88	54	61.4					
>=65 years	139	93	66.9	132	90	68.2					
Sex											
Male	116	82	70.7	111	69	62.2					
Female	106	71	67.0	109	75	68.8					
Baseline FVC percent predicted											
<=70%	118	86	72.9	96	56	58.3					
>70%	104	67	64.4	124	88	71.0					
Baseline HRCT pattern											
UIP-like	158	108	68.4	154	100	64.9					
Other fibrotic patterns	64	45	70.3	66	44	66.7					
Underlying ILD diagnosis											
iNSIP	40	28	70.0	55	32	58.2					
Unclassifiable IIP	36	25	69.4	40	25	62.5					
HP	39	25	64.1	30	18	60.0					
Autoimmune ILD	71	45	63.4	70	49	70.0					
Other ILD	36	30	83.3	25	20	80.0					
Region											
Europe	40	30	75.0	53	35	66.0					
Asia	106	76	71.7	107	72	67.3					
Canada and USA	30	22	73.3	17	13	76.5					
Rest of the World	46	25	54.3	43	24	55.8					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Injury, poisoning and procedural complications

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	27	12.2	220	22	10.0	0.4691	0.82 (0.48, 1.40)	0.80 (0.44, 1.46)	-2.16 (-8.12, 3.78)	
Age											
<65 years	83	5	6.0	88	7	8.0					
>=65 years	139	22	15.8	132	15	11.4					
Sex											
Male	116	12	10.3	111	8	7.2					
Female	106	15	14.2	109	14	12.8					
Baseline FVC percent predicted											
<=70%	118	6	5.1	96	9	9.4					
>70%	104	21	20.2	124	13	10.5					
Baseline HRCT pattern											
UIP-like	158	21	13.3	154	16	10.4					
Other fibrotic patterns	64	6	9.4	66	6	9.1					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	3	5.5					
Unclassifiable IIP	36	9	25.0	40	5	12.5					
HP	39	4	10.3	30	1	3.3					
Autoimmune ILD	71	7	9.9	70	9	12.9					
Other ILD	36	5	13.9	25	4	16.0					
Region											
Europe	40	7	17.5	53	7	13.2					
Asia	106	11	10.4	107	13	12.1					
Canada and USA	30	6	20.0	17	0	0.0					
Rest of the World	46	3	6.5	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Investigations

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	44	19.8	220	59	26.8	0.0818	1.35 (0.96, 1.91)	1.48 (0.95, 2.31)	7.00 (-0.89, 14.80)	
Age											
<65 years	83	18	21.7	88	18	20.5					
>=65 years	139	26	18.7	132	41	31.1					
Sex											
Male	116	22	19.0	111	33	29.7					
Female	106	22	20.8	109	26	23.9					
Baseline FVC percent predicted											
<=70%	118	29	24.6	96	26	27.1					
>70%	104	15	14.4	124	33	26.6					
Baseline HRCT pattern											
UIP-like	158	28	17.7	154	47	30.5					
Other fibrotic patterns	64	16	25.0	66	12	18.2					
Underlying ILD diagnosis											
iNSIP	40	6	15.0	55	14	25.5					
Unclassifiable IIP	36	5	13.9	40	15	37.5					
HP	39	9	23.1	30	5	16.7					
Autoimmune ILD	71	18	25.4	70	18	25.7					
Other ILD	36	6	16.7	25	7	28.0					
Region											
Europe	40	7	17.5	53	9	17.0					
Asia	106	23	21.7	107	37	34.6					
Canada and USA	30	9	30.0	17	6	35.3					
Rest of the World	46	5	10.9	43	7	16.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Metabolism and nutrition disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	42	18.9	220	30	13.6	0.1326	0.72 (0.47, 1.11)	0.68 (0.41, 1.13)	-5.28 (-12.17, 1.64)	
Age											
<65 years	83	12	14.5	88	8	9.1					
>=65 years	139	30	21.6	132	22	16.7					
Sex											
Male	116	19	16.4	111	17	15.3					
Female	106	23	21.7	109	13	11.9					
Baseline FVC percent predicted											
<=70%	118	27	22.9	96	13	13.5					
>70%	104	15	14.4	124	17	13.7					
Baseline HRCT pattern											
UIP-like	158	32	20.3	154	25	16.2					
Other fibrotic patterns	64	10	15.6	66	5	7.6					
Underlying ILD diagnosis											
iNSIP	40	7	17.5	55	5	9.1					
Unclassifiable IIP	36	7	19.4	40	4	10.0					
HP	39	6	15.4	30	3	10.0					
Autoimmune ILD	71	17	23.9	70	13	18.6					
Other ILD	36	5	13.9	25	5	20.0					
Region											
Europe	40	8	20.0	53	5	9.4					
Asia	106	25	23.6	107	18	16.8					
Canada and USA	30	5	16.7	17	2	11.8					
Rest of the World	46	4	8.7	43	5	11.6					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Musculoskeletal and connective tissue disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	60	27.0	220	54	24.5	0.5510	0.91 (0.66, 1.25)	0.88 (0.57, 1.35)	-2.48 (-10.58, 5.67)	
Age											
<65 years	83	22	26.5	88	20	22.7					
>=65 years	139	38	27.3	132	34	25.8					
Sex											
Male	116	29	25.0	111	24	21.6					
Female	106	31	29.2	109	30	27.5					
Baseline FVC percent predicted											
<=70%	118	29	24.6	96	31	32.3					
>70%	104	31	29.8	124	23	18.5					
Baseline HRCT pattern											
UIP-like	158	46	29.1	154	37	24.0					
Other fibrotic patterns	64	14	21.9	66	17	25.8					
Underlying ILD diagnosis											
iNSIP	40	9	22.5	55	8	14.5					
Unclassifiable IIP	36	10	27.8	40	10	25.0					
HP	39	10	25.6	30	8	26.7					
Autoimmune ILD	71	20	28.2	70	18	25.7					
Other ILD	36	11	30.6	25	10	40.0					
Region											
Europe	40	12	30.0	53	22	41.5					
Asia	106	34	32.1	107	19	17.8					
Canada and USA	30	6	20.0	17	6	35.3					
Rest of the World	46	8	17.4	43	7	16.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	9	4.1	220	11	5.0	0.6324	1.23 (0.52, 2.92)	1.25 (0.51, 3.07)	0.95 (-3.15, 5.14)	
Age											
<65 years	83	4	4.8	88	4	4.5					
>=65 years	139	5	3.6	132	7	5.3					
Sex											
Male	116	7	6.0	111	4	3.6					
Female	106	2	1.9	109	7	6.4					
Baseline FVC percent predicted											
<=70%	118	3	2.5	96	4	4.2					
>70%	104	6	5.8	124	7	5.6					
Baseline HRCT pattern											
UIP-like	158	5	3.2	154	9	5.8					
Other fibrotic patterns	64	4	6.3	66	2	3.0					
Underlying ILD diagnosis											
iNSIP	40	3	7.5	55	3	5.5					
Unclassifiable IIP	36	2	5.6	40	1	2.5					
HP	39	2	5.1	30	1	3.3					
Autoimmune ILD	71	1	1.4	70	3	4.3					
Other ILD	36	1	2.8	25	3	12.0					
Region											
Europe	40	1	2.5	53	2	3.8					
Asia	106	3	2.8	107	4	3.7					
Canada and USA	30	4	13.3	17	1	5.9					
Rest of the World	46	1	2.2	43	4	9.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Nervous system disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	40	18.0	220	48	21.8	0.3171	1.21 (0.83, 1.76)	1.27 (0.79, 2.03)	3.80 (-3.66, 11.23)	
Age											
<65 years	83	14	16.9	88	13	14.8					
>=65 years	139	26	18.7	132	35	26.5					
Sex											
Male	116	21	18.1	111	25	22.5					
Female	106	19	17.9	109	23	21.1					
Baseline FVC percent predicted											
<=70%	118	20	16.9	96	20	20.8					
>70%	104	20	19.2	124	28	22.6					
Baseline HRCT pattern											
UIP-like	158	26	16.5	154	37	24.0					
Other fibrotic patterns	64	14	21.9	66	11	16.7					
Underlying ILD diagnosis											
iNSIP	40	3	7.5	55	8	14.5					
Unclassifiable IIP	36	7	19.4	40	7	17.5					
HP	39	13	33.3	30	10	33.3					
Autoimmune ILD	71	11	15.5	70	18	25.7					
Other ILD	36	6	16.7	25	5	20.0					
Region											
Europe	40	10	25.0	53	16	30.2					
Asia	106	15	14.2	107	18	16.8					
Canada and USA	30	6	20.0	17	5	29.4					
Rest of the World	46	9	19.6	43	9	20.9					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Psychiatric disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	47	21.2	220	51	23.2	0.6109	1.09 (0.77, 1.55)	1.12 (0.72, 1.76)	2.01 (-5.73, 9.74)	
Age											
<65 years	83	16	19.3	88	17	19.3					
>=65 years	139	31	22.3	132	34	25.8					
Sex											
Male	116	27	23.3	111	24	21.6					
Female	106	20	18.9	109	27	24.8					
Baseline FVC percent predicted											
<=70%	118	30	25.4	96	23	24.0					
>70%	104	17	16.3	124	28	22.6					
Baseline HRCT pattern											
UIP-like	158	33	20.9	154	33	21.4					
Other fibrotic patterns	64	14	21.9	66	18	27.3					
Underlying ILD diagnosis											
iNSIP	40	10	25.0	55	9	16.4					
Unclassifiable IIP	36	6	16.7	40	11	27.5					
HP	39	11	28.2	30	6	20.0					
Autoimmune ILD	71	14	19.7	70	17	24.3					
Other ILD	36	6	16.7	25	8	32.0					
Region											
Europe	40	12	30.0	53	14	26.4					
Asia	106	22	20.8	107	22	20.6					
Canada and USA	30	7	23.3	17	7	41.2					
Rest of the World	46	6	13.0	43	8	18.6					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Renal and urinary disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	15	6.8	220	11	5.0	0.4326	0.74 (0.35, 1.57)	0.73 (0.33, 1.62)	-1.76 (-6.39, 2.80)	
Age											
<65 years	83	3	3.6	88	2	2.3					
>=65 years	139	12	8.6	132	9	6.8					
Sex											
Male	116	10	8.6	111	5	4.5					
Female	106	5	4.7	109	6	5.5					
Baseline FVC percent predicted											
<=70%	118	9	7.6	96	4	4.2					
>70%	104	6	5.8	124	7	5.6					
Baseline HRCT pattern											
UIP-like	158	12	7.6	154	6	3.9					
Other fibrotic patterns	64	3	4.7	66	5	7.6					
Underlying ILD diagnosis											
iNSIP	40	7	17.5	55	2	3.6					
Unclassifiable IIP	36	0	0.0	40	1	2.5					
HP	39	1	2.6	30	2	6.7					
Autoimmune ILD	71	5	7.0	70	3	4.3					
Other ILD	36	2	5.6	25	3	12.0					
Region											
Europe	40	6	15.0	53	2	3.8					
Asia	106	9	8.5	107	6	5.6					
Canada and USA	30	0	0.0	17	2	11.8					
Rest of the World	46	0	0.0	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)		Odds ratio (95% CI)		Risk diff. (95% CI)		Interaction p-value**
Overall	222	85	38.3	220	84	38.2	0.9816	1.00 (0.79,	1.26)	1.00 (0.68,	1.46)	-0.11 (-9.10,	8.89)	
Age														
<65 years	83	29	34.9	88	26	29.5								
>=65 years	139	56	40.3	132	58	43.9								
Sex														
Male	116	42	36.2	111	45	40.5								
Female	106	43	40.6	109	39	35.8								
Baseline FVC percent predicted														
<=70%	118	50	42.4	96	45	46.9								
>70%	104	35	33.7	124	39	31.5								
Baseline HRCT pattern														
UIP-like	158	55	34.8	154	57	37.0								
Other fibrotic patterns	64	30	46.9	66	27	40.9								
Underlying ILD diagnosis														
iNSIP	40	10	25.0	55	17	30.9								
Unclassifiable IIP	36	12	33.3	40	14	35.0								
HP	39	25	64.1	30	14	46.7								
Autoimmune ILD	71	23	32.4	70	24	34.3								
Other ILD	36	15	41.7	25	15	60.0								
Region														
Europe	40	18	45.0	53	27	50.9								
Asia	106	39	36.8	107	37	34.6								
Canada and USA	30	10	33.3	17	12	70.6								
Rest of the World	46	18	39.1	43	8	18.6								

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Skin and subcutaneous tissue disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	27	12.2	220	22	10.0	0.4691	0.82 (0.48, 1.40)	0.80 (0.44, 1.46)	-2.16 (-8.12, 3.78)	
Age											
<65 years	83	8	9.6	88	8	9.1					
>=65 years	139	19	13.7	132	14	10.6					
Sex											
Male	116	13	11.2	111	9	8.1					
Female	106	14	13.2	109	13	11.9					
Baseline FVC percent predicted											
<=70%	118	10	8.5	96	11	11.5					
>70%	104	17	16.3	124	11	8.9					
Baseline HRCT pattern											
UIP-like	158	19	12.0	154	18	11.7					
Other fibrotic patterns	64	8	12.5	66	4	6.1					
Underlying ILD diagnosis											
iNSIP	40	3	7.5	55	5	9.1					
Unclassifiable IIP	36	6	16.7	40	3	7.5					
HP	39	6	15.4	30	2	6.7					
Autoimmune ILD	71	6	8.5	70	9	12.9					
Other ILD	36	6	16.7	25	3	12.0					
Region											
Europe	40	7	17.5	53	4	7.5					
Asia	106	12	11.3	107	13	12.1					
Canada and USA	30	7	23.3	17	1	5.9					
Rest of the World	46	1	2.2	43	4	9.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Vascular disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	21	9.5	220	16	7.3	0.4066	0.77 (0.41, 1.43)	0.75 (0.38, 1.48)	-2.19 (-7.52, 3.10)	
Age											
<65 years	83	8	9.6	88	4	4.5					
>=65 years	139	13	9.4	132	12	9.1					
Sex											
Male	116	14	12.1	111	5	4.5					
Female	106	7	6.6	109	11	10.1					
Baseline FVC percent predicted											
<=70%	118	15	12.7	96	6	6.3					
>70%	104	6	5.8	124	10	8.1					
Baseline HRCT pattern											
UIP-like	158	13	8.2	154	10	6.5					
Other fibrotic patterns	64	8	12.5	66	6	9.1					
Underlying ILD diagnosis											
iNSIP	40	8	20.0	55	4	7.3					
Unclassifiable IIP	36	1	2.8	40	2	5.0					
HP	39	4	10.3	30	2	6.7					
Autoimmune ILD	71	4	5.6	70	5	7.1					
Other ILD	36	4	11.1	25	3	12.0					
Region											
Europe	40	5	12.5	53	7	13.2					
Asia	106	9	8.5	107	5	4.7					
Canada and USA	30	2	6.7	17	1	5.9					
Rest of the World	46	5	10.9	43	3	7.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Cardiac disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	9	4.1	220	11	5.0	0.6324	1.23 (0.52, 2.92)	1.25 (0.51, 3.07)	0.95 (-3.15, 5.14)	
Age											
<65 years	83	3	3.6	88	3	3.4					
>=65 years	139	6	4.3	132	8	6.1					
Sex											
Male	116	3	2.6	111	6	5.4					
Female	106	6	5.7	109	5	4.6					
Baseline FVC percent predicted											
<=70%	118	7	5.9	96	5	5.2					
>70%	104	2	1.9	124	6	4.8					
Baseline HRCT pattern											
UIP-like	158	5	3.2	154	9	5.8					
Other fibrotic patterns	64	4	6.3	66	2	3.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	2	3.6					
Unclassifiable IIP	36	2	5.6	40	1	2.5					
HP	39	2	5.1	30	2	6.7					
Autoimmune ILD	71	4	5.6	70	5	7.1					
Other ILD	36	1	2.8	25	1	4.0					
Region											
Europe	40	4	10.0	53	4	7.5					
Asia	106	4	3.8	107	3	2.8					
Canada and USA	30	1	3.3	17	1	5.9					
Rest of the World	46	0	0.0	43	3	7.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	29	13.1	220	13	5.9	0.0103	0.45 (0.24, 0.85)	0.42 (0.21, 0.83)	-7.15 (-12.77, -1.67)	
Age											0.8961
<65 years	83	12	14.5	88	6	6.8	0.1038	0.47 (0.19, 1.20)	0.43 (0.15, 1.21)	-7.64 (-17.48, 1.78)	
>=65 years	139	17	12.2	132	7	5.3	0.0448	0.43 (0.19, 1.01)	0.40 (0.16, 1.00)	-6.93 (-13.95, -0.05)	
Sex											0.3751
Male	116	18	15.5	111	6	5.4	0.0133	0.35 (0.14, 0.85)	0.31 (0.12, 0.82)	-10.11 (-18.32, -2.07)	
Female	106	11	10.4	109	7	6.4	0.2952	0.62 (0.25, 1.54)	0.59 (0.22, 1.59)	-3.96 (-11.92, 3.73)	
Baseline FVC percent predicted											0.7556
<=70%	118	23	19.5	96	10	10.4	0.0675	0.53 (0.27, 1.07)	0.48 (0.22, 1.07)	-9.07 (-18.39, 0.78)	
>70%	104	6	5.8	124	3	2.4	0.1957	0.42 (0.11, 1.64)	0.40 (0.10, 1.66)	-3.35 (-9.80, 2.07)	
Baseline HRCT pattern											0.3483
UIP-like	158	24	15.2	154	9	5.8	0.0073	0.38 (0.18, 0.80)	0.35 (0.16, 0.77)	-9.35 (-16.32, -2.52)	
Other fibrotic patterns	64	5	7.8	66	4	6.1	0.6940	0.78 (0.22, 2.76)	0.76 (0.19, 2.97)	-1.75 (-11.67, 7.84)	
Underlying ILD diagnosis											0.1595
iNSIP	40	3	7.5	55	5	9.1	0.7828	1.21 (0.31, 4.78)	1.23 (0.28, 5.49)	1.59 (-11.80, 13.17)	
Unclassifiable IIP	36	3	8.3	40	3	7.5	0.8930	0.90 (0.19, 4.18)	0.89 (0.17, 4.73)	-0.83 (-15.19, 12.68)	
HP	39	7	17.9	30	0	0.0	0.0235	0.09 (0.01, 1.45)	0.00 (NC, NC)	-17.95 (-32.67, -3.48)	
Autoimmune ILD	71	10	14.1	70	1	1.4	0.0051	0.10 (0.01, 0.77)	0.09 (0.01, 0.71)	-12.66 (-22.66, -3.83)	
Other ILD	36	6	16.7	25	4	16.0	0.9449	0.96 (0.30, 3.06)	0.95 (0.24, 3.80)	-0.67 (-18.66, 19.96)	
Region											0.5313
Europe	40	4	10.0	53	4	7.5	0.6762	0.75 (0.20, 2.84)	0.73 (0.17, 3.14)	-2.45 (-16.28, 9.50)	
Asia	106	16	15.1	107	9	8.4	0.1297	0.56 (0.26, 1.20)	0.52 (0.22, 1.23)	-6.68 (-15.62, 2.12)	
Canada and USA	30	3	10.0	17	0	0.0	0.2941	0.25 (0.01, 4.50)	0.00 (NC, NC)	-10.00 (-25.62, 9.56)	
Rest of the World	46	6	13.0	43	0	0.0	0.0232	0.08 (0.00, 1.42)	0.00 (NC, NC)	-13.04 (-25.67, -2.31)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	44	19.8	220	34	15.5	0.2287	0.78 (0.52, 1.17)	0.74 (0.45, 1.21)	-4.37 (-11.46, 2.77)	
Age											
<65 years	83	13	15.7	88	5	5.7					
>=65 years	139	31	22.3	132	29	22.0					
Sex											
Male	116	25	21.6	111	19	17.1					
Female	106	19	17.9	109	15	13.8					
Baseline FVC percent predicted											
<=70%	118	30	25.4	96	18	18.8					
>70%	104	14	13.5	124	16	12.9					
Baseline HRCT pattern											
UIP-like	158	32	20.3	154	26	16.9					
Other fibrotic patterns	64	12	18.8	66	8	12.1					
Underlying ILD diagnosis											
iNSIP	40	5	12.5	55	9	16.4					
Unclassifiable IIP	36	8	22.2	40	6	15.0					
HP	39	6	15.4	30	3	10.0					
Autoimmune ILD	71	14	19.7	70	9	12.9					
Other ILD	36	11	30.6	25	7	28.0					
Region											
Europe	40	5	12.5	53	11	20.8					
Asia	106	27	25.5	107	19	17.8					
Canada and USA	30	5	16.7	17	2	11.8					
Rest of the World	46	7	15.2	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Nervous system disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	4	1.8	220	10	4.5	0.0996	2.52 (0.80, 7.92)	2.60 (0.80, 8.40)	2.74 (-0.68, 6.52)	
Age											
<65 years	83	1	1.2	88	2	2.3					
>=65 years	139	3	2.2	132	8	6.1					
Sex											
Male	116	1	0.9	111	7	6.3					
Female	106	3	2.8	109	3	2.8					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	4	4.2					
>70%	104	4	3.8	124	6	4.8					
Baseline HRCT pattern											
UIP-like	158	2	1.3	154	7	4.5					
Other fibrotic patterns	64	2	3.1	66	3	4.5					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	5	9.1					
Unclassifiable IIP	36	0	0.0	40	2	5.0					
HP	39	1	2.6	30	0	0.0					
Autoimmune ILD	71	1	1.4	70	1	1.4					
Other ILD	36	0	0.0	25	2	8.0					
Region											
Europe	40	0	0.0	53	2	3.8					
Asia	106	2	1.9	107	7	6.5					
Canada and USA	30	0	0.0	17	1	5.9					
Rest of the World	46	2	4.3	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo						
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)		Odds ratio (95% CI)		Risk diff.	(95% CI)	Interaction p-value**
Overall	222	33	14.9	220	19	8.6	0.0421	0.58 (0.34,	0.99)	0.54 (0.30,	0.98)	-6.23	(-12.32, -0.19)	
Age														0.3565
<65 years	83	10	12.0	88	4	4.5	0.0737	0.38 (0.12,	1.16)	0.35 (0.10,	1.16)	-7.50	(-16.66, 0.98)	
>=65 years	139	23	16.5	132	15	11.4	0.2193	0.69 (0.37,	1.26)	0.65 (0.32,	1.30)	-5.18	(-13.48, 3.21)	
Sex														0.3239
Male	116	17	14.7	111	12	10.8	0.3857	0.74 (0.37,	1.47)	0.71 (0.32,	1.55)	-3.84	(-12.66, 5.05)	
Female	106	16	15.1	109	7	6.4	0.0397	0.43 (0.18,	0.99)	0.39 (0.15,	0.98)	-8.67	(-17.34, -0.30)	
Baseline FVC percent predicted														0.9791
<=70%	118	25	21.2	96	13	13.5	0.1455	0.64 (0.35,	1.18)	0.58 (0.28,	1.21)	-7.64	(-17.51, 2.81)	
>70%	104	8	7.7	124	6	4.8	0.3713	0.63 (0.23,	1.75)	0.61 (0.20,	1.82)	-2.85	(-10.09, 3.65)	
Baseline HRCT pattern														0.1749
UIP-like	158	17	10.8	154	13	8.4	0.4875	0.78 (0.39,	1.56)	0.76 (0.36,	1.63)	-2.32	(-9.06, 4.41)	
Other fibrotic patterns	64	16	25.0	66	6	9.1	0.0156	0.36 (0.15,	0.87)	0.30 (0.11,	0.83)	-15.91	(-28.68, -2.94)	
Underlying ILD diagnosis														0.4939
iNSIP	40	2	5.0	55	5	9.1	0.4511	1.82 (0.37,	8.90)	1.90 (0.35,	10.33)	4.09	(-8.51, 15.18)	
Unclassifiable IIP	36	5	13.9	40	4	10.0	0.6003	0.72 (0.21,	2.48)	0.69 (0.17,	2.79)	-3.89	(-19.85, 11.32)	
HP	39	10	25.6	30	2	6.7	0.0393	0.26 (0.06,	1.10)	0.21 (0.04,	1.03)	-18.97	(-35.15, -0.61)	
Autoimmune ILD	71	8	11.3	70	4	5.7	0.2374	0.51 (0.16,	1.61)	0.48 (0.14,	1.66)	-5.55	(-15.59, 4.19)	
Other ILD	36	8	22.2	25	4	16.0	0.5477	0.72 (0.24,	2.13)	0.67 (0.18,	2.51)	-6.22	(-24.76, 15.19)	
Region														0.3179
Europe	40	9	22.5	53	4	7.5	0.0395	0.34 (0.11,	1.01)	0.28 (0.08,	0.99)	-14.95	(-30.64, -0.46)	
Asia	106	14	13.2	107	13	12.1	0.8165	0.92 (0.45,	1.86)	0.91 (0.41,	2.04)	-1.06	(-10.23, 8.08)	
Canada and USA	30	4	13.3	17	0	0.0	0.1907	0.19 (0.01,	3.35)	0.00 (NC,	NC)	-13.33	(-29.68, 6.77)	
Rest of the World	46	6	13.0	43	2	4.7	0.1666	0.36 (0.08,	1.67)	0.33 (0.06,	1.71)	-8.39	(-21.46, 4.44)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Cardiac disorders

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo						
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)		Odds ratio (95% CI)		Risk diff.	(95% CI)	Interaction p-value**
Overall	222	6	2.7	220	10	4.5	0.2997	1.68 (0.62,	4.55)	1.71 (0.61,	4.80)	1.84 (-1.85,	5.74)	
Age														
<65 years	83	1	1.2	88	3	3.4								
>=65 years	139	5	3.6	132	7	5.3								
Sex														
Male	116	3	2.6	111	5	4.5								
Female	106	3	2.8	109	5	4.6								
Baseline FVC percent predicted														
<=70%	118	5	4.2	96	5	5.2								
>70%	104	1	1.0	124	5	4.0								
Baseline HRCT pattern														
UIP-like	158	4	2.5	154	8	5.2								
Other fibrotic patterns	64	2	3.1	66	2	3.0								
Underlying ILD diagnosis														
iNSIP	40	0	0.0	55	2	3.6								
Unclassifiable IIP	36	2	5.6	40	1	2.5								
HP	39	1	2.6	30	2	6.7								
Autoimmune ILD	71	2	2.8	70	4	5.7								
Other ILD	36	1	2.8	25	1	4.0								
Region														
Europe	40	3	7.5	53	4	7.5								
Asia	106	3	2.8	107	2	1.9								
Canada and USA	30	0	0.0	17	1	5.9								
Rest of the World	46	0	0.0	43	3	7.0								

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo								
Category	N	n	%	N	n	%	p-value*	Risk ratio	(95% CI)		Odds ratio	(95% CI)		Risk diff.	(95% CI)		Interaction p-value**
Overall	222	27	12.2	220	14	6.4	0.0356	0.52	(0.28,	0.97)	0.49	(0.25,	0.96)	-5.80	(-11.36,	-0.35)	
Age																	0.9710
<65 years	83	11	13.3	88	6	6.8	0.1599	0.51	(0.20,	1.33)	0.48	(0.17,	1.36)	-6.43	(-16.09,	2.80)	
>=65 years	139	16	11.5	132	8	6.1	0.1145	0.53	(0.23,	1.19)	0.50	(0.20,	1.20)	-5.45	(-12.47,	1.49)	
Sex																	0.4729
Male	116	17	14.7	111	7	6.3	0.0409	0.43	(0.19,	1.00)	0.39	(0.16,	0.99)	-8.35	(-16.57,	-0.24)	
Female	106	10	9.4	109	7	6.4	0.4132	0.68	(0.27,	1.72)	0.66	(0.24,	1.80)	-3.01	(-10.80,	4.53)	
Baseline FVC percent predicted																	0.8065
<=70%	118	22	18.6	96	10	10.4	0.0932	0.56	(0.28,	1.12)	0.51	(0.23,	1.13)	-8.23	(-17.46,	1.54)	
>70%	104	5	4.8	124	4	3.2	0.5412	0.67	(0.18,	2.43)	0.66	(0.17,	2.52)	-1.58	(-7.85,	3.92)	
Baseline HRCT pattern																	0.3161
UIP-like	158	23	14.6	154	10	6.5	0.0206	0.45	(0.22,	0.91)	0.41	(0.19,	0.89)	-8.06	(-15.05,	-1.20)	
Other fibrotic patterns	64	4	6.3	66	4	6.1	0.9642	0.97	(0.25,	3.71)	0.97	(0.23,	4.05)	-0.19	(-9.68,	9.13)	
Underlying ILD diagnosis																	0.1801
iNSIP	40	2	5.0	55	5	9.1	0.4511	1.82	(0.37,	8.90)	1.90	(0.35,	10.33)	4.09	(-8.51,	15.18)	
Unclassifiable IIP	36	3	8.3	40	3	7.5	0.8930	0.90	(0.19,	4.18)	0.89	(0.17,	4.73)	-0.83	(-15.19,	12.68)	
HP	39	6	15.4	30	0	0.0	0.0402	0.10	(0.01,	1.70)	0.00	(NC,	NC)	-15.38	(-29.73,	-1.42)	
Autoimmune ILD	71	10	14.1	70	2	2.9	0.0169	0.20	(0.05,	0.89)	0.18	(0.04,	0.85)	-11.23	(-21.38,	-1.86)	
Other ILD	36	6	16.7	25	4	16.0	0.9449	0.96	(0.30,	3.06)	0.95	(0.24,	3.80)	-0.67	(-18.66,	19.96)	
Region																	0.6272
Europe	40	3	7.5	53	4	7.5	0.9932	1.01	(0.24,	4.25)	1.01	(0.21,	4.78)	0.05	(-13.14,	11.47)	
Asia	106	16	15.1	107	9	8.4	0.1297	0.56	(0.26,	1.20)	0.52	(0.22,	1.23)	-6.68	(-15.62,	2.12)	
Canada and USA	30	3	10.0	17	0	0.0	0.2941	0.25	(0.01,	4.50)	0.00	(NC,	NC)	-10.00	(-25.62,	9.56)	
Rest of the World	46	5	10.9	43	1	2.3	0.1082	0.21	(0.03,	1.76)	0.20	(0.02,	1.74)	-8.54	(-20.86,	2.96)	

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Infections and infestations

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff.	(95% CI)	Interaction p-value**
Overall	222	41	18.5	220	29	13.2	0.1280	0.71 (0.46, 1.11)	0.67 (0.40, 1.12)	-5.29	(-12.10, 1.56)	
Age												
<65 years	83	12	14.5	88	5	5.7						
>=65 years	139	29	20.9	132	24	18.2						
Sex												
Male	116	22	19.0	111	14	12.6						
Female	106	19	17.9	109	15	13.8						
Baseline FVC percent predicted												
<=70%	118	28	23.7	96	17	17.7						
>70%	104	13	12.5	124	12	9.7						
Baseline HRCT pattern												
UIP-like	158	31	19.6	154	21	13.6						
Other fibrotic patterns	64	10	15.6	66	8	12.1						
Underlying ILD diagnosis												
iNSIP	40	4	10.0	55	9	16.4						
Unclassifiable IIP	36	8	22.2	40	4	10.0						
HP	39	6	15.4	30	1	3.3						
Autoimmune ILD	71	12	16.9	70	8	11.4						
Other ILD	36	11	30.6	25	7	28.0						
Region												
Europe	40	4	10.0	53	10	18.9						
Asia	106	25	23.6	107	14	13.1						
Canada and USA	30	5	16.7	17	2	11.8						
Rest of the World	46	7	15.2	43	3	7.0						

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	24	10.8	220	16	7.3	0.1949	0.67 (0.37, 1.23)	0.65 (0.33, 1.25)	-3.54 (-9.04, 1.90)	
Age											
<65 years	83	6	7.2	88	3	3.4					
>=65 years	139	18	12.9	132	13	9.8					
Sex											
Male	116	13	11.2	111	8	7.2					
Female	106	11	10.4	109	8	7.3					
Baseline FVC percent predicted											
<=70%	118	18	15.3	96	11	11.5					
>70%	104	6	5.8	124	5	4.0					
Baseline HRCT pattern											
UIP-like	158	14	8.9	154	11	7.1					
Other fibrotic patterns	64	10	15.6	66	5	7.6					
Underlying ILD diagnosis											
iNSIP	40	1	2.5	55	5	9.1					
Unclassifiable IIP	36	5	13.9	40	2	5.0					
HP	39	8	20.5	30	2	6.7					
Autoimmune ILD	71	6	8.5	70	4	5.7					
Other ILD	36	4	11.1	25	3	12.0					
Region											
Europe	40	5	12.5	53	4	7.5					
Asia	106	10	9.4	107	10	9.3					
Canada and USA	30	3	10.0	17	0	0.0					
Rest of the World	46	6	13.0	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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I.2.2.2.1.5 Adverse events on PT level over the whole trial

Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo						
								Risk	Odds	Risk			Interaction
Category	N	n	%	N	n	%	p-value*	ratio (95% CI)	ratio (95% CI)	diff.	(95% CI)		p-value**
Overall	222	36	16.2	220	59	26.8	0.0067	1.65 (1.14, 2.39)	1.89 (1.19, 3.01)	10.60	(2.94, 18.14)		
Age													0.0173
<65 years	83	16	19.3	88	15	17.0	0.7050	0.88 (0.47, 1.67)	0.86 (0.40, 1.87)	-2.23	(-13.93, 9.35)		
>=65 years	139	20	14.4	132	44	33.3	0.0002	2.32 (1.45, 3.71)	2.98 (1.64, 5.40)	18.94	(8.85, 28.67)		
Sex													0.5054
Male	116	20	17.2	111	28	25.2	0.1409	1.46 (0.88, 2.44)	1.62 (0.85, 3.09)	7.98	(-2.67, 18.53)		
Female	106	16	15.1	109	31	28.4	0.0179	1.88 (1.10, 3.24)	2.24 (1.14, 4.39)	13.35	(2.28, 24.01)		
Baseline FVC percent predicted													0.2967
<=70%	118	24	20.3	96	28	29.2	0.1343	1.43 (0.89, 2.30)	1.61 (0.86, 3.02)	8.83	(-2.69, 20.42)		
>70%	104	12	11.5	124	31	25.0	0.0097	2.17 (1.17, 4.00)	2.56 (1.24, 5.28)	13.46	(3.30, 23.05)		
Baseline HRCT pattern													0.3434
UIP-like	158	25	15.8	154	45	29.2	0.0046	1.85 (1.19, 2.85)	2.20 (1.27, 3.81)	13.40	(4.14, 22.44)		
Other fibrotic patterns	64	11	17.2	66	14	21.2	0.5605	1.23 (0.61, 2.51)	1.30 (0.54, 3.12)	4.02	(-9.68, 17.48)		
Underlying ILD diagnosis													0.6254
iNSIP	40	4	10.0	55	13	23.6	0.0869	2.36 (0.83, 6.71)	2.79 (0.83, 9.30)	13.64	(-2.37, 27.71)		
Unclassifiable IIP	36	5	13.9	40	11	27.5	0.1461	1.98 (0.76, 5.15)	2.35 (0.73, 7.59)	13.61	(-5.04, 30.82)		
HP	39	8	20.5	30	10	33.3	0.2293	1.63 (0.73, 3.61)	1.94 (0.65, 5.74)	12.82	(-7.78, 33.18)		
Autoimmune ILD	71	14	19.7	70	16	22.9	0.6489	1.16 (0.61, 2.19)	1.21 (0.54, 2.71)	3.14	(-10.39, 16.58)		
Other ILD	36	5	13.9	25	9	36.0	0.0434	2.59 (0.99, 6.82)	3.49 (1.00, 12.16)	22.11	(0.52, 43.10)		
Region													0.4349
Europe	40	5	12.5	53	16	30.2	0.0434	2.42 (0.97, 6.04)	3.03 (1.00, 9.14)	17.69	(0.39, 32.78)		
Asia	106	18	17.0	107	22	20.6	0.5036	1.21 (0.69, 2.12)	1.27 (0.63, 2.52)	3.58	(-6.98, 14.05)		
Canada and USA	30	7	23.3	17	7	41.2	0.1987	1.76 (0.75, 4.18)	2.30 (0.64, 8.31)	17.84	(-8.47, 43.41)		
Rest of the World	46	6	13.0	43	14	32.6	0.0275	2.50 (1.05, 5.91)	3.22 (1.10, 9.38)	19.51	(2.05, 35.97)		

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk ratio (95% CI) p-value*	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	9	4.1	220	15	6.8	0.1998 1.68 (0.75, 3.76)	1.73 (0.74, 4.04)	2.76 (-1.60, 7.31)	
Age										
<65 years	83	3	3.6	88	4	4.5				
>=65 years	139	6	4.3	132	11	8.3				
Sex										
Male	116	2	1.7	111	8	7.2				
Female	106	7	6.6	109	7	6.4				
Baseline FVC percent predicted										
<=70%	118	6	5.1	96	8	8.3				
>70%	104	3	2.9	124	7	5.6				
Baseline HRCT pattern										
UIP-like	158	4	2.5	154	12	7.8				
Other fibrotic patterns	64	5	7.8	66	3	4.5				
Underlying ILD diagnosis										
iNSIP	40	1	2.5	55	1	1.8				
Unclassifiable IIP	36	3	8.3	40	3	7.5				
HP	39	4	10.3	30	3	10.0				
Autoimmune ILD	71	0	0.0	70	5	7.1				
Other ILD	36	1	2.8	25	3	12.0				
Region										
Europe	40	3	7.5	53	3	5.7				
Asia	106	1	0.9	107	5	4.7				
Canada and USA	30	3	10.0	17	2	11.8				
Rest of the World	46	2	4.3	43	5	11.6				

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	38	17.1	220	20	9.1	0.0125	0.53 (0.32, 0.88)	0.48 (0.27, 0.86)	-8.03 (-14.36, -1.72)	
Age											0.6884
<65 years	83	16	19.3	88	10	11.4	0.1498	0.59 (0.28, 1.22)	0.54 (0.23, 1.26)	-7.91 (-18.92, 2.98)	
>=65 years	139	22	15.8	132	10	7.6	0.0354	0.48 (0.24, 0.97)	0.44 (0.20, 0.96)	-8.25 (-16.01, -0.50)	
Sex											0.7682
Male	116	23	19.8	111	11	9.9	0.0363	0.50 (0.26, 0.98)	0.44 (0.21, 0.96)	-9.92 (-19.14, -0.57)	
Female	106	15	14.2	109	9	8.3	0.1700	0.58 (0.27, 1.28)	0.55 (0.23, 1.31)	-5.89 (-14.68, 2.70)	
Baseline FVC percent predicted											0.5261
<=70%	118	25	21.2	96	13	13.5	0.1455	0.64 (0.35, 1.18)	0.58 (0.28, 1.21)	-7.64 (-17.51, 2.81)	
>70%	104	13	12.5	124	7	5.6	0.0684	0.45 (0.19, 1.09)	0.42 (0.16, 1.09)	-6.85 (-15.10, 0.65)	
Baseline HRCT pattern											0.3832
UIP-like	158	29	18.4	154	13	8.4	0.0103	0.46 (0.25, 0.85)	0.41 (0.20, 0.82)	-9.91 (-17.50, -2.33)	
Other fibrotic patterns	64	9	14.1	66	7	10.6	0.5487	0.75 (0.30, 1.90)	0.73 (0.25, 2.08)	-3.46 (-15.30, 8.22)	
Underlying ILD diagnosis											0.1286
iNSIP	40	7	17.5	55	5	9.1	0.2232	0.52 (0.18, 1.52)	0.47 (0.14, 1.61)	-8.41 (-23.75, 5.25)	
Unclassifiable IIP	36	3	8.3	40	4	10.0	0.8019	1.20 (0.29, 5.00)	1.22 (0.25, 5.87)	1.67 (-13.12, 15.81)	
HP	39	10	25.6	30	1	3.3	0.0121	0.13 (0.02, 0.96)	0.10 (0.01, 0.83)	-22.31 (-37.99, -4.97)	
Autoimmune ILD	71	12	16.9	70	4	5.7	0.0363	0.34 (0.11, 1.00)	0.30 (0.09, 0.97)	-11.19 (-22.11, -0.52)	
Other ILD	36	6	16.7	25	6	24.0	0.4786	1.44 (0.52, 3.95)	1.58 (0.44, 5.62)	7.33 (-12.37, 28.66)	
Region											0.9943
Europe	40	8	20.0	53	6	11.3	0.2465	0.57 (0.21, 1.50)	0.51 (0.16, 1.61)	-8.68 (-24.62, 6.05)	
Asia	106	17	16.0	107	9	8.4	0.0891	0.52 (0.24, 1.12)	0.48 (0.20, 1.13)	-7.63 (-16.67, 1.30)	
Canada and USA	30	4	13.3	17	1	5.9	0.4260	0.44 (0.05, 3.64)	0.41 (0.04, 3.96)	-7.45 (-24.50, 15.12)	
Rest of the World	46	9	19.6	43	4	9.3	0.1707	0.48 (0.16, 1.43)	0.42 (0.12, 1.49)	-10.26 (-24.99, 4.93)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions
PT: Fatigue

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	11	5.0	220	8	3.6	0.4944	0.73 (0.30, 1.79)	0.72 (0.29, 1.84)	-1.32 (-5.42, 2.69)	
Age											
<65 years	83	3	3.6	88	2	2.3					
>=65 years	139	8	5.8	132	6	4.5					
Sex											
Male	116	4	3.4	111	4	3.6					
Female	106	7	6.6	109	4	3.7					
Baseline FVC percent predicted											
<=70%	118	6	5.1	96	3	3.1					
>70%	104	5	4.8	124	5	4.0					
Baseline HRCT pattern											
UIP-like	158	7	4.4	154	5	3.2					
Other fibrotic patterns	64	4	6.3	66	3	4.5					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	2	3.6					
Unclassifiable IIP	36	2	5.6	40	1	2.5					
HP	39	3	7.7	30	2	6.7					
Autoimmune ILD	71	2	2.8	70	2	2.9					
Other ILD	36	2	5.6	25	1	4.0					
Region											
Europe	40	2	5.0	53	3	5.7					
Asia	106	2	1.9	107	2	1.9					
Canada and USA	30	7	23.3	17	2	11.8					
Rest of the World	46	0	0.0	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions
PT: Pyrexia

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	17	7.7	220	12	5.5	0.3496	0.71 (0.35, 1.46)	0.70 (0.32, 1.49)	-2.20 (-7.05, 2.56)	
Age											
<65 years	83	10	12.0	88	5	5.7					
>=65 years	139	7	5.0	132	7	5.3					
Sex											
Male	116	8	6.9	111	5	4.5					
Female	106	9	8.5	109	7	6.4					
Baseline FVC percent predicted											
<=70%	118	10	8.5	96	8	8.3					
>70%	104	7	6.7	124	4	3.2					
Baseline HRCT pattern											
UIP-like	158	9	5.7	154	8	5.2					
Other fibrotic patterns	64	8	12.5	66	4	6.1					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	3	5.5					
Unclassifiable IIP	36	2	5.6	40	2	5.0					
HP	39	2	5.1	30	0	0.0					
Autoimmune ILD	71	9	12.7	70	4	5.7					
Other ILD	36	4	11.1	25	3	12.0					
Region											
Europe	40	1	2.5	53	3	5.7					
Asia	106	13	12.3	107	7	6.5					
Canada and USA	30	1	3.3	17	0	0.0					
Rest of the World	46	2	4.3	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Bronchitis

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	15	6.8	220	14	6.4	0.8675	0.94 (0.47, 1.90)	0.94 (0.44, 1.99)	-0.39 (-5.21, 4.42)	
Age											
<65 years	83	4	4.8	88	6	6.8					
>=65 years	139	11	7.9	132	8	6.1					
Sex											
Male	116	6	5.2	111	6	5.4					
Female	106	9	8.5	109	8	7.3					
Baseline FVC percent predicted											
<=70%	118	6	5.1	96	5	5.2					
>70%	104	9	8.7	124	9	7.3					
Baseline HRCT pattern											
UIP-like	158	8	5.1	154	9	5.8					
Other fibrotic patterns	64	7	10.9	66	5	7.6					
Underlying ILD diagnosis											
iNSIP	40	4	10.0	55	3	5.5					
Unclassifiable IIP	36	5	13.9	40	3	7.5					
HP	39	3	7.7	30	1	3.3					
Autoimmune ILD	71	1	1.4	70	2	2.9					
Other ILD	36	2	5.6	25	5	20.0					
Region											
Europe	40	9	22.5	53	7	13.2					
Asia	106	5	4.7	107	2	1.9					
Canada and USA	30	0	0.0	17	3	17.6					
Rest of the World	46	1	2.2	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: COVID-19

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	32	14.4	220	29	13.2	0.7072	0.91 (0.57, 1.46)	0.90 (0.52, 1.55)	-1.23 (-7.72, 5.26)	
Age											
<65 years	83	15	18.1	88	10	11.4					
>=65 years	139	17	12.2	132	19	14.4					
Sex											
Male	116	17	14.7	111	12	10.8					
Female	106	15	14.2	109	17	15.6					
Baseline FVC percent predicted											
<=70%	118	22	18.6	96	10	10.4					
>70%	104	10	9.6	124	19	15.3					
Baseline HRCT pattern											
UIP-like	158	19	12.0	154	18	11.7					
Other fibrotic patterns	64	13	20.3	66	11	16.7					
Underlying ILD diagnosis											
iNSIP	40	7	17.5	55	6	10.9					
Unclassifiable IIP	36	5	13.9	40	6	15.0					
HP	39	7	17.9	30	5	16.7					
Autoimmune ILD	71	7	9.9	70	8	11.4					
Other ILD	36	6	16.7	25	4	16.0					
Region											
Europe	40	7	17.5	53	7	13.2					
Asia	106	18	17.0	107	15	14.0					
Canada and USA	30	6	20.0	17	3	17.6					
Rest of the World	46	1	2.2	43	4	9.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Influenza

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	11	5.0	220	12	5.5	0.8131	1.10 (0.50, 2.44)	1.11 (0.48, 2.56)	0.50 (-3.86, 4.90)	
Age											
<65 years	83	7	8.4	88	3	3.4					
>=65 years	139	4	2.9	132	9	6.8					
Sex											
Male	116	3	2.6	111	5	4.5					
Female	106	8	7.5	109	7	6.4					
Baseline FVC percent predicted											
<=70%	118	6	5.1	96	3	3.1					
>70%	104	5	4.8	124	9	7.3					
Baseline HRCT pattern											
UIP-like	158	9	5.7	154	9	5.8					
Other fibrotic patterns	64	2	3.1	66	3	4.5					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	3	5.5					
Unclassifiable IIP	36	1	2.8	40	2	5.0					
HP	39	1	2.6	30	1	3.3					
Autoimmune ILD	71	7	9.9	70	4	5.7					
Other ILD	36	2	5.6	25	2	8.0					
Region											
Europe	40	3	7.5	53	3	5.7					
Asia	106	3	2.8	107	9	8.4					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	5	10.9	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Nasopharyngitis

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	21	9.5	220	23	10.5	0.7268	1.11 (0.63, 1.94)	1.12 (0.60, 2.08)	1.00 (-4.69, 6.71)	
Age											
<65 years	83	10	12.0	88	8	9.1					
>=65 years	139	11	7.9	132	15	11.4					
Sex											
Male	116	11	9.5	111	13	11.7					
Female	106	10	9.4	109	10	9.2					
Baseline FVC percent predicted											
<=70%	118	10	8.5	96	10	10.4					
>70%	104	11	10.6	124	13	10.5					
Baseline HRCT pattern											
UIP-like	158	17	10.8	154	14	9.1					
Other fibrotic patterns	64	4	6.3	66	9	13.6					
Underlying ILD diagnosis											
iNSIP	40	4	10.0	55	4	7.3					
Unclassifiable IIP	36	6	16.7	40	6	15.0					
HP	39	3	7.7	30	5	16.7					
Autoimmune ILD	71	6	8.5	70	7	10.0					
Other ILD	36	2	5.6	25	1	4.0					
Region											
Europe	40	3	7.5	53	6	11.3					
Asia	106	15	14.2	107	12	11.2					
Canada and USA	30	1	3.3	17	2	11.8					
Rest of the World	46	2	4.3	43	3	7.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Pneumonia

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	32	14.4	220	33	15.0	0.8620	1.04 (0.66, 1.63)	1.05 (0.62, 1.77)	0.59 (-6.07, 7.25)	
Age											
<65 years	83	10	12.0	88	6	6.8					
>=65 years	139	22	15.8	132	27	20.5					
Sex											
Male	116	17	14.7	111	17	15.3					
Female	106	15	14.2	109	16	14.7					
Baseline FVC percent predicted											
<=70%	118	20	16.9	96	15	15.6					
>70%	104	12	11.5	124	18	14.5					
Baseline HRCT pattern											
UIP-like	158	20	12.7	154	24	15.6					
Other fibrotic patterns	64	12	18.8	66	9	13.6					
Underlying ILD diagnosis											
iNSIP	40	4	10.0	55	10	18.2					
Unclassifiable IIP	36	3	8.3	40	5	12.5					
HP	39	3	7.7	30	4	13.3					
Autoimmune ILD	71	13	18.3	70	11	15.7					
Other ILD	36	9	25.0	25	3	12.0					
Region											
Europe	40	3	7.5	53	8	15.1					
Asia	106	23	21.7	107	19	17.8					
Canada and USA	30	2	6.7	17	3	17.6					
Rest of the World	46	4	8.7	43	3	7.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Respiratory tract infection

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	10	4.5	220	16	7.3	0.2162	1.61 (0.75, 3.48)	1.66 (0.74, 3.75)	2.77 (-1.75, 7.45)	
Age											
<65 years	83	3	3.6	88	6	6.8					
>=65 years	139	7	5.0	132	10	7.6					
Sex											
Male	116	8	6.9	111	6	5.4					
Female	106	2	1.9	109	10	9.2					
Baseline FVC percent predicted											
<=70%	118	2	1.7	96	4	4.2					
>70%	104	8	7.7	124	12	9.7					
Baseline HRCT pattern											
UIP-like	158	8	5.1	154	14	9.1					
Other fibrotic patterns	64	2	3.1	66	2	3.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	6	10.9					
Unclassifiable IIP	36	3	8.3	40	3	7.5					
HP	39	1	2.6	30	1	3.3					
Autoimmune ILD	71	3	4.2	70	5	7.1					
Other ILD	36	3	8.3	25	1	4.0					
Region											
Europe	40	3	7.5	53	4	7.5					
Asia	106	3	2.8	107	6	5.6					
Canada and USA	30	3	10.0	17	1	5.9					
Rest of the World	46	1	2.2	43	5	11.6					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Upper respiratory tract infection

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	46	20.7	220	34	15.5	0.1505	0.75 (0.50, 1.12)	0.70 (0.43, 1.14)	-5.27 (-12.42, 1.94)	
Age											
<65 years	83	22	26.5	88	16	18.2					
>=65 years	139	24	17.3	132	18	13.6					
Sex											
Male	116	26	22.4	111	12	10.8					
Female	106	20	18.9	109	22	20.2					
Baseline FVC percent predicted											
<=70%	118	27	22.9	96	11	11.5					
>70%	104	19	18.3	124	23	18.5					
Baseline HRCT pattern											
UIP-like	158	34	21.5	154	25	16.2					
Other fibrotic patterns	64	12	18.8	66	9	13.6					
Underlying ILD diagnosis											
iNSIP	40	5	12.5	55	5	9.1					
Unclassifiable IIP	36	5	13.9	40	7	17.5					
HP	39	10	25.6	30	1	3.3					
Autoimmune ILD	71	15	21.1	70	16	22.9					
Other ILD	36	11	30.6	25	5	20.0					
Region											
Europe	40	8	20.0	53	2	3.8					
Asia	106	27	25.5	107	25	23.4					
Canada and USA	30	9	30.0	17	5	29.4					
Rest of the World	46	2	4.3	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Urinary tract infection

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	14	6.3	220	14	6.4	0.9803	1.01 (0.49, 2.07)	1.01 (0.47, 2.17)	0.06 (-4.68, 4.81)	
Age											
<65 years	83	2	2.4	88	1	1.1					
>=65 years	139	12	8.6	132	13	9.8					
Sex											
Male	116	2	1.7	111	2	1.8					
Female	106	12	11.3	109	12	11.0					
Baseline FVC percent predicted											
<=70%	118	6	5.1	96	7	7.3					
>70%	104	8	7.7	124	7	5.6					
Baseline HRCT pattern											
UIP-like	158	10	6.3	154	8	5.2					
Other fibrotic patterns	64	4	6.3	66	6	9.1					
Underlying ILD diagnosis											
iNSIP	40	6	15.0	55	6	10.9					
Unclassifiable IIP	36	3	8.3	40	1	2.5					
HP	39	2	5.1	30	2	6.7					
Autoimmune ILD	71	3	4.2	70	4	5.7					
Other ILD	36	0	0.0	25	1	4.0					
Region											
Europe	40	2	5.0	53	6	11.3					
Asia	106	5	4.7	107	1	0.9					
Canada and USA	30	2	6.7	17	1	5.9					
Rest of the World	46	5	10.9	43	6	14.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Investigations
PT: Weight decreased

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	11	5.0	220	28	12.7	0.0040	2.57 (1.31, 5.03)	2.80 (1.36, 5.77)	7.77 (2.49, 13.27)	
Age											0.5212
<65 years	83	4	4.8	88	8	9.1	0.2744	1.89 (0.59, 6.03)	1.98 (0.57, 6.82)	4.27 (-3.94, 12.64)	
>=65 years	139	7	5.0	132	20	15.2	0.0055	3.01 (1.32, 6.88)	3.37 (1.37, 8.26)	10.12 (2.96, 17.66)	
Sex											0.7779
Male	116	7	6.0	111	16	14.4	0.0365	2.39 (1.02, 5.58)	2.62 (1.03, 6.65)	8.38 (0.42, 16.70)	
Female	106	4	3.8	109	12	11.0	0.0433	2.92 (0.97, 8.76)	3.15 (0.98, 10.12)	7.24 (0.04, 14.84)	
Baseline FVC percent predicted											0.0515
<=70%	118	11	9.3	96	13	13.5	0.3306	1.45 (0.68, 3.10)	1.52 (0.65, 3.57)	4.22 (-4.34, 13.41)	
>70%	104	0	0.0	124	15	12.1	0.0004	>10 (1.58, >99)	NC (NC, NC)	12.10 (6.26, 19.00)	
Baseline HRCT pattern											0.4177
UIP-like	158	7	4.4	154	21	13.6	0.0044	3.08 (1.35, 7.03)	3.41 (1.40, 8.27)	9.21 (2.86, 15.91)	
Other fibrotic patterns	64	4	6.3	66	7	10.6	0.3723	1.70 (0.52, 5.52)	1.78 (0.49, 6.40)	4.36 (-5.91, 14.78)	
Underlying ILD diagnosis											0.7869
iNSIP	40	1	2.5	55	3	5.5	0.4790	2.18 (0.24, 20.21)	2.25 (0.23, 22.46)	2.95 (-8.03, 12.58)	
Unclassifiable IIP	36	2	5.6	40	8	20.0	0.0629	3.60 (0.82, 15.86)	4.25 (0.84, 21.54)	14.44 (-1.33, 29.74)	
HP	39	2	5.1	30	1	3.3	0.7170	0.65 (0.06, 6.83)	0.64 (0.06, 7.39)	-1.79 (-13.87, 12.05)	
Autoimmune ILD	71	3	4.2	70	10	14.3	0.0390	3.38 (0.97, 11.77)	3.78 (0.99, 14.37)	10.06 (0.26, 20.49)	
Other ILD	36	3	8.3	25	6	24.0	0.0897	2.88 (0.79, 10.45)	3.47 (0.78, 15.51)	15.67 (-2.73, 35.85)	
Region											0.8089
Europe	40	1	2.5	53	4	7.5	0.2853	3.02 (0.35, 25.98)	3.18 (0.34, 29.65)	5.05 (-6.30, 15.56)	
Asia	106	8	7.5	107	17	15.9	0.0586	2.11 (0.95, 4.67)	2.31 (0.95, 5.62)	8.34 (-0.43, 17.23)	
Canada and USA	30	2	6.7	17	5	29.4	0.0353	4.41 (0.96, 20.34)	5.83 (0.99, 34.38)	22.75 (0.95, 46.95)	
Rest of the World	46	0	0.0	43	2	4.7	0.2176	5.34 (0.26, >99)	NC (NC, NC)	4.65 (-3.76, 15.46)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	15	6.8	220	15	6.8	0.9795	1.01 (0.51, 2.01)	1.01 (0.48, 2.12)	0.06 (-4.81, 4.95)	
Age											
<65 years	83	2	2.4	88	5	5.7					
>=65 years	139	13	9.4	132	10	7.6					
Sex											
Male	116	5	4.3	111	5	4.5					
Female	106	10	9.4	109	10	9.2					
Baseline FVC percent predicted											
<=70%	118	12	10.2	96	8	8.3					
>70%	104	3	2.9	124	7	5.6					
Baseline HRCT pattern											
UIP-like	158	11	7.0	154	11	7.1					
Other fibrotic patterns	64	4	6.3	66	4	6.1					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	4	7.3					
Unclassifiable IIP	36	4	11.1	40	2	5.0					
HP	39	3	7.7	30	1	3.3					
Autoimmune ILD	71	4	5.6	70	5	7.1					
Other ILD	36	2	5.6	25	3	12.0					
Region											
Europe	40	1	2.5	53	2	3.8					
Asia	106	10	9.4	107	8	7.5					
Canada and USA	30	4	13.3	17	1	5.9					
Rest of the World	46	0	0.0	43	4	9.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	14	6.3	220	16	7.3	0.6863	1.15 (0.58, 2.31)	1.17 (0.55, 2.45)	0.97 (-3.89, 5.87)	
Age											
<65 years	83	4	4.8	88	4	4.5					
>=65 years	139	10	7.2	132	12	9.1					
Sex											
Male	116	8	6.9	111	8	7.2					
Female	106	6	5.7	109	8	7.3					
Baseline FVC percent predicted											
<=70%	118	5	4.2	96	10	10.4					
>70%	104	9	8.7	124	6	4.8					
Baseline HRCT pattern											
UIP-like	158	10	6.3	154	10	6.5					
Other fibrotic patterns	64	4	6.3	66	6	9.1					
Underlying ILD diagnosis											
iNSIP	40	1	2.5	55	1	1.8					
Unclassifiable IIP	36	4	11.1	40	3	7.5					
HP	39	3	7.7	30	4	13.3					
Autoimmune ILD	71	2	2.8	70	5	7.1					
Other ILD	36	4	11.1	25	3	12.0					
Region											
Europe	40	5	12.5	53	11	20.8					
Asia	106	4	3.8	107	1	0.9					
Canada and USA	30	3	10.0	17	1	5.9					
Rest of the World	46	2	4.3	43	3	7.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Musculoskeletal and connective tissue disorders
PT: Back pain

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	6	2.7	220	16	7.3	0.0272	2.69 (1.07, 6.75)	2.82 (1.08, 7.36)	4.57 (0.45, 9.03)	
Age											0.4082
<65 years	83	1	1.2	88	6	6.8	0.0641	5.66 (0.70, 46.01)	6.00 (0.71, 50.95)	5.61 (-0.83, 12.95)	
>=65 years	139	5	3.6	132	10	7.6	0.1522	2.11 (0.74, 6.00)	2.20 (0.73, 6.61)	3.98 (-1.70, 10.14)	
Sex											0.6015
Male	116	2	1.7	111	7	6.3	0.0770	3.66 (0.78, 17.23)	3.84 (0.78, 18.88)	4.58 (-0.82, 10.85)	
Female	106	4	3.8	109	9	8.3	0.1679	2.19 (0.69, 6.89)	2.30 (0.68, 7.69)	4.48 (-2.26, 11.56)	
Baseline FVC percent predicted											0.0939
<=70%	118	1	0.8	96	8	8.3	0.0067	9.83 (1.25, 77.25)	>10 (1.31, 86.61)	7.49 (1.93, 14.78)	
>70%	104	5	4.8	124	8	6.5	0.5939	1.34 (0.45, 3.98)	1.37 (0.43, 4.31)	1.64 (-5.09, 8.02)	
Baseline HRCT pattern											0.3528
UIP-like	158	6	3.8	154	12	7.8	0.1303	2.05 (0.79, 5.33)	2.14 (0.78, 5.86)	3.99 (-1.36, 9.71)	
Other fibrotic patterns	64	0	0.0	66	4	6.1	0.0736	8.73 (0.48, >99)	NC (NC, NC)	6.06 (-0.69, 14.57)	
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	6	10.9					
Unclassifiable IIP	36	1	2.8	40	4	10.0					
HP	39	2	5.1	30	2	6.7					
Autoimmune ILD	71	2	2.8	70	1	1.4					
Other ILD	36	1	2.8	25	3	12.0					
Region											0.6969
Europe	40	2	5.0	53	10	18.9	0.0483	3.77 (0.87, 16.28)	4.42 (0.91, 21.44)	13.87 (-0.31, 26.87)	
Asia	106	3	2.8	107	5	4.7	0.4794	1.65 (0.40, 6.74)	1.68 (0.39, 7.23)	1.84 (-3.96, 7.94)	
Canada and USA	30	1	3.3	17	0	0.0	0.7252	0.57 (0.02, 13.36)	0.00 (NC, NC)	-3.33 (-16.67, 15.30)	
Rest of the World	46	0	0.0	43	1	2.3	0.4457	3.20 (0.13, 76.60)	NC (NC, NC)	2.33 (-5.62, 12.06)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Nervous system disorders
PT: Dizziness

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk ratio p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	9	4.1	220	10	4.5	0.7990	1.12 (0.46, 2.71)	1.13 (0.45, 2.83)	0.49 (-3.54, 4.58)	
Age											
<65 years	83	1	1.2	88	3	3.4					
>=65 years	139	8	5.8	132	7	5.3					
Sex											
Male	116	5	4.3	111	3	2.7					
Female	106	4	3.8	109	7	6.4					
Baseline FVC percent predicted											
<=70%	118	3	2.5	96	2	2.1					
>70%	104	6	5.8	124	8	6.5					
Baseline HRCT pattern											
UIP-like	158	7	4.4	154	10	6.5					
Other fibrotic patterns	64	2	3.1	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	1	1.8					
Unclassifiable IIP	36	5	13.9	40	2	5.0					
HP	39	2	5.1	30	1	3.3					
Autoimmune ILD	71	1	1.4	70	6	8.6					
Other ILD	36	1	2.8	25	0	0.0					
Region											
Europe	40	4	10.0	53	1	1.9					
Asia	106	3	2.8	107	5	4.7					
Canada and USA	30	1	3.3	17	0	0.0					
Rest of the World	46	1	2.2	43	4	9.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Nervous system disorders
PT: Headache

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	19	8.6	220	17	7.7	0.7494	0.90 (0.48, 1.69)	0.89 (0.45, 1.77)	-0.83 (-6.09, 4.42)	
Age											
<65 years	83	10	12.0	88	4	4.5					
>=65 years	139	9	6.5	132	13	9.8					
Sex											
Male	116	9	7.8	111	9	8.1					
Female	106	10	9.4	109	8	7.3					
Baseline FVC percent predicted											
<=70%	118	11	9.3	96	11	11.5					
>70%	104	8	7.7	124	6	4.8					
Baseline HRCT pattern											
UIP-like	158	12	7.6	154	12	7.8					
Other fibrotic patterns	64	7	10.9	66	5	7.6					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	1	1.8					
Unclassifiable IIP	36	4	11.1	40	1	2.5					
HP	39	4	10.3	30	5	16.7					
Autoimmune ILD	71	6	8.5	70	7	10.0					
Other ILD	36	3	8.3	25	3	12.0					
Region											
Europe	40	6	15.0	53	7	13.2					
Asia	106	8	7.5	107	5	4.7					
Canada and USA	30	2	6.7	17	1	5.9					
Rest of the World	46	3	6.5	43	4	9.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Psychiatric disorders
PT: Anxiety

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk ratio p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	22	9.9	220	27	12.3	0.4289	1.24 (0.73, 2.11)	1.27 (0.70, 2.31)	2.36 (-3.57, 8.33)	
Age											
<65 years	83	10	12.0	88	13	14.8					
>=65 years	139	12	8.6	132	14	10.6					
Sex											
Male	116	15	12.9	111	12	10.8					
Female	106	7	6.6	109	15	13.8					
Baseline FVC percent predicted											
<=70%	118	13	11.0	96	12	12.5					
>70%	104	9	8.7	124	15	12.1					
Baseline HRCT pattern											
UIP-like	158	17	10.8	154	18	11.7					
Other fibrotic patterns	64	5	7.8	66	9	13.6					
Underlying ILD diagnosis											
iNSIP	40	6	15.0	55	3	5.5					
Unclassifiable IIP	36	3	8.3	40	4	10.0					
HP	39	4	10.3	30	3	10.0					
Autoimmune ILD	71	7	9.9	70	14	20.0					
Other ILD	36	2	5.6	25	3	12.0					
Region											
Europe	40	7	17.5	53	7	13.2					
Asia	106	10	9.4	107	10	9.3					
Canada and USA	30	4	13.3	17	5	29.4					
Rest of the World	46	1	2.2	43	5	11.6					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Psychiatric disorders
PT: Depression

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	26	11.7	220	25	11.4	0.9088	0.97 (0.58, 1.63)	0.97 (0.54, 1.73)	-0.35 (-6.39, 5.71)	
Age											
<65 years	83	7	8.4	88	10	11.4					
>=65 years	139	19	13.7	132	15	11.4					
Sex											
Male	116	16	13.8	111	10	9.0					
Female	106	10	9.4	109	15	13.8					
Baseline FVC percent predicted											
<=70%	118	19	16.1	96	13	13.5					
>70%	104	7	6.7	124	12	9.7					
Baseline HRCT pattern											
UIP-like	158	17	10.8	154	15	9.7					
Other fibrotic patterns	64	9	14.1	66	10	15.2					
Underlying ILD diagnosis											
iNSIP	40	4	10.0	55	1	1.8					
Unclassifiable IIP	36	4	11.1	40	5	12.5					
HP	39	6	15.4	30	4	13.3					
Autoimmune ILD	71	9	12.7	70	10	14.3					
Other ILD	36	3	8.3	25	5	20.0					
Region											
Europe	40	6	15.0	53	8	15.1					
Asia	106	13	12.3	107	12	11.2					
Canada and USA	30	3	10.0	17	4	23.5					
Rest of the World	46	4	8.7	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	32	14.4	220	37	16.8	0.4863	1.17 (0.76, 1.80)	1.20 (0.72, 2.01)	2.40 (-4.40, 9.22)	
Age											
<65 years	83	11	13.3	88	16	18.2					
>=65 years	139	21	15.1	132	21	15.9					
Sex											
Male	116	14	12.1	111	20	18.0					
Female	106	18	17.0	109	17	15.6					
Baseline FVC percent predicted											
<=70%	118	16	13.6	96	20	20.8					
>70%	104	16	15.4	124	17	13.7					
Baseline HRCT pattern											
UIP-like	158	24	15.2	154	20	13.0					
Other fibrotic patterns	64	8	12.5	66	17	25.8					
Underlying ILD diagnosis											
iNSIP	40	4	10.0	55	7	12.7					
Unclassifiable IIP	36	5	13.9	40	6	15.0					
HP	39	10	25.6	30	7	23.3					
Autoimmune ILD	71	9	12.7	70	10	14.3					
Other ILD	36	4	11.1	25	7	28.0					
Region											
Europe	40	7	17.5	53	13	24.5					
Asia	106	13	12.3	107	13	12.1					
Canada and USA	30	3	10.0	17	8	47.1					
Rest of the World	46	9	19.6	43	3	7.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	14	6.3	220	21	9.5	0.2073	1.51 (0.79, 2.90)	1.57 (0.78, 3.17)	3.24 (-1.89, 8.49)	
Age											
<65 years	83	3	3.6	88	6	6.8					
>=65 years	139	11	7.9	132	15	11.4					
Sex											
Male	116	5	4.3	111	10	9.0					
Female	106	9	8.5	109	11	10.1					
Baseline FVC percent predicted											
<=70%	118	11	9.3	96	12	12.5					
>70%	104	3	2.9	124	9	7.3					
Baseline HRCT pattern											
UIP-like	158	7	4.4	154	14	9.1					
Other fibrotic patterns	64	7	10.9	66	7	10.6					
Underlying ILD diagnosis											
iNSIP	40	4	10.0	55	4	7.3					
Unclassifiable IIP	36	1	2.8	40	2	5.0					
HP	39	3	7.7	30	5	16.7					
Autoimmune ILD	71	4	5.6	70	5	7.1					
Other ILD	36	2	5.6	25	5	20.0					
Region											
Europe	40	4	10.0	53	10	18.9					
Asia	106	6	5.7	107	3	2.8					
Canada and USA	30	3	10.0	17	5	29.4					
Rest of the World	46	1	2.2	43	3	7.0					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Interstitial lung disease

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	11	5.0	220	6	2.7	0.2233	0.55 (0.21, 1.46)	0.54 (0.20, 1.48)	-2.23 (-6.21, 1.55)	
Age											
<65 years	83	5	6.0	88	0	0.0					
>=65 years	139	6	4.3	132	6	4.5					
Sex											
Male	116	7	6.0	111	1	0.9					
Female	106	4	3.8	109	5	4.6					
Baseline FVC percent predicted											
<=70%	118	7	5.9	96	2	2.1					
>70%	104	4	3.8	124	4	3.2					
Baseline HRCT pattern											
UIP-like	158	9	5.7	154	5	3.2					
Other fibrotic patterns	64	2	3.1	66	1	1.5					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	0	0.0					
Unclassifiable IIP	36	2	5.6	40	3	7.5					
HP	39	4	10.3	30	1	3.3					
Autoimmune ILD	71	1	1.4	70	2	2.9					
Other ILD	36	2	5.6	25	0	0.0					
Region											
Europe	40	2	5.0	53	1	1.9					
Asia	106	6	5.7	107	3	2.8					
Canada and USA	30	1	3.3	17	1	5.9					
Rest of the World	46	2	4.3	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 1 Proportion of patients with frequent AEs by SOC and PT (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Vascular disorders
PT: Hypertension

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	10	4.5	220	9	4.1	0.8303	0.91 (0.38, 2.19)	0.90 (0.36, 2.27)	-0.41 (-4.48, 3.64)	
Age											
<65 years	83	4	4.8	88	2	2.3					
>=65 years	139	6	4.3	132	7	5.3					
Sex											
Male	116	6	5.2	111	1	0.9					
Female	106	4	3.8	109	8	7.3					
Baseline FVC percent predicted											
<=70%	118	8	6.8	96	5	5.2					
>70%	104	2	1.9	124	4	3.2					
Baseline HRCT pattern											
UIP-like	158	7	4.4	154	6	3.9					
Other fibrotic patterns	64	3	4.7	66	3	4.5					
Underlying ILD diagnosis											
iNSIP	40	3	7.5	55	1	1.8					
Unclassifiable IIP	36	0	0.0	40	2	5.0					
HP	39	3	7.7	30	1	3.3					
Autoimmune ILD	71	3	4.2	70	3	4.3					
Other ILD	36	1	2.8	25	2	8.0					
Region											
Europe	40	1	2.5	53	4	7.5					
Asia	106	4	3.8	107	2	1.9					
Canada and USA	30	1	3.3	17	1	5.9					
Rest of the World	46	4	8.7	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 2 Proportion of patients with frequent serious AEs by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	24	10.8	220	11	5.0	0.0237	0.46 (0.23, 0.92)	0.43 (0.21, 0.91)	-5.81 (-11.06, -0.74)	
Age											0.5633
<65 years	83	10	12.0	88	6	6.8	0.2405	0.57 (0.22, 1.49)	0.53 (0.19, 1.54)	-5.23 (-14.69, 3.81)	
>=65 years	139	14	10.1	132	5	3.8	0.0429	0.38 (0.14, 1.02)	0.35 (0.12, 1.01)	-6.28 (-12.78, -0.07)	
Sex											0.5420
Male	116	16	13.8	111	6	5.4	0.0327	0.39 (0.16, 0.97)	0.36 (0.13, 0.95)	-8.39 (-16.38, -0.58)	
Female	106	8	7.5	109	5	4.6	0.3626	0.61 (0.21, 1.80)	0.59 (0.19, 1.86)	-2.96 (-10.10, 3.82)	
Baseline FVC percent predicted											0.7672
<=70%	118	20	16.9	96	9	9.4	0.1074	0.55 (0.26, 1.16)	0.51 (0.22, 1.17)	-7.57 (-16.50, 1.84)	
>70%	104	4	3.8	124	2	1.6	0.2941	0.42 (0.08, 2.24)	0.41 (0.07, 2.28)	-2.23 (-7.98, 2.47)	
Baseline HRCT pattern											0.2176
UIP-like	158	20	12.7	154	7	4.5	0.0108	0.36 (0.16, 0.82)	0.33 (0.13, 0.80)	-8.11 (-14.63, -1.85)	
Other fibrotic patterns	64	4	6.3	66	4	6.1	0.9642	0.97 (0.25, 3.71)	0.97 (0.23, 4.05)	-0.19 (-9.68, 9.13)	
Underlying ILD diagnosis											0.1875
iNSIP	40	3	7.5	55	3	5.5	0.6857	0.73 (0.15, 3.42)	0.71 (0.14, 3.72)	-2.05 (-14.92, 8.56)	
Unclassifiable IIP	36	1	2.8	40	3	7.5	0.3573	2.70 (0.29, 24.81)	2.84 (0.28, 28.59)	4.72 (-7.69, 17.30)	
HP	39	6	15.4	30	0	0.0	0.0402	0.10 (0.01, 1.70)	0.00 (NC, NC)	-15.38 (-29.73, -1.42)	
Autoimmune ILD	71	8	11.3	70	1	1.4	0.0169	0.13 (0.02, 0.99)	0.11 (0.01, 0.94)	-9.84 (-19.33, -1.56)	
Other ILD	36	6	16.7	25	4	16.0	0.9449	0.96 (0.30, 3.06)	0.95 (0.24, 3.80)	-0.67 (-18.66, 19.96)	
Region											0.7460
Europe	40	4	10.0	53	4	7.5	0.6762	0.75 (0.20, 2.84)	0.73 (0.17, 3.14)	-2.45 (-16.28, 9.50)	
Asia	106	14	13.2	107	7	6.5	0.1028	0.50 (0.21, 1.18)	0.46 (0.18, 1.19)	-6.67 (-15.10, 1.53)	
Canada and USA	30	3	10.0	17	0	0.0	0.2941	0.25 (0.01, 4.50)	0.00 (NC, NC)	-10.00 (-25.62, 9.56)	
Rest of the World	46	3	6.5	43	0	0.0	0.1423	0.15 (0.01, 2.87)	0.00 (NC, NC)	-6.52 (-17.50, 2.73)	

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 2 Proportion of patients with frequent serious AEs by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	21	9.5	220	20	9.1	0.8938	0.96 (0.54, 1.72)	0.96 (0.50, 1.82)	-0.37 (-5.91, 5.17)	
Age											
<65 years	83	3	3.6	88	3	3.4					
>=65 years	139	18	12.9	132	17	12.9					
Sex											
Male	116	11	9.5	111	9	8.1					
Female	106	10	9.4	109	11	10.1					
Baseline FVC percent predicted											
<=70%	118	14	11.9	96	13	13.5					
>70%	104	7	6.7	124	7	5.6					
Baseline HRCT pattern											
UIP-like	158	14	8.9	154	13	8.4					
Other fibrotic patterns	64	7	10.9	66	7	10.6					
Underlying ILD diagnosis											
iNSIP	40	3	7.5	55	8	14.5					
Unclassifiable IIP	36	2	5.6	40	3	7.5					
HP	39	2	5.1	30	1	3.3					
Autoimmune ILD	71	9	12.7	70	6	8.6					
Other ILD	36	5	13.9	25	2	8.0					
Region											
Europe	40	2	5.0	53	6	11.3					
Asia	106	14	13.2	107	12	11.2					
Canada and USA	30	2	6.7	17	1	5.9					
Rest of the World	46	3	6.5	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk ratio p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff.	(95% CI)	Interaction p-value**
Overall	222	23	10.4	220	12	5.5	0.0562	0.53 (0.27, 1.03)	0.50 (0.24, 1.03)	-4.91	(-10.15, 0.19)	
Age												
<65 years	83	10	12.0	88	6	6.8						
>=65 years	139	13	9.4	132	6	4.5						
Sex												
Male	116	16	13.8	111	7	6.3						
Female	106	7	6.6	109	5	4.6						
Baseline FVC percent predicted												
<=70%	118	19	16.1	96	9	9.4						
>70%	104	4	3.8	124	3	2.4						
Baseline HRCT pattern												
UIP-like	158	20	12.7	154	8	5.2						
Other fibrotic patterns	64	3	4.7	66	4	6.1						
Underlying ILD diagnosis												
iNSIP	40	2	5.0	55	3	5.5						
Unclassifiable IIP	36	1	2.8	40	3	7.5						
HP	39	6	15.4	30	0	0.0						
Autoimmune ILD	71	8	11.3	70	2	2.9						
Other ILD	36	6	16.7	25	4	16.0						
Region												
Europe	40	3	7.5	53	4	7.5						
Asia	106	14	13.2	107	7	6.5						
Canada and USA	30	3	10.0	17	0	0.0						
Rest of the World	46	3	6.5	43	1	2.3						

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table I.2.2.2.1.5: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC and PT (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Infections and infestations
PT: Pneumonia

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo				
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	20	9.0	220	18	8.2	0.7564	0.91 (0.49, 1.67)	0.90 (0.46, 1.75)	-0.83 (-6.20, 4.54)	
Age											
<65 years	83	2	2.4	88	3	3.4					
>=65 years	139	18	12.9	132	15	11.4					
Sex											
Male	116	10	8.6	111	7	6.3					
Female	106	10	9.4	109	11	10.1					
Baseline FVC percent predicted											
<=70%	118	12	10.2	96	13	13.5					
>70%	104	8	7.7	124	5	4.0					
Baseline HRCT pattern											
UIP-like	158	14	8.9	154	11	7.1					
Other fibrotic patterns	64	6	9.4	66	7	10.6					
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	8	14.5					
Unclassifiable IIP	36	2	5.6	40	2	5.0					
HP	39	2	5.1	30	1	3.3					
Autoimmune ILD	71	8	11.3	70	5	7.1					
Other ILD	36	6	16.7	25	2	8.0					
Region											
Europe	40	1	2.5	53	5	9.4					
Asia	106	14	13.2	107	11	10.3					
Canada and USA	30	2	6.7	17	1	5.9					
Rest of the World	46	3	6.5	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Subgroup analyses are only performed in case of a significant p-value for the overall comparison (at 5% level).

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I.2.2.3 Further analysis

I.2.2.3.1 Further safety analysis

Table I.2.2.3.1: 1 Proportion of patients with specific AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)
PT: Abdominal pain

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	5	2.3	220	6	2.7	0.7486	1.21 (0.38, 3.91)	1.22 (0.37, 4.05)	0.48 (-2.79, 3.83)	
Age											
<65 years	83	1	1.2	88	1	1.1					
>=65 years	139	4	2.9	132	5	3.8					
Sex											
Male	116	2	1.7	111	3	2.7					
Female	106	3	2.8	109	3	2.8					
Baseline FVC percent predicted											
<=70%	118	2	1.7	96	3	3.1					
>70%	104	3	2.9	124	3	2.4					
Baseline HRCT pattern											0.5487
UIP-like	158	5	3.2	154	5	3.2	0.9671	1.03 (0.30, 3.47)	1.03 (0.29, 3.62)	0.08 (-4.35, 4.59)	
Other fibrotic patterns	64	0	0.0	66	1	1.5	0.4896	2.91 (0.12, 70.15)	NC (NC, NC)	1.52 (-4.28, 8.10)	
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	1	1.8					
Unclassifiable IIP	36	2	5.6	40	2	5.0					
HP	39	1	2.6	30	0	0.0					
Autoimmune ILD	71	1	1.4	70	2	2.9					
Other ILD	36	1	2.8	25	1	4.0					
Region											
Europe	40	0	0.0	53	2	3.8					
Asia	106	0	0.0	107	2	1.9					
Canada and USA	30	2	6.7	17	0	0.0					
Rest of the World	46	3	6.5	43	2	4.7					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 1 Proportion of patients with specific AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)
PT: Abdominal pain upper

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	6	2.7	220	6	2.7	0.9873	1.01 (0.33, 3.08)	1.01 (0.32, 3.18)	0.02 (-3.38, 3.45)	
Age											
<65 years	83	3	3.6	88	3	3.4					
>=65 years	139	3	2.2	132	3	2.3					
Sex											
Male	116	3	2.6	111	5	4.5					
Female	106	3	2.8	109	1	0.9					
Baseline FVC percent predicted											
<=70%	118	5	4.2	96	3	3.1					
>70%	104	1	1.0	124	3	2.4					
Baseline HRCT pattern											
UIP-like	158	3	1.9	154	4	2.6					
Other fibrotic patterns	64	3	4.7	66	2	3.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	3	5.5					
Unclassifiable IIP	36	2	5.6	40	2	5.0					
HP	39	2	5.1	30	0	0.0					
Autoimmune ILD	71	1	1.4	70	1	1.4					
Other ILD	36	1	2.8	25	0	0.0					
Region											
Europe	40	1	2.5	53	1	1.9					
Asia	106	4	3.8	107	5	4.7					
Canada and USA	30	1	3.3	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 1 Proportion of patients with specific AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)
PT: Decreased appetite

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	15	6.8	220	15	6.8	0.9795	1.01 (0.51, 2.01)	1.01 (0.48, 2.12)	0.06 (-4.81, 4.95)	
Age											0.2433
<65 years	83	2	2.4	88	5	5.7	0.2805	2.36 (0.47, 11.82)	2.44 (0.46, 12.94)	3.27 (-3.50, 10.43)	
>=65 years	139	13	9.4	132	10	7.6	0.5999	0.81 (0.37, 1.78)	0.79 (0.34, 1.88)	-1.78 (-8.67, 5.17)	
Sex											0.9236
Male	116	5	4.3	111	5	4.5	0.9432	1.05 (0.31, 3.51)	1.05 (0.29, 3.72)	0.19 (-5.77, 6.32)	
Female	106	10	9.4	109	10	9.2	0.9478	0.97 (0.42, 2.24)	0.97 (0.39, 2.43)	-0.26 (-8.44, 7.83)	
Baseline FVC percent predicted											0.2795
<=70%	118	12	10.2	96	8	8.3	0.6463	0.82 (0.35, 1.92)	0.80 (0.31, 2.05)	-1.84 (-9.72, 6.58)	
>70%	104	3	2.9	124	7	5.6	0.3107	1.96 (0.52, 7.38)	2.01 (0.51, 7.99)	2.76 (-3.23, 8.63)	
Baseline HRCT pattern											0.9437
UIP-like	158	11	7.0	154	11	7.1	0.9503	1.03 (0.46, 2.30)	1.03 (0.43, 2.45)	0.18 (-5.77, 6.19)	
Other fibrotic patterns	64	4	6.3	66	4	6.1	0.9642	0.97 (0.25, 3.71)	0.97 (0.23, 4.05)	-0.19 (-9.68, 9.13)	
Underlying ILD diagnosis											
iNSIP	40	2	5.0	55	4	7.3					
Unclassifiable IIP	36	4	11.1	40	2	5.0					
HP	39	3	7.7	30	1	3.3					
Autoimmune ILD	71	4	5.6	70	5	7.1					
Other ILD	36	2	5.6	25	3	12.0					
Region											0.3518
Europe	40	1	2.5	53	2	3.8	0.7307	1.51 (0.14, 16.07)	1.53 (0.13, 17.48)	1.27 (-9.46, 10.49)	
Asia	106	10	9.4	107	8	7.5	0.6076	0.79 (0.33, 1.93)	0.78 (0.29, 2.05)	-1.96 (-9.91, 5.87)	
Canada and USA	30	4	13.3	17	1	5.9	0.4260	0.44 (0.05, 3.64)	0.41 (0.04, 3.96)	-7.45 (-24.50, 15.12)	
Rest of the World	46	0	0.0	43	4	9.3	0.0552	9.61 (0.53, >99)	NC (NC, NC)	9.30 (-0.24, 21.60)	

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 1 Proportion of patients with specific AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)

PT: Diarrhoea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	36	16.2	220	59	26.8	0.0067	1.65 (1.14, 2.39)	1.89 (1.19, 3.01)	10.60 (2.94, 18.14)	
Age											0.0173
<65 years	83	16	19.3	88	15	17.0	0.7050	0.88 (0.47, 1.67)	0.86 (0.40, 1.87)	-2.23 (-13.93, 9.35)	
>=65 years	139	20	14.4	132	44	33.3	0.0002	2.32 (1.45, 3.71)	2.98 (1.64, 5.40)	18.94 (8.85, 28.67)	
Sex											0.5054
Male	116	20	17.2	111	28	25.2	0.1409	1.46 (0.88, 2.44)	1.62 (0.85, 3.09)	7.98 (-2.67, 18.53)	
Female	106	16	15.1	109	31	28.4	0.0179	1.88 (1.10, 3.24)	2.24 (1.14, 4.39)	13.35 (2.28, 24.01)	
Baseline FVC percent predicted											0.2967
<=70%	118	24	20.3	96	28	29.2	0.1343	1.43 (0.89, 2.30)	1.61 (0.86, 3.02)	8.83 (-2.69, 20.42)	
>70%	104	12	11.5	124	31	25.0	0.0097	2.17 (1.17, 4.00)	2.56 (1.24, 5.28)	13.46 (3.30, 23.05)	
Baseline HRCT pattern											0.3434
UIP-like	158	25	15.8	154	45	29.2	0.0046	1.85 (1.19, 2.85)	2.20 (1.27, 3.81)	13.40 (4.14, 22.44)	
Other fibrotic patterns	64	11	17.2	66	14	21.2	0.5605	1.23 (0.61, 2.51)	1.30 (0.54, 3.12)	4.02 (-9.68, 17.48)	
Underlying ILD diagnosis											0.6254
iNSIP	40	4	10.0	55	13	23.6	0.0869	2.36 (0.83, 6.71)	2.79 (0.83, 9.30)	13.64 (-2.37, 27.71)	
Unclassifiable IIP	36	5	13.9	40	11	27.5	0.1461	1.98 (0.76, 5.15)	2.35 (0.73, 7.59)	13.61 (-5.04, 30.82)	
HP	39	8	20.5	30	10	33.3	0.2293	1.63 (0.73, 3.61)	1.94 (0.65, 5.74)	12.82 (-7.78, 33.18)	
Autoimmune ILD	71	14	19.7	70	16	22.9	0.6489	1.16 (0.61, 2.19)	1.21 (0.54, 2.71)	3.14 (-10.39, 16.58)	
Other ILD	36	5	13.9	25	9	36.0	0.0434	2.59 (0.99, 6.82)	3.49 (1.00, 12.16)	22.11 (0.52, 43.10)	
Region											0.4349
Europe	40	5	12.5	53	16	30.2	0.0434	2.42 (0.97, 6.04)	3.03 (1.00, 9.14)	17.69 (0.39, 32.78)	
Asia	106	18	17.0	107	22	20.6	0.5036	1.21 (0.69, 2.12)	1.27 (0.63, 2.52)	3.58 (-6.98, 14.05)	
Canada and USA	30	7	23.3	17	7	41.2	0.1987	1.76 (0.75, 4.18)	2.30 (0.64, 8.31)	17.84 (-8.47, 43.41)	
Rest of the World	46	6	13.0	43	14	32.6	0.0275	2.50 (1.05, 5.91)	3.22 (1.10, 9.38)	19.51 (2.05, 35.97)	

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 1 Proportion of patients with specific AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)
PT: Hepatic function abnormal

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	4	1.8	220	4	1.8	0.9897	1.01 (0.26, 3.98)	1.01 (0.25, 4.09)	0.02 (-2.94, 2.99)	
Age											
<65 years	83	1	1.2	88	2	2.3					
>=65 years	139	3	2.2	132	2	1.5					
Sex											
Male	116	3	2.6	111	4	3.6					
Female	106	1	0.9	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	3	2.5	96	1	1.0					
>70%	104	1	1.0	124	3	2.4					
Baseline HRCT pattern											
UIP-like	158	3	1.9	154	4	2.6					
Other fibrotic patterns	64	1	1.6	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	1	2.6	30	0	0.0					
Autoimmune ILD	71	2	2.8	70	2	2.9					
Other ILD	36	1	2.8	25	2	8.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	4	3.8	107	4	3.7					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 1 Proportion of patients with specific AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)

PT: Nausea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	9	4.1	220	15	6.8	0.1998	1.68 (0.75, 3.76)	1.73 (0.74, 4.04)	2.76 (-1.60, 7.31)	
Age											0.6324
<65 years	83	3	3.6	88	4	4.5	0.7588	1.26 (0.29, 5.45)	1.27 (0.28, 5.85)	0.93 (-6.12, 7.91)	
>=65 years	139	6	4.3	132	11	8.3	0.1729	1.93 (0.73, 5.07)	2.02 (0.72, 5.61)	4.02 (-1.98, 10.43)	
Sex											0.1189
Male	116	2	1.7	111	8	7.2	0.0442	4.18 (0.91, 19.26)	4.43 (0.92, 21.33)	5.48 (-0.10, 11.98)	
Female	106	7	6.6	109	7	6.4	0.9569	0.97 (0.35, 2.68)	0.97 (0.33, 2.87)	-0.18 (-7.38, 6.91)	
Baseline FVC percent predicted											0.8357
<=70%	118	6	5.1	96	8	8.3	0.3391	1.64 (0.59, 4.56)	1.70 (0.57, 5.07)	3.25 (-3.64, 11.00)	
>70%	104	3	2.9	124	7	5.6	0.3107	1.96 (0.52, 7.38)	2.01 (0.51, 7.99)	2.76 (-3.23, 8.63)	
Baseline HRCT pattern											0.0663
UIP-like	158	4	2.5	154	12	7.8	0.0352	3.08 (1.01, 9.34)	3.25 (1.03, 10.32)	5.26 (0.24, 10.81)	
Other fibrotic patterns	64	5	7.8	66	3	4.5	0.4384	0.58 (0.14, 2.33)	0.56 (0.13, 2.46)	-3.27 (-12.95, 5.87)	
Underlying ILD diagnosis											
iNSIP	40	1	2.5	55	1	1.8					
Unclassifiable IIP	36	3	8.3	40	3	7.5					
HP	39	4	10.3	30	3	10.0					
Autoimmune ILD	71	0	0.0	70	5	7.1					
Other ILD	36	1	2.8	25	3	12.0					
Region											
Europe	40	3	7.5	53	3	5.7					
Asia	106	1	0.9	107	5	4.7					
Canada and USA	30	3	10.0	17	2	11.8					
Rest of the World	46	2	4.3	43	5	11.6					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 1 Proportion of patients with specific AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)

PT: Vomiting

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	5	2.3	220	9	4.1	0.2698	1.82 (0.62, 5.33)	1.85 (0.61, 5.61)	1.84 (-1.65, 5.57)	
Age											0.0611
<65 years	83	3	3.6	88	1	1.1	0.2839	0.31 (0.03, 2.96)	0.31 (0.03, 3.01)	-2.48 (-9.03, 3.08)	
>=65 years	139	2	1.4	132	8	6.1	0.0437	4.21 (0.91, 19.47)	4.42 (0.92, 21.21)	4.62 (-0.08, 10.16)	
Sex											
Male	116	1	0.9	111	4	3.6					
Female	106	4	3.8	109	5	4.6					
Baseline FVC percent predicted											
<=70%	118	2	1.7	96	5	5.2					
>70%	104	3	2.9	124	4	3.2					
Baseline HRCT pattern											0.2904
UIP-like	158	5	3.2	154	6	3.9	0.7261	1.23 (0.38, 3.95)	1.24 (0.37, 4.15)	0.73 (-3.81, 5.43)	
Other fibrotic patterns	64	0	0.0	66	3	4.5	0.1355	6.79 (0.36, >99)	NC (NC, NC)	4.55 (-1.86, 12.53)	
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	1	1.8					
Unclassifiable IIP	36	3	8.3	40	3	7.5					
HP	39	0	0.0	30	1	3.3					
Autoimmune ILD	71	2	2.8	70	4	5.7					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	1	2.5	53	1	1.9					
Asia	106	2	1.9	107	7	6.5					
Canada and USA	30	1	3.3	17	0	0.0					
Rest of the World	46	1	2.2	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 1 Proportion of patients with specific AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Gastrointestinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	80	36.0	220	99	45.0	0.0549	1.25 (0.99, 1.57)	1.45 (0.99, 2.13)	8.96 (-0.18, 17.91)	
Age											0.0172
<65 years	83	33	39.8	88	30	34.1	0.4425	0.86 (0.58, 1.27)	0.78 (0.42, 1.46)	-5.67 (-19.73, 8.64)	
>=65 years	139	47	33.8	132	69	52.3	0.0021	1.55 (1.16, 2.05)	2.14 (1.31, 3.50)	18.46 (6.67, 29.56)	
Sex											0.7609
Male	116	38	32.8	111	47	42.3	0.1359	1.29 (0.92, 1.81)	1.51 (0.88, 2.59)	9.58 (-2.97, 21.76)	
Female	106	42	39.6	109	52	47.7	0.2322	1.20 (0.89, 1.64)	1.39 (0.81, 2.39)	8.08 (-5.11, 20.88)	
Baseline FVC percent predicted											0.2437
<=70%	118	47	39.8	96	42	43.8	0.5629	1.10 (0.80, 1.51)	1.17 (0.68, 2.03)	3.92 (-9.17, 16.95)	
>70%	104	33	31.7	124	57	46.0	0.0285	1.45 (1.03, 2.04)	1.83 (1.06, 3.15)	14.24 (1.51, 26.21)	
Baseline HRCT pattern											0.1123
UIP-like	158	54	34.2	154	74	48.1	0.0127	1.41 (1.07, 1.84)	1.78 (1.13, 2.81)	13.87 (2.96, 24.35)	
Other fibrotic patterns	64	26	40.6	66	25	37.9	0.7485	0.93 (0.61, 1.43)	0.89 (0.44, 1.80)	-2.75 (-19.02, 13.69)	
Underlying ILD diagnosis											0.9525
iNSIP	40	10	25.0	55	18	32.7	0.4147	1.31 (0.68, 2.53)	1.46 (0.59, 3.63)	7.73 (-10.98, 24.77)	
Unclassifiable IIP	36	14	38.9	40	21	52.5	0.2346	1.35 (0.82, 2.24)	1.74 (0.70, 4.33)	13.61 (-8.50, 33.89)	
HP	39	16	41.0	30	13	43.3	0.8473	1.06 (0.61, 1.84)	1.10 (0.42, 2.88)	2.31 (-19.98, 24.66)	
Autoimmune ILD	71	26	36.6	70	33	47.1	0.2053	1.29 (0.87, 1.91)	1.54 (0.79, 3.03)	10.52 (-5.64, 25.95)	
Other ILD	36	14	38.9	25	14	56.0	0.1872	1.44 (0.84, 2.46)	2.00 (0.71, 5.63)	17.11 (-7.84, 39.46)	
Region											0.8776
Europe	40	13	32.5	53	24	45.3	0.2124	1.39 (0.82, 2.38)	1.72 (0.73, 4.04)	12.78 (-7.19, 30.95)	
Asia	106	40	37.7	107	48	44.9	0.2911	1.19 (0.86, 1.64)	1.34 (0.78, 2.32)	7.12 (-6.02, 19.92)	
Canada and USA	30	14	46.7	17	9	52.9	0.6793	1.13 (0.63, 2.04)	1.29 (0.39, 4.24)	6.27 (-21.63, 32.86)	
Rest of the World	46	13	28.3	43	18	41.9	0.1784	1.48 (0.83, 2.64)	1.83 (0.76, 4.42)	13.60 (-6.04, 32.01)	

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 1 Proportion of patients with specific AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Hepatobiliary disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	6	2.7	220	9	4.1	0.4203	1.51 (0.55, 4.18)	1.54 (0.54, 4.39)	1.39 (-2.23, 5.18)	
Age											0.3148
<65 years	83	1	1.2	88	4	4.5	0.1950	3.77 (0.43, 33.07)	3.90 (0.43, 35.68)	3.34 (-2.64, 9.98)	
>=65 years	139	5	3.6	132	5	3.8	0.9336	1.05 (0.31, 3.55)	1.06 (0.30, 3.73)	0.19 (-4.84, 5.39)	
Sex											0.3008
Male	116	5	4.3	111	5	4.5	0.9432	1.05 (0.31, 3.51)	1.05 (0.29, 3.72)	0.19 (-5.77, 6.32)	
Female	106	1	0.9	109	4	3.7	0.1848	3.89 (0.44, 34.24)	4.00 (0.44, 36.39)	2.73 (-2.04, 8.17)	
Baseline FVC percent predicted											
<=70%	118	3	2.5	96	3	3.1					
>70%	104	3	2.9	124	6	4.8					
Baseline HRCT pattern											0.8229
UIP-like	158	5	3.2	154	7	4.5	0.5260	1.44 (0.47, 4.43)	1.46 (0.45, 4.69)	1.38 (-3.27, 6.27)	
Other fibrotic patterns	64	1	1.6	66	2	3.0	0.5774	1.94 (0.18, 20.87)	1.97 (0.17, 22.26)	1.47 (-5.65, 8.94)	
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	1	1.8					
Unclassifiable IIP	36	1	2.8	40	2	5.0					
HP	39	1	2.6	30	0	0.0					
Autoimmune ILD	71	3	4.2	70	3	4.3					
Other ILD	36	1	2.8	25	3	12.0					
Region											0.9984
Europe	40	1	2.5	53	2	3.8	0.7307	1.51 (0.14, 16.07)	1.53 (0.13, 17.48)	1.27 (-9.46, 10.49)	
Asia	106	5	4.7	107	7	6.5	0.5635	1.39 (0.45, 4.23)	1.41 (0.43, 4.60)	1.83 (-4.91, 8.72)	
Canada and USA	30	0	0.0	17	0	0.0	0.7810	1.72 (0.04, 83.12)	NC (NC, NC)	0.00 (NC, NC)	
Rest of the World	46	0	0.0	43	0	0.0	0.9735	1.07 (0.02, 52.68)	NC (NC, NC)	0.00 (NC, NC)	

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)
PT: Abdominal pain

Subgroup / Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)
PT: Abdominal pain upper

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)
PT: Decreased appetite

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)
PT: Diarrhoea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)
PT: Hepatic function abnormal

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)

PT: Nausea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)

PT: Vomiting

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Gastrointestinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	5	2.3	220	6	2.7	0.7486	1.21 (0.38, 3.91)	1.22 (0.37, 4.05)	0.48 (-2.79, 3.83)	
Age											
<65 years	83	2	2.4	88	1	1.1					
>=65 years	139	3	2.2	132	5	3.8					
Sex											
Male	116	3	2.6	111	2	1.8					
Female	106	2	1.9	109	4	3.7					
Baseline FVC percent predicted											
<=70%	118	3	2.5	96	2	2.1					
>70%	104	2	1.9	124	4	3.2					
Baseline HRCT pattern											
UIP-like	158	3	1.9	154	4	2.6					
Other fibrotic patterns	64	2	3.1	66	2	3.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	1	1.8					
Unclassifiable IIP	36	0	0.0	40	2	5.0					
HP	39	1	2.6	30	0	0.0					
Autoimmune ILD	71	3	4.2	70	3	4.3					
Other ILD	36	1	2.8	25	0	0.0					
Region											
Europe	40	2	5.0	53	0	0.0					
Asia	106	2	1.9	107	5	4.7					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	1	2.2	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 2 Proportion of patients with specific serious AEs over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Hepatobiliary disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	2	0.9	220	0	0.0	0.2498	0.20 (0.01, 4.18)	0.00 (NC, NC)	-0.90 (-3.22, 0.94)	
Age											
<65 years	83	1	1.2	88	0	0.0					
>=65 years	139	1	0.7	132	0	0.0					
Sex											
Male	116	1	0.9	111	0	0.0					
Female	106	1	0.9	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	1	0.8	96	0	0.0					
>70%	104	1	1.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	1	0.6	154	0	0.0					
Other fibrotic patterns	64	1	1.6	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	1	2.8	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	1	2.8	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	2	1.9	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial (DBL1) - 18mg - TS (non-AF background)
PT: Abdominal pain

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial (DBL1) - 18mg - TS (non-AF background)
PT: Abdominal pain upper

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial (DBL1) - 18mg - TS (non-AF background)
PT: Decreased appetite

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial (DBL1) - 18mg - TS (non-AF background)
PT: Diarrhoea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial (DBL1) - 18mg - TS (non-AF background)
PT: Hepatic function abnormal

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial (DBL1) - 18mg - TS (non-AF background)

PT: Nausea

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial (DBL1) - 18mg - TS (non-AF background)
PT: Vomiting

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00 (NC, NC)	
Age											
<65 years	83	0	0.0	88	0	0.0					
>=65 years	139	0	0.0	132	0	0.0					
Sex											
Male	116	0	0.0	111	0	0.0					
Female	106	0	0.0	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	0	0.0	96	0	0.0					
>70%	104	0	0.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	0	0.0	154	0	0.0					
Other fibrotic patterns	64	0	0.0	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	0	0.0	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	0	0.0	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	0	0.0	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Gastrointestinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	3	1.4	220	7	3.2	0.1957	2.35 (0.62, 8.99)	2.40 (0.61, 9.40)	1.83 (-1.19, 5.19)	
Age											
<65 years	83	1	1.2	88	1	1.1					
>=65 years	139	2	1.4	132	6	4.5					
Sex											
Male	116	2	1.7	111	3	2.7					
Female	106	1	0.9	109	4	3.7					
Baseline FVC percent predicted											
<=70%	118	2	1.7	96	2	2.1					
>70%	104	1	1.0	124	5	4.0					
Baseline HRCT pattern											
UIP-like	158	3	1.9	154	5	3.2					
Other fibrotic patterns	64	0	0.0	66	2	3.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	1	1.8					
Unclassifiable IIP	36	0	0.0	40	2	5.0					
HP	39	1	2.6	30	0	0.0					
Autoimmune ILD	71	2	2.8	70	3	4.3					
Other ILD	36	0	0.0	25	1	4.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	2	1.9	107	5	4.7					
Canada and USA	30	0	0.0	17	1	5.9					
Rest of the World	46	1	2.2	43	1	2.3					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 3 Proportion of patients with specific AEs with CTCAE grade >=3 over the whole trial (DBL1) - 18mg - TS (non-AF background)
SOC: Hepatobiliary disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	2	0.9	220	0	0.0	0.2498	0.20 (0.01, 4.18)	0.00 (NC, NC)	-0.90 (-3.22, 0.94)	
Age											
<65 years	83	1	1.2	88	0	0.0					
>=65 years	139	1	0.7	132	0	0.0					
Sex											
Male	116	1	0.9	111	0	0.0					
Female	106	1	0.9	109	0	0.0					
Baseline FVC percent predicted											
<=70%	118	1	0.8	96	0	0.0					
>70%	104	1	1.0	124	0	0.0					
Baseline HRCT pattern											
UIP-like	158	1	0.6	154	0	0.0					
Other fibrotic patterns	64	1	1.6	66	0	0.0					
Underlying ILD diagnosis											
iNSIP	40	0	0.0	55	0	0.0					
Unclassifiable IIP	36	1	2.8	40	0	0.0					
HP	39	0	0.0	30	0	0.0					
Autoimmune ILD	71	0	0.0	70	0	0.0					
Other ILD	36	1	2.8	25	0	0.0					
Region											
Europe	40	0	0.0	53	0	0.0					
Asia	106	2	1.9	107	0	0.0					
Canada and USA	30	0	0.0	17	0	0.0					
Rest of the World	46	0	0.0	43	0	0.0					

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).

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Table I.2.2.3.1: 4 Proportion of patients with Diarrhoea with CTCAE grade <3 over the whole trial (DBL1) - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	222	36	16.2	220	59	26.8	0.0067	1.65 (1.14, 2.39)	1.89 (1.19, 3.01)	10.60 (2.94, 18.14)	
Age											0.0173
<65 years	83	16	19.3	88	15	17.0	0.7050	0.88 (0.47, 1.67)	0.86 (0.40, 1.87)	-2.23 (-13.93, 9.35)	
>=65 years	139	20	14.4	132	44	33.3	0.0002	2.32 (1.45, 3.71)	2.98 (1.64, 5.40)	18.94 (8.85, 28.67)	
Sex											0.5054
Male	116	20	17.2	111	28	25.2	0.1409	1.46 (0.88, 2.44)	1.62 (0.85, 3.09)	7.98 (-2.67, 18.53)	
Female	106	16	15.1	109	31	28.4	0.0179	1.88 (1.10, 3.24)	2.24 (1.14, 4.39)	13.35 (2.28, 24.01)	
Baseline FVC percent predicted											0.2967
<=70%	118	24	20.3	96	28	29.2	0.1343	1.43 (0.89, 2.30)	1.61 (0.86, 3.02)	8.83 (-2.69, 20.42)	
>70%	104	12	11.5	124	31	25.0	0.0097	2.17 (1.17, 4.00)	2.56 (1.24, 5.28)	13.46 (3.30, 23.05)	
Baseline HRCT pattern											0.3434
UIP-like	158	25	15.8	154	45	29.2	0.0046	1.85 (1.19, 2.85)	2.20 (1.27, 3.81)	13.40 (4.14, 22.44)	
Other fibrotic patterns	64	11	17.2	66	14	21.2	0.5605	1.23 (0.61, 2.51)	1.30 (0.54, 3.12)	4.02 (-9.68, 17.48)	
Underlying ILD diagnosis											0.6254
iNSIP	40	4	10.0	55	13	23.6	0.0869	2.36 (0.83, 6.71)	2.79 (0.83, 9.30)	13.64 (-2.37, 27.71)	
Unclassifiable IIP	36	5	13.9	40	11	27.5	0.1461	1.98 (0.76, 5.15)	2.35 (0.73, 7.59)	13.61 (-5.04, 30.82)	
HP	39	8	20.5	30	10	33.3	0.2293	1.63 (0.73, 3.61)	1.94 (0.65, 5.74)	12.82 (-7.78, 33.18)	
Autoimmune ILD	71	14	19.7	70	16	22.9	0.6489	1.16 (0.61, 2.19)	1.21 (0.54, 2.71)	3.14 (-10.39, 16.58)	
Other ILD	36	5	13.9	25	9	36.0	0.0434	2.59 (0.99, 6.82)	3.49 (1.00, 12.16)	22.11 (0.52, 43.10)	
Region											0.4349
Europe	40	5	12.5	53	16	30.2	0.0434	2.42 (0.97, 6.04)	3.03 (1.00, 9.14)	17.69 (0.39, 32.78)	
Asia	106	18	17.0	107	22	20.6	0.5036	1.21 (0.69, 2.12)	1.27 (0.63, 2.52)	3.58 (-6.98, 14.05)	
Canada and USA	30	7	23.3	17	7	41.2	0.1987	1.76 (0.75, 4.18)	2.30 (0.64, 8.31)	17.84 (-8.47, 43.41)	
Rest of the World	46	6	13.0	43	14	32.6	0.0275	2.50 (1.05, 5.91)	3.22 (1.10, 9.38)	19.51 (2.05, 35.97)	

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: Each patient is considered only once with the worst CTCAE grade.

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Table I.2.2.3.1: 5 Proportion of patients with Diarrhoea with CTCAE grade >=3 over the whole trial (DBL1) - 18mg - TS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg vs Placebo: Risk ratio p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff.	(95% CI)	Interaction p-value**
Overall	222	0	0.0	220	0	0.0	0.9964	1.01 (0.02, 50.63)	NC (NC, NC)	0.00	(NC, NC)	
Age												
<65 years	83	0	0.0	88	0	0.0						
>=65 years	139	0	0.0	132	0	0.0						
Sex												
Male	116	0	0.0	111	0	0.0						
Female	106	0	0.0	109	0	0.0						
Baseline FVC percent predicted												
<=70%	118	0	0.0	96	0	0.0						
>70%	104	0	0.0	124	0	0.0						
Baseline HRCT pattern												
UIP-like	158	0	0.0	154	0	0.0						
Other fibrotic patterns	64	0	0.0	66	0	0.0						
Underlying ILD diagnosis												
iNSIP	40	0	0.0	55	0	0.0						
Unclassifiable IIP	36	0	0.0	40	0	0.0						
HP	39	0	0.0	30	0	0.0						
Autoimmune ILD	71	0	0.0	70	0	0.0						
Other ILD	36	0	0.0	25	0	0.0						
Region												
Europe	40	0	0.0	53	0	0.0						
Asia	106	0	0.0	107	0	0.0						
Canada and USA	30	0	0.0	17	0	0.0						
Rest of the World	46	0	0.0	43	0	0.0						

Study: 1305-0023. MedDRA version: 27.1. Missing CTCAE grade is assigned to >= 3.
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
*Pearson Chi2 test ** Cochran's Q-Test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: Each patient is considered only once with the worst CTCAE grade.

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I.2.2.3.2 Time to event analyses: treatment policy approach to lung transplant

Table I.2.2.3.2: 1 Cox model for time to first confirmed acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (non-AF background)

Subgroup	Placebo				Nera 18mg				Nera 18mg vs Placebo			Interaction
Category	N	n (e/ d)	%	Rate°	N	n (e/ d)	%	Rate°	Hazard ratio	(95% CI)	p-value	p-value
Overall	222	42 (20/ 22)	18.9	16.40	220	22 (12/ 10)	10.0	8.42	0.61	(0.36, 1.02)	0.0598	
Age												0.3566
<65 years	83	11 (6/ 5)	13.3	10.82	88	8 (5/ 3)	9.1	7.42	0.85	(0.34, 2.13)	0.7299	
>=65 years	139	31 (14/ 17)	22.3	20.08	132	14 (7/ 7)	10.6	9.11	0.50	(0.27, 0.95)	0.0353	
Sex												0.5020
Male	116	26 (13/ 13)	22.4	19.96	111	11 (5/ 6)	9.9	8.52	0.52	(0.25, 1.06)	0.0705	
Female	106	16 (7/ 9)	15.1	12.72	109	11 (7/ 4)	10.1	8.31	0.74	(0.34, 1.60)	0.4423	
Baseline FVC percent predicted												0.2559
<=70%	118	33 (16/ 17)	28.0	24.61	96	13 (8/ 5)	13.5	11.61	0.49	(0.26, 0.94)	0.0324	
>70%	104	9 (4/ 5)	8.7	7.38	124	9 (4/ 5)	7.3	6.02	0.96	(0.37, 2.50)	0.9396	
Baseline HRCT pattern												0.6609
UIP-like	158	30 (15/ 15)	19.0	16.68	154	15 (7/ 8)	9.7	8.18	0.56	(0.30, 1.05)	0.0706	
Other fibrotic patterns	64	12 (5/ 7)	18.8	15.74	66	7 (5/ 2)	10.6	8.96	0.72	(0.28, 1.88)	0.5073	
Underlying ILD diagnosis												0.1949
iNSIP	40	6 (3/ 3)	15.0	12.13	55	7 (3/ 4)	12.7	10.71	1.04	(0.35, 3.13)	0.9395	
Unclassifiable IIP	36	4 (1/ 3)	11.1	9.53	40	4 (4/ 0)	10.0	8.61	1.14	(0.28, 4.60)	0.8554	
HP	39	11 (7/ 4)	28.2	28.85	30	2 (0/ 2)	6.7	5.86	0.25	(0.06, 1.16)	0.0770	
Autoimmune ILD	71	14 (6/ 8)	19.7	16.49	70	4 (1/ 3)	5.7	4.62	0.29	(0.10, 0.90)	0.0314	
Other ILD	36	7 (3/ 4)	19.4	16.82	25	5 (4/ 1)	20.0	17.36	1.28	(0.41, 4.06)	0.6710	
Region												0.4539
Europe	40	7 (2/ 5)	17.5	15.68	53	8 (4/ 4)	15.1	13.98	1.01	(0.36, 2.80)	0.9832	
Asia	106	16 (11/ 5)	15.1	12.16	107	11 (6/ 5)	10.3	8.23	0.78	(0.36, 1.69)	0.5253	
Canada and USA	30	7 (3/ 4)	23.3	21.46	17	0 (0/ 0)	0.0	0.00	0.00	(NC, NC)	0.9849	
Rest of the World	46	12 (4/ 8)	26.1	25.39	43	3 (2/ 1)	7.0	6.02	0.28	(0.08, 0.99)	0.0481	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb). The subgroup model additionally includes the subgroup and treatment by subgroup interaction. Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined). N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk. e:Number of confirmed acute ILD exacerbations, d:Number of deaths, NC:Not calculable If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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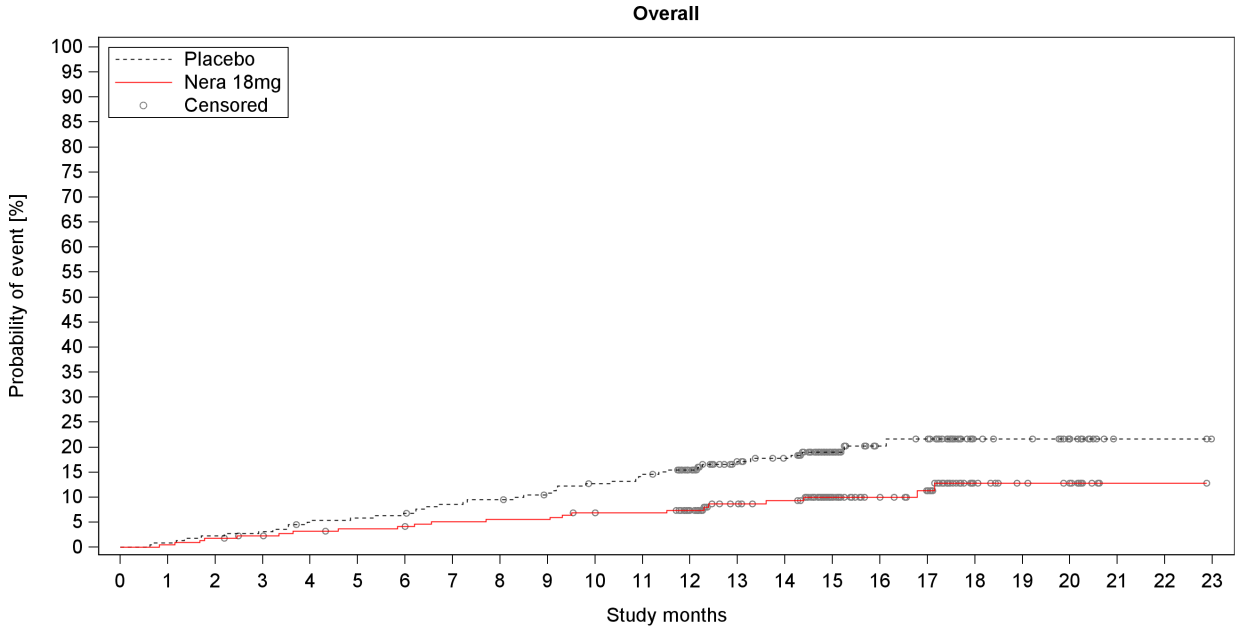

Number at risk (percentage relative to baseline)

Placebo	222	220	217	215	210	208	206	201	199	194	189	185	167	139	133	75	58	56	26	24	18	2	2	0
%	100.0	99.1	97.7	96.8	94.6	93.7	92.8	90.5	89.6	87.4	85.1	83.3	75.2	62.6	59.9	33.8	26.1	25.2	11.7	10.8	8.1	0.9	0.9	0.0
Nera 18mg	220	219	216	213	210	208	207	204	203	203	199	198	173	142	137	85	71	65	26	20	18	1	1	0
%	100.0	99.5	98.2	96.8	95.5	94.5	94.1	92.7	92.3	92.3	90.5	90.0	78.6	64.5	62.3	38.6	32.3	29.5	11.8	9.1	8.2	0.5	0.5	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	1	1	1	2	2	4	5	5	21	46	51	107	123	124	154	156	162	178	178	180
%	0.0	0.0	0.0	0.0	0.5	0.5	0.5	0.9	0.9	1.8	2.3	2.3	9.5	20.7	23.0	48.2	55.4	55.9	69.4	70.3	73.0	80.2	80.2	81.1
Nera 18mg	0	0	0	2	3	4	4	5	5	5	6	7	31	60	64	115	129	134	172	178	180	197	197	198
%	0.0	0.0	0.0	0.9	1.4	1.8	1.8	2.3	2.3	2.3	2.7	3.2	14.1	27.3	29.1	52.3	58.6	60.9	78.2	80.9	81.8	89.5	89.5	90.0

Study: 1305-0023

Figure I.2.2.3.2: 1 Time to first confirmed acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (non-AF background)

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Figure I.2.2.3.2: 1

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Table I.2.2.3.2: 2 Cox model for time to first confirmed or suspected acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (non-AF background)

Subgroup	Placebo					Nera 18mg					Nera 18mg vs Placebo				
Category	N	n	e/ d)	%	Rate°	N	n	e/ d)	%	Rate°	Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	222	48	30/ 18)	21.6	19.20	220	26	17/ 9)	11.8	10.07	0.60	(0.37,	0.98)	0.0393	
Age															0.3232
<65 years	83	15	12/ 3)	18.1	15.27	88	11	9/ 2)	12.5	10.38	0.82	(0.38,	1.80)	0.6222	
>=65 years	139	33	18/ 15)	23.7	21.74	132	15	8/ 7)	11.4	9.84	0.50	(0.27,	0.92)	0.0263	
Sex															0.7000
Male	116	29	19/ 10)	25.0	22.81	111	14	9/ 5)	12.6	11.03	0.55	(0.29,	1.06)	0.0743	
Female	106	19	11/ 8)	17.9	15.47	109	12	8/ 4)	11.0	9.13	0.67	(0.33,	1.38)	0.2803	
Baseline FVC percent predicted															0.3552
<=70%	118	36	21/ 15)	30.5	27.52	96	15	11/ 4)	15.6	13.62	0.51	(0.28,	0.94)	0.0296	
>70%	104	12	9/ 3)	11.5	10.07	124	11	6/ 5)	8.9	7.42	0.83	(0.36,	1.92)	0.6671	
Baseline HRCT pattern															0.7172
UIP-like	158	33	21/ 12)	20.9	18.63	154	17	10/ 7)	11.0	9.34	0.57	(0.31,	1.02)	0.0587	
Other fibrotic patterns	64	15	9/ 6)	23.4	20.60	66	9	7/ 2)	13.6	11.79	0.68	(0.30,	1.58)	0.3760	
Underlying ILD diagnosis															0.4979
iNSIP	40	8	7/ 1)	20.0	16.94	55	8	4/ 4)	14.5	12.28	0.77	(0.29,	2.07)	0.6068	
Unclassifiable IIP	36	4	1/ 3)	11.1	9.53	40	4	4/ 0)	10.0	8.61	1.08	(0.27,	4.34)	0.9159	
HP	39	12	9/ 3)	30.8	32.24	30	3	1/ 2)	10.0	8.97	0.34	(0.09,	1.21)	0.0965	
Autoimmune ILD	71	16	9/ 7)	22.5	19.34	70	6	3/ 3)	8.6	7.10	0.40	(0.16,	1.03)	0.0578	
Other ILD	36	8	4/ 4)	22.2	19.58	25	5	5/ 0)	20.0	17.37	1.07	(0.35,	3.27)	0.9103	
Region															0.5184
Europe	40	8	6/ 2)	20.0	18.73	53	10	6/ 4)	18.9	17.94	1.01	(0.40,	2.56)	0.9894	
Asia	106	17	12/ 5)	16.0	13.05	107	11	7/ 4)	10.3	8.23	0.72	(0.34,	1.55)	0.4057	
Canada and USA	30	8	4/ 4)	26.7	25.11	17	0	0/ 0)	0.0	0.00	0.00	(NC,	NC)	0.9836	
Rest of the World	46	15	8/ 7)	32.6	33.21	43	5	4/ 1)	11.6	10.37	0.35	(0.13,	0.99)	0.0468	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb). The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
e:Number of confirmed or suspected acute ILD exacerbations, d:Number of deaths, NC:Not calculable
If multiple components occur on the day of first event, the patient is counted only in the first component according to the order of the abbreviations.

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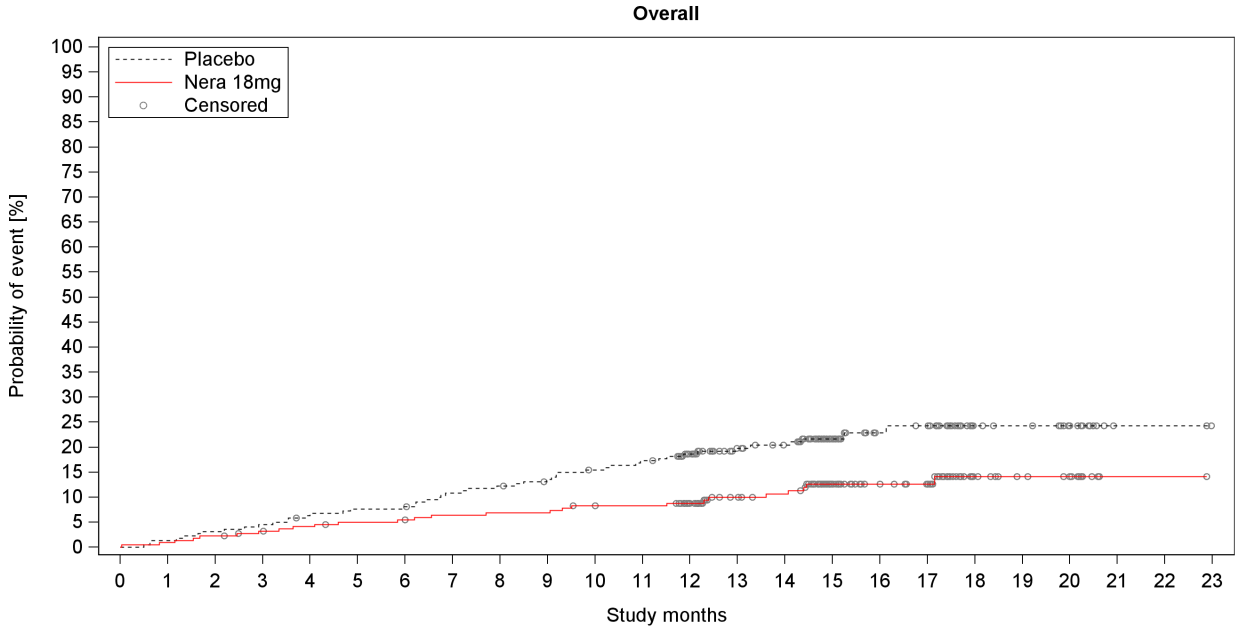

Number at risk (percentage relative to baseline)

Placebo	222	219	215	212	207	204	203	196	193	188	183	179	161	134	128	71	55	53	25	23	17	2	2	0
%	100.0	98.6	96.8	95.5	93.2	91.9	91.4	88.3	86.9	84.7	82.4	80.6	72.5	60.4	57.7	32.0	24.8	23.9	11.3	10.4	7.7	0.9	0.9	0.0
Nera 18mg	220	218	215	211	208	205	204	201	200	200	196	195	171	140	135	84	70	65	26	20	18	1	1	0
%	100.0	99.1	97.7	95.9	94.5	93.2	92.7	91.4	90.9	90.9	89.1	88.6	77.7	63.6	61.4	38.2	31.8	29.5	11.8	9.1	8.2	0.5	0.5	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	1	1	1	2	2	4	5	5	20	45	50	105	120	121	149	151	157	172	172	174
%	0.0	0.0	0.0	0.0	0.5	0.5	0.5	0.9	0.9	1.8	2.3	2.3	9.0	20.3	22.5	47.3	54.1	54.5	67.1	68.0	70.7	77.5	77.5	78.4
Nera 18mg	0	0	0	2	3	4	4	5	5	5	6	7	30	59	63	111	125	130	168	174	176	193	193	194
%	0.0	0.0	0.0	0.9	1.4	1.8	1.8	2.3	2.3	2.3	2.7	3.2	13.6	26.8	28.6	50.5	56.8	59.1	76.4	79.1	80.0	87.7	87.7	88.2

Study: 1305-0023

Figure I.2.2.3.2: 2 Time to first confirmed or suspected acute ILD exacerbation or death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (non-AF background)

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Table I.2.2.3.2: 3 Cox model for time to death - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	222	30	13.5	11.25	220	11	5.0	4.09	0.43	(0.21,	0.86)	0.0172	
Age													0.2541
<65 years	83	6	7.2	5.73	88	4	4.5	3.64	0.80	(0.23,	2.87)	0.7364	
>=65 years	139	24	17.3	14.83	132	7	5.3	4.41	0.33	(0.14,	0.77)	0.0107	
Sex													0.7505
Male	116	19	16.4	13.88	111	6	5.4	4.56	0.39	(0.15,	1.00)	0.0490	
Female	106	11	10.4	8.48	109	5	4.6	3.64	0.49	(0.17,	1.42)	0.1915	
Baseline FVC percent predicted													0.2863
<=70%	118	24	20.3	16.87	96	6	6.3	5.14	0.33	(0.13,	0.80)	0.0147	
>70%	104	6	5.8	4.83	124	5	4.0	3.29	0.73	(0.22,	2.41)	0.6100	
Baseline HRCT pattern													0.9268
UIP-like	158	22	13.9	11.69	154	8	5.2	4.26	0.42	(0.19,	0.95)	0.0371	
Other fibrotic patterns	64	8	12.5	10.20	66	3	4.5	3.71	0.45	(0.12,	1.71)	0.2429	
Underlying ILD diagnosis													0.5838
iNSIP	40	3	7.5	5.82	55	4	7.3	6.01	1.39	(0.31,	6.27)	0.6693	
Unclassifiable IIP	36	3	8.3	7.02	40	1	2.5	2.04	0.37	(0.04,	3.56)	0.3873	
HP	39	8	20.5	19.51	30	2	6.7	5.86	0.41	(0.09,	1.94)	0.2583	
Autoimmune ILD	71	10	14.1	11.31	70	3	4.3	3.44	0.28	(0.08,	1.05)	0.0595	
Other ILD	36	6	16.7	14.02	25	1	4.0	3.13	0.28	(0.03,	2.37)	0.2446	
Region													0.4275
Europe	40	6	15.0	12.95	53	5	9.4	8.45	0.76	(0.23,	2.52)	0.6580	
Asia	106	8	7.5	5.79	107	5	4.7	3.63	0.72	(0.23,	2.22)	0.5693	
Canada and USA	30	7	23.3	21.17	17	0	0.0	0.00	0.00	(NC,	NC)	0.9840	
Rest of the World	46	9	19.6	18.39	43	1	2.3	1.95	0.11	(0.01,	0.89)	0.0383	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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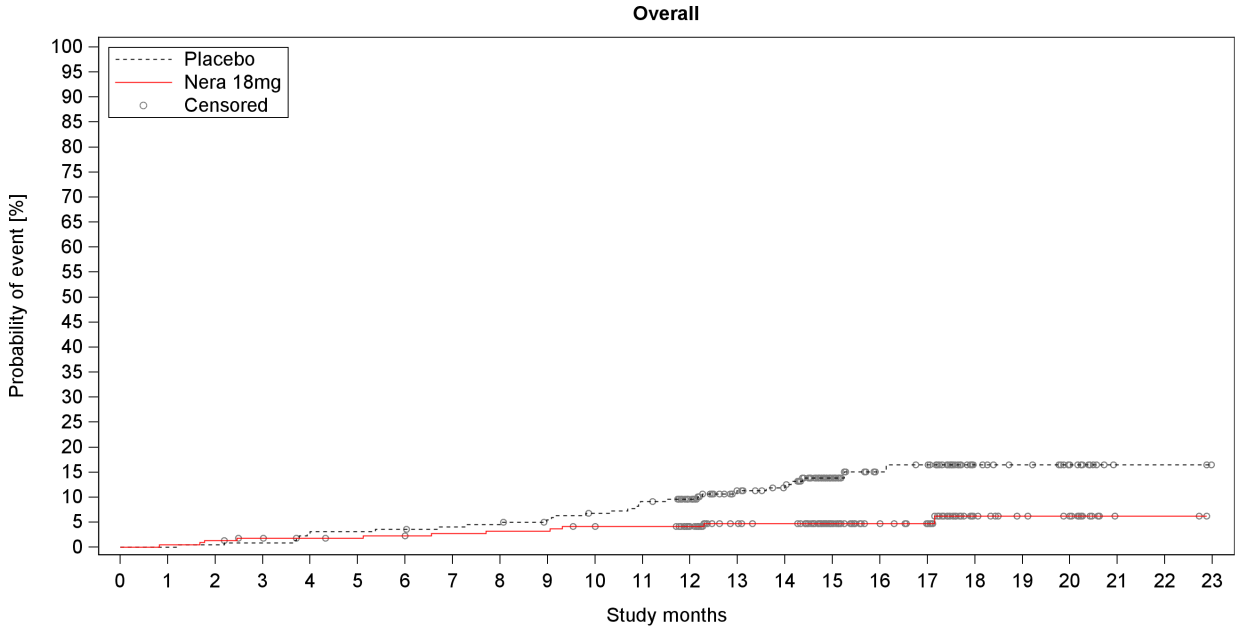

Number at risk (percentage relative to baseline)

Placebo	222	222	221	220	215	214	213	211	210	206	202	197	180	147	140	78	61	59	28	24	18	2	2	0
%	100.0	100.0	99.5	99.1	96.8	96.4	95.9	95.0	94.6	92.8	91.0	88.7	81.1	66.2	63.1	35.1	27.5	26.6	12.6	10.8	8.1	0.9	0.9	0.0
Nera 18mg	220	219	217	214	213	212	211	209	208	208	205	204	179	148	144	91	76	71	29	23	21	2	2	0
%	100.0	99.5	98.6	97.3	96.8	96.4	95.9	95.0	94.5	94.5	93.2	92.7	81.4	67.3	65.5	41.4	34.5	32.3	13.2	10.5	9.5	0.9	0.9	0.0

Number censored (percentage relative to number at risk at baseline)

Placebo	0	0	0	0	1	1	1	2	2	4	5	5	21	51	57	116	132	133	164	168	174	190	190	192
%	0.0	0.0	0.0	0.0	0.5	0.5	0.5	0.9	0.9	1.8	2.3	2.3	9.5	23.0	25.7	52.3	59.5	59.9	73.9	75.7	78.4	85.6	85.6	86.5
Nera 18mg	0	0	0	2	3	4	4	5	5	5	6	7	32	62	66	119	134	139	180	186	188	207	207	209
%	0.0	0.0	0.0	0.9	1.4	1.8	1.8	2.3	2.3	2.3	2.7	3.2	14.5	28.2	30.0	54.1	60.9	63.2	81.8	84.5	85.5	94.1	94.1	95.0

Study: 1305-0023

Figure I.2.2.3.2: 3 Time to death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (non-AF background)

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Table I.2.2.3.2: 4 Cox model for time to first confirmed acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	222	20	9.0	7.81	220	12	5.5	4.59	0.72	(0.35, 1.48)	0.3693	
Age												0.4729
<65 years	83	6	7.2	5.90	88	5	5.7	4.64	1.01	(0.30, 3.35)	0.9907	
>=65 years	139	14	10.1	9.07	132	7	5.3	4.56	0.58	(0.23, 1.45)	0.2436	
Sex												0.3283
Male	116	13	11.2	9.98	111	5	4.5	3.88	0.50	(0.18, 1.44)	0.1993	
Female	106	7	6.6	5.57	109	7	6.4	5.29	1.05	(0.37, 3.01)	0.9229	
Baseline FVC percent predicted												0.5185
<=70%	118	16	13.6	11.93	96	8	8.3	7.15	0.63	(0.27, 1.48)	0.2886	
>70%	104	4	3.8	3.28	124	4	3.2	2.68	1.11	(0.25, 4.98)	0.8888	
Baseline HRCT pattern												0.3182
UIP-like	158	15	9.5	8.34	154	7	4.5	3.82	0.56	(0.22, 1.37)	0.2024	
Other fibrotic patterns	64	5	7.8	6.56	66	5	7.6	6.40	1.26	(0.34, 4.72)	0.7341	
Underlying ILD diagnosis												
iNSIP	40	3	7.5		55	3	5.5					
Unclassifiable IIP	36	1	2.8		40	4	10.0					
HP	39	7	17.9		30	0	0.0					
Autoimmune ILD	71	6	8.5		70	1	1.4					
Other ILD	36	3	8.3		25	4	16.0					
Region												0.8190
Europe	40	2	5.0	4.48	53	4	7.5	6.99	1.67	(0.30, 9.17)	0.5547	
Asia	106	11	10.4	8.36	107	6	5.6	4.49	0.65	(0.24, 1.77)	0.3974	
Canada and USA	30	3	10.0	9.20	17	0	0.0	0.00	0.00	(NC, NC)	0.9887	
Rest of the World	46	4	8.7	8.46	43	2	4.7	4.02	0.67	(0.11, 4.01)	0.6594	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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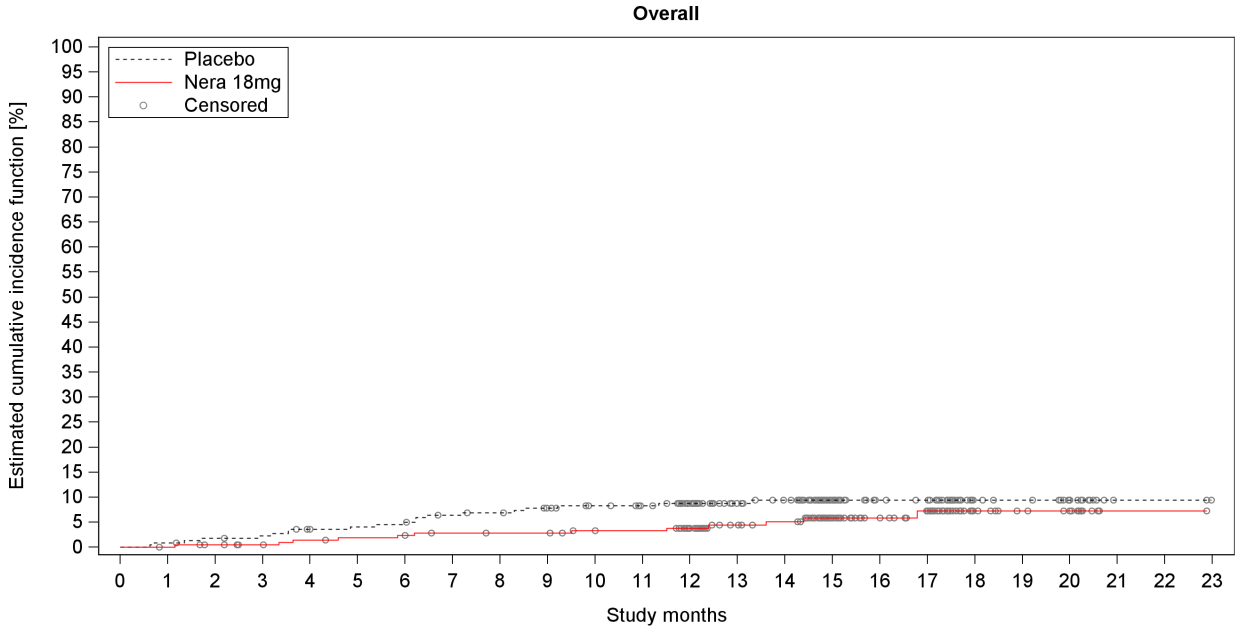

Number at risk (percentage relative to baseline)																								
Placebo	222	220	217	215	210	208	206	201	199	194	189	185	167	139	133	75	58	56	26	24	18	2	2	0
%	100.0	99.1	97.7	96.8	94.6	93.7	92.8	90.5	89.6	87.4	85.1	83.3	75.2	62.6	59.9	33.8	26.1	25.2	11.7	10.8	8.1	0.9	0.9	0.0
Nera 18mg	220	219	216	213	210	208	207	204	203	203	199	198	173	142	137	85	71	64	26	20	18	1	1	0
%	100.0	99.5	98.2	96.8	95.5	94.5	94.1	92.7	92.3	92.3	90.5	90.0	78.6	64.5	62.3	38.6	32.3	29.1	11.8	9.1	8.2	0.5	0.5	0.0
Number censored (percentage relative to number at risk at baseline)																								
Placebo	0	0	1	2	4	5	5	7	8	11	15	19	36	64	69	127	144	146	176	178	184	200	200	202
%	0.0	0.0	0.5	0.9	1.8	2.3	2.3	3.2	3.6	5.0	6.8	8.6	16.2	28.8	31.1	57.2	64.9	65.8	79.3	80.2	82.9	90.1	90.1	91.0
Nera 18mg	0	1	3	6	7	8	8	10	11	11	14	15	39	69	73	124	138	144	182	188	190	207	207	208
%	0.0	0.5	1.4	2.7	3.2	3.6	3.6	4.5	5.0	5.0	6.4	6.8	17.7	31.4	33.2	56.4	62.7	65.5	82.7	85.5	86.4	94.1	94.1	94.5

Study: 1305-0023

Figure I.2.2.3.2: 4 Time to first confirmed acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (non-AF background)

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Table I.2.2.3.2: 5 Cox model for time to first confirmed or suspected acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (non-AF background)

Subgroup	Placebo				Nera 18mg				Nera 18mg vs Placebo			
Category	N	n	%	Rate°	N	n	%	Rate°	Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	222	30	13.5	12.00	220	17	7.7	6.58	0.63	(0.35, 1.16)	0.1367	
Age												0.4171
<65 years	83	12	14.5	12.22	88	9	10.2	8.50	0.83	(0.35, 1.97)	0.6667	
>=65 years	139	18	12.9	11.86	132	8	6.1	5.25	0.50	(0.22, 1.16)	0.1068	
Sex												0.6081
Male	116	19	16.4	14.94	111	9	8.1	7.10	0.55	(0.25, 1.24)	0.1501	
Female	106	11	10.4	8.95	109	8	7.3	6.09	0.76	(0.31, 1.89)	0.5558	
Baseline FVC percent predicted												0.9315
<=70%	118	21	17.8	16.05	96	11	11.5	9.99	0.64	(0.31, 1.34)	0.2379	
>70%	104	9	8.7	7.55	124	6	4.8	4.05	0.61	(0.21, 1.76)	0.3583	
Baseline HRCT pattern												0.4359
UIP-like	158	21	13.3	11.85	154	10	6.5	5.50	0.53	(0.25, 1.13)	0.1024	
Other fibrotic patterns	64	9	14.1	12.36	66	7	10.6	9.17	0.88	(0.32, 2.44)	0.8066	
Underlying ILD diagnosis												0.0741
iNSIP	40	7	17.5	14.82	55	4	7.3	6.14	0.41	(0.12, 1.41)	0.1556	
Unclassifiable IIP	36	1	2.8	2.38	40	4	10.0	8.61	3.99	(0.44, 35.84)	0.2173	
HP	39	9	23.1	24.18	30	1	3.3	2.99	0.14	(0.02, 1.16)	0.0688	
Autoimmune ILD	71	9	12.7	10.88	70	3	4.3	3.55	0.39	(0.11, 1.46)	0.1625	
Other ILD	36	4	11.1	9.79	25	5	20.0	17.37	2.01	(0.54, 7.51)	0.2992	
Region												0.9865
Europe	40	6	15.0	14.05	53	6	11.3	10.76	0.76	(0.25, 2.38)	0.6430	
Asia	106	12	11.3	9.21	107	7	6.5	5.24	0.67	(0.26, 1.71)	0.4050	
Canada and USA	30	4	13.3	12.56	17	0	0.0	0.00	0.00	(NC, NC)	0.9867	
Rest of the World	46	8	17.4	17.71	43	4	9.3	8.31	0.56	(0.16, 1.90)	0.3493	

Study: 1305-0023. Based on a Cox regression model estimated in overall with categorical treatment, baseline HRCT pattern (UIP-like/Other fibrotic patterns), continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups are only analysed if at least 10 events occurred in at least one category (both treatments combined).
N:Number of patients analysed, n:Number of patients with event, °Incidence rate, events per 100 patient years at risk.
NC=not calculable.

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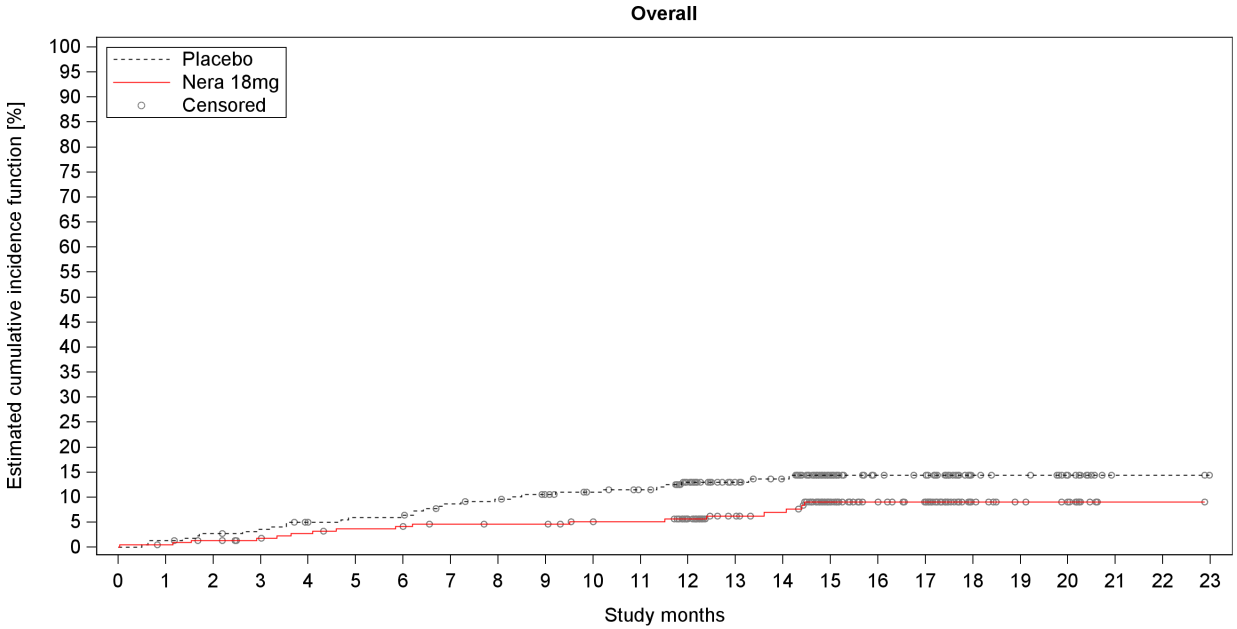

Number at risk (percentage relative to baseline)																								
Placebo	222	219	215	212	207	204	203	196	193	188	183	179	161	134	128	71	55	53	25	23	17	2	2	0
%	100.0	98.6	96.8	95.5	93.2	91.9	91.4	88.3	86.9	84.7	82.4	80.6	72.5	60.4	57.7	32.0	24.8	23.9	11.3	10.4	7.7	0.9	0.9	0.0
Nera 18mg	220	218	215	211	208	205	204	201	200	200	196	195	171	140	135	84	70	64	26	20	18	1	1	0
%	100.0	99.1	97.7	95.9	94.5	93.2	92.7	91.4	90.9	90.9	89.1	88.6	77.7	63.6	61.4	38.2	31.8	29.1	11.8	9.1	8.2	0.5	0.5	0.0
Number censored (percentage relative to number at risk at baseline)																								
Placebo	0	0	1	2	4	5	5	7	8	11	15	18	33	60	65	121	137	139	167	169	175	190	190	192
%	0.0	0.0	0.5	0.9	1.8	2.3	2.3	3.2	3.6	5.0	6.8	8.1	14.9	27.0	29.3	54.5	61.7	62.6	75.2	76.1	78.8	85.6	85.6	86.5
Nera 18mg	0	1	2	5	6	7	7	9	10	10	13	14	37	67	71	119	133	139	177	183	185	202	202	203
%	0.0	0.5	0.9	2.3	2.7	3.2	3.2	4.1	4.5	4.5	5.9	6.4	16.8	30.5	32.3	54.1	60.5	63.2	80.5	83.2	84.1	91.8	91.8	92.3

Study: 1305-0023

Figure I.2.2.3.2: 5 Time to first confirmed or suspected acute ILD exacerbation - treatment policy approach to lung transplant - over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (non-AF background)

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2 Auswertungen zu Nintedanib (für den indirekten Vergleich)

2.1 Auswertungen zur Studie INBUILD® aus dem Jahr 2026

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3.11 375-DOS-2511-SAF-DISCONT-EXCL-DISEASE-RELATED

3.11.1 Results

3.11.1.1 Analysis #1 - safety analyses

Table 11.1.1.1 Proportion of patients with any adverse event leading to treatment discontinuation excluding acute ILD exacerbation over the whole trial

	Placebo			Nintedanib			Nintedanib vs Placebo [2]									
							p-value	Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	331	41	12.4	332	71	21.4	0.002	1.73	(1.21	2.46)	1.92	(1.27	2.93)	0.09	(0.03	0.15)	
Age group																	0.481
<65 years	121	11	9.1	139	19	13.7	0.249	1.50	(0.75	3.03)	1.58	(0.72	3.48)	0.05	(-0.03	0.12)	
>=65 years	210	30	14.3	193	52	26.9	0.002	1.89	(1.26	2.83)	2.21	(1.34	3.65)	0.13	(0.05	0.21)	
Gender																	0.993
Male	177	23	13.0	179	40	22.3	0.021	1.72	(1.08	2.75)	1.93	(1.10	3.38)	0.09	(0.01	0.17)	
Female	154	18	11.7	153	31	20.3	0.040	1.73	(1.01	2.96)	1.92	(1.02	3.61)	0.09	(0.00	0.17)	
HRCT pattern																	0.460
UIP-like pattern only	206	26	12.6	206	49	23.8	0.003	1.88	(1.22	2.91)	2.16	(1.28	3.64)	0.11	(0.04	0.19)	
Other fibrotic patterns	125	15	12.0	126	22	17.5	0.222	1.46	(0.79	2.67)	1.55	(0.76	3.15)	0.05	(-0.03	0.14)	
Baseline FVC % predicted																	0.280
<=70%	193	28	14.5	196	42	21.4	0.076	1.48	(0.96	2.28)	1.61	(0.95	2.72)	0.07	(-0.01	0.15)	
>70%	138	13	9.4	136	29	21.3	0.006	2.26	(1.23	4.17)	2.61	(1.29	5.27)	0.12	(0.03	0.20)	
Underlying ILD Diagnosis in Groups																	0.773
Hypersensitivity pneumonitis	89	11	12.4	84	17	20.2	0.160	1.64	(0.82	3.29)	1.80	(0.79	4.11)	0.08	(-0.03	0.19)	
Idiopathic nonspecific interstitial pneumonia	61	5	8.2	64	14	21.9	0.033	2.67	(1.02	6.96)	3.14	(1.05	9.33)	0.14	(0.01	0.26)	
Unclassifiable idiopathic interstitial pneumonia	50	10	20.0	64	15	23.4	0.660	1.17	(0.58	2.38)	1.22	(0.50	3.02)	0.03	(-0.12	0.19)	
Autoimmune ILDs	88	10	11.4	82	17	20.7	0.095	1.82	(0.89	3.75)	2.04	(0.87	4.76)	0.09	(-0.02	0.20)	
Other ILDs	43	5	11.6	38	8	21.1	0.249	1.81	(0.65	5.06)	2.03	(0.60	6.83)	0.09	(-0.07	0.26)	
Region																	0.840
Asia	76	12	15.8	79	19	24.1	0.199	1.52	(0.79	2.92)	1.69	(0.76	3.77)	0.08	(-0.04	0.21)	
Europe	147	17	11.6	154	31	20.1	0.042	1.74	(1.01	3.01)	1.93	(1.02	3.66)	0.09	(0.00	0.17)	
Canada and United States	69	8	11.6	67	17	25.4	0.038	2.19	(1.01	4.73)	2.59	(1.03	6.50)	0.14	(0.01	0.27)	
Rest of World	39	4	10.3	32	4	12.5	0.766	1.22	(0.33	4.49)	1.25	(0.29	5.45)	0.02	(-0.13	0.17)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +28 days.
Subgroups with all categories are only presented, where at least one subgroup category has >= 10 events.
AEs meeting the protocol definition of an acute ILD exacerbation are excluded from the analysis.

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2.2 Kaplan-Meier-Plots zur Studie INBUILD® aus dem Jahr 2020

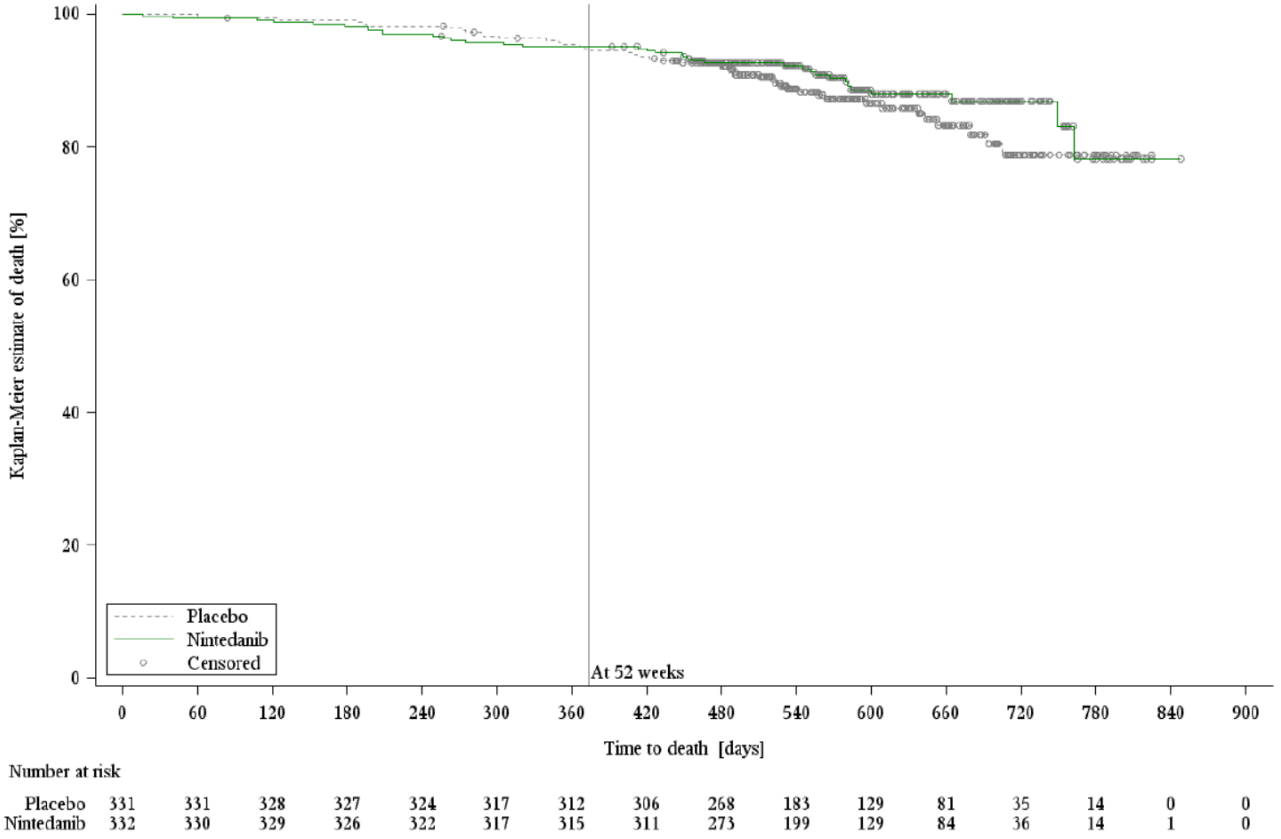

Abbildung 5 aus [1].

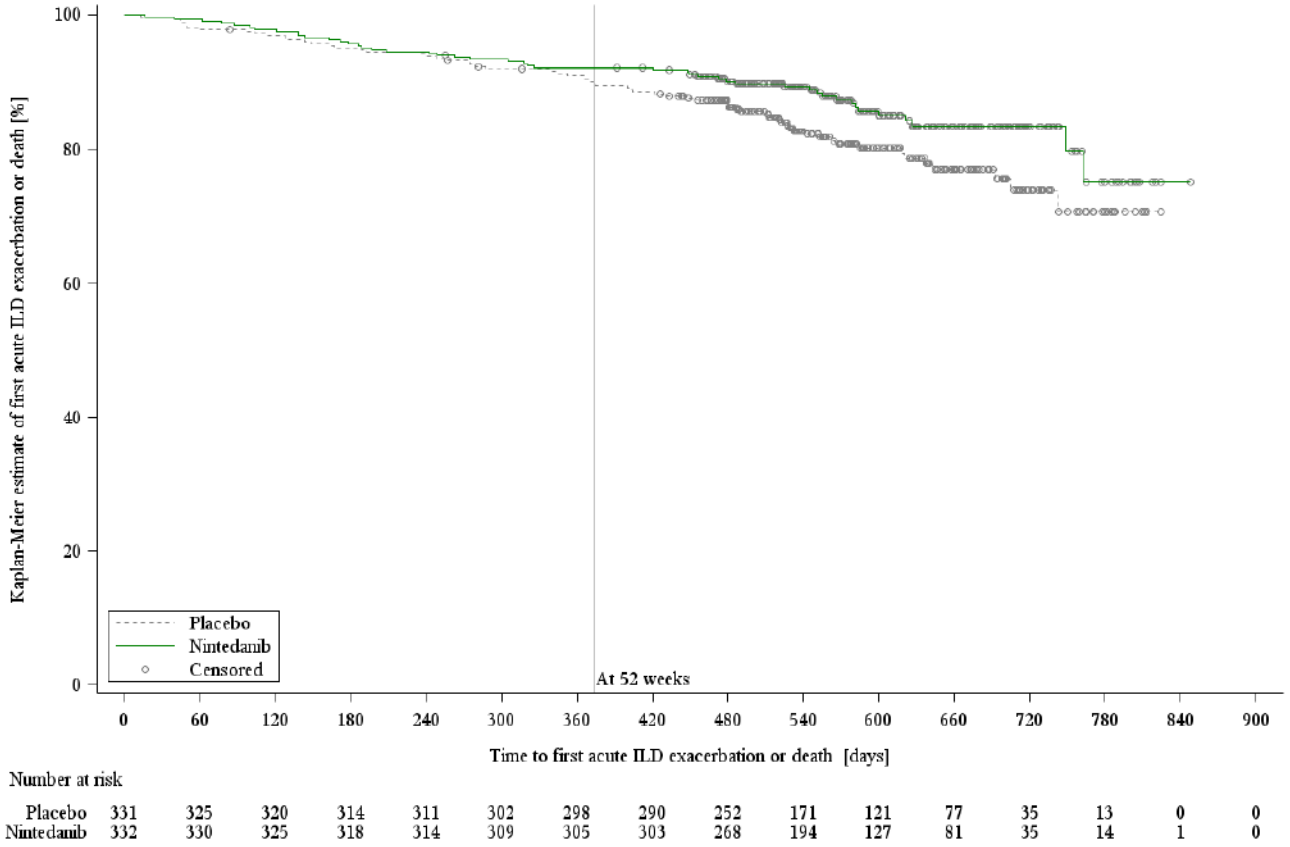

Abbildung 9 aus [1].

2.3 Auswertungen zur Studie 1199.434

1.1 Observation time

1.1.1 Observation time

Table 1.1.1 Duration of observation time over the whole trial
Treated Set

	Placebo		Nintedanib		Total	
Number of patients (N, %)	27	100.0	54	100.0	81	100.0
Observation [months] [1]						
N	27		54		81	
Mean	11.62		11.34		11.43	
SD	1.69		2.44		2.21	
Min	5.9		3.1		3.1	
Q1	11.97		11.93		11.97	
Median	12.20		12.20		12.20	
Q3	12.33		12.33		12.33	
Max	13.0		13.6		13.6	

[1] Duration of observation time in months over the whole trial is calculated as
(min(end of study date, death date) - randomization date +1)/30.5

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1.2 Efficacy - Time to event

1.2.1 Time to event analyses - Total population

Table 2.1.1 Time to death over the whole trial - Treated set

Treatment	Number at risk [1]	Failure: Number Failed	Failure: %	Censored: Number Censored	Censored: %	Probability of survival	Comparison vs Placebo: Hazard ratio [2]	95% confidence interval: Lower	95% confidence interval: Upper	Treatment vs. placebo p-value [3]
										0.9446
Placebo	27	3	11.1	24	88.9	0.8873				
Nintedanib	54	6	11.1	48	88.9	0.8860	1.05	0.26	4.20	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment stratified by HRCT pattern
[3] Based on a stratified log-rank test, stratified by HRCT pattern

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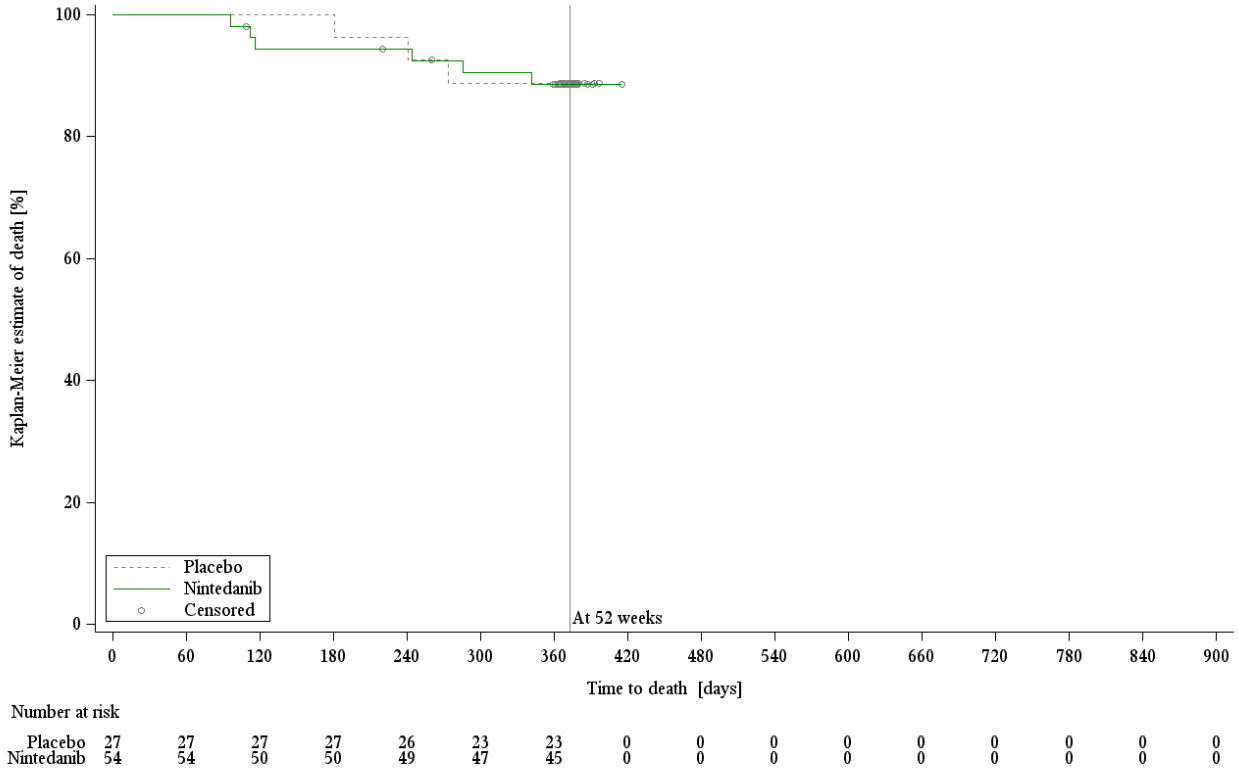

Figure 2.1.2 Kaplan Meier Plot of time to death over the whole trial - Treated set

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Table 2.1.3 Time to first acute ILD exacerbation or death over the whole trial - Treated Set

Treatment	Number at risk [1]	Failure: Number Failed	Failure: %	Censored: Number Censored	Censored: %	Probability of survival	Comparison vs Placebo: Hazard ratio [2]	95% confidence interval: Lower	95% confidence interval: Upper	Treatment vs. placebo p-value [3]
										0.4758
Placebo	27	7	25.9	20	74.1	0.7357				
Nintedanib	54	10	18.5	44	81.5	0.8096	0.71	0.27	1.85	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment stratified by HRCT pattern
[3] Based on a stratified log-rank test, stratified by HRCT pattern

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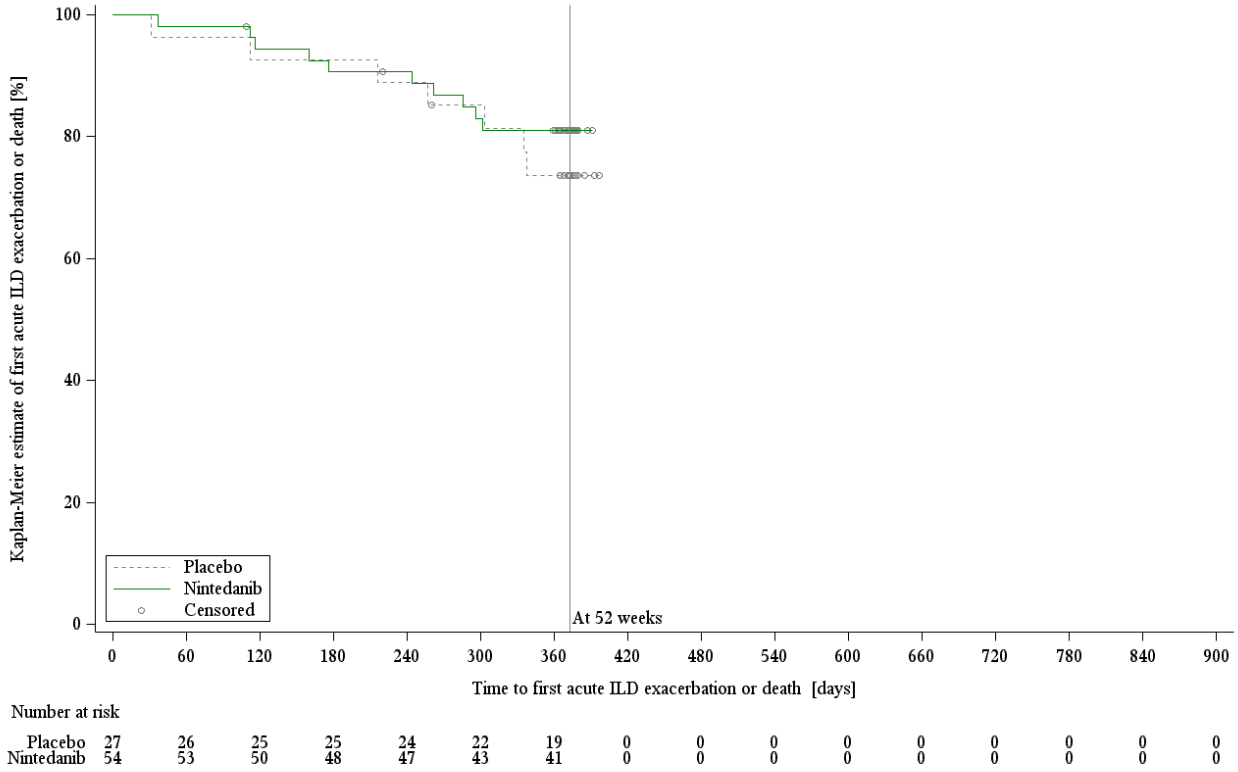

Figure 2.1.4 Kaplan Meier Plot of time to first acute ILD exacerbation or death over the whole trial - Treated Set

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Table 2.1.5 Time to first acute ILD exacerbation over the whole trial - Treated Set

Treatment	Number at risk [1]	Failure: Number Failed	Failure: %	Censored: Number Censored	Censored: %	Probability of survival	Comparison vs Placebo: Hazard ratio [2]	95% confidence interval: Lower	95% confidence interval: Upper	Treatment vs. placebo p-value [3]
										0.1118
Placebo	27	7	25.9	20	74.1	0.7357				
Nintedanib	54	6	11.1	48	88.9	0.8798	0.42	0.14	1.26	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment stratified by HRCT pattern
[3] Based on a stratified log-rank test, stratified by HRCT pattern

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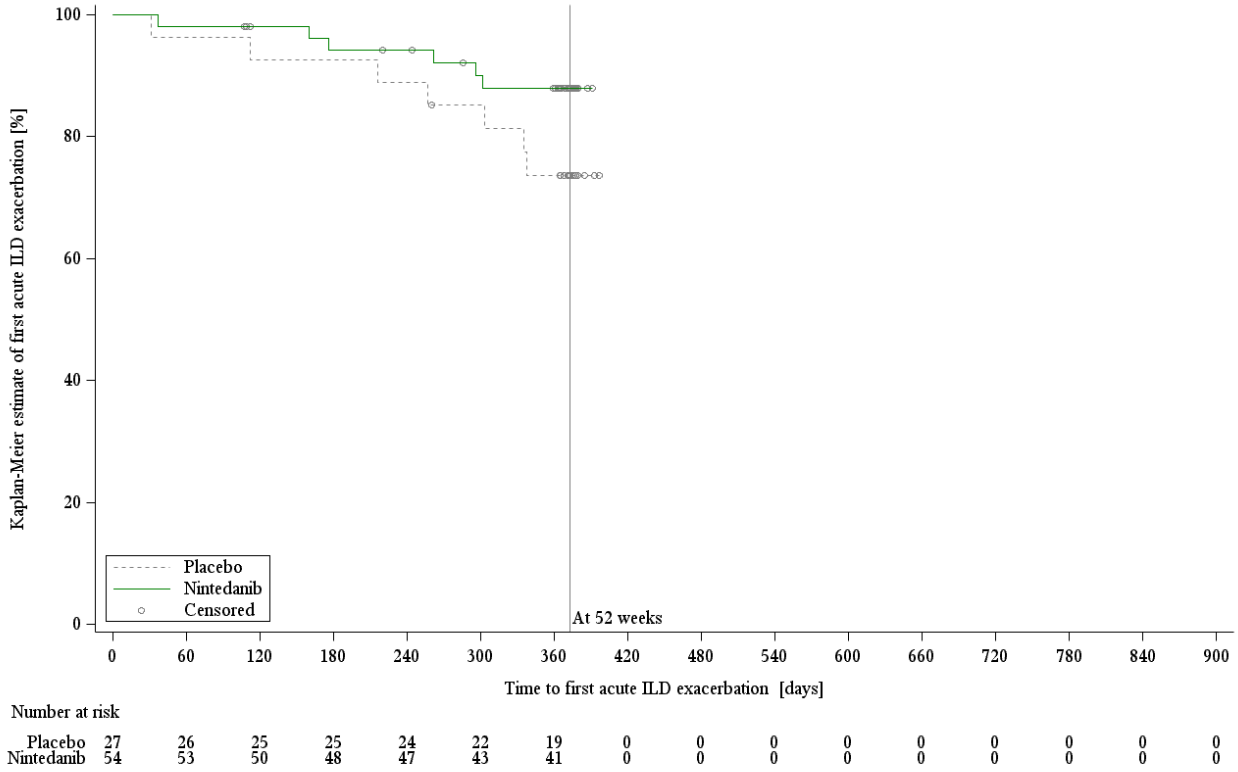

Figure 2.1.6 Kaplan Meier Plot of time to first acute ILD exacerbation over the whole trial - Treated Set

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1.2.2 Time to event analyses - Subgroup Age group (<65 / >=65)

Table 2.2.1 Time to death over the whole trial by age group - Treated set

Age group/ Treatment	Number at risk [1]	Failure: Number Failed	Failure: %	Censored: Number Censored	Censored: %	Probability of survival	Comparison vs Placebo: Hazard ratio [2]	95% confidence interval: Lower	95% confidence interval: Upper	Treatment by subgroup interaction p-value [3]
										0.9936
<65 years										
Placebo	9	0	0.0	9	100.0	1.0000				
Nintedanib	25	2	8.0	23	92.0	0.9183	NC	-	-	
>=65 years										
Placebo	18	3	16.7	15	83.3	0.8296				
Nintedanib	29	4	13.8	25	86.2	0.8594	0.79	0.18	3.52	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment stratified by HRCT pattern
[3] Based on a Cox regression model with terms for treatment, subgroup and treatment by subgroup, stratified by HRCT pattern

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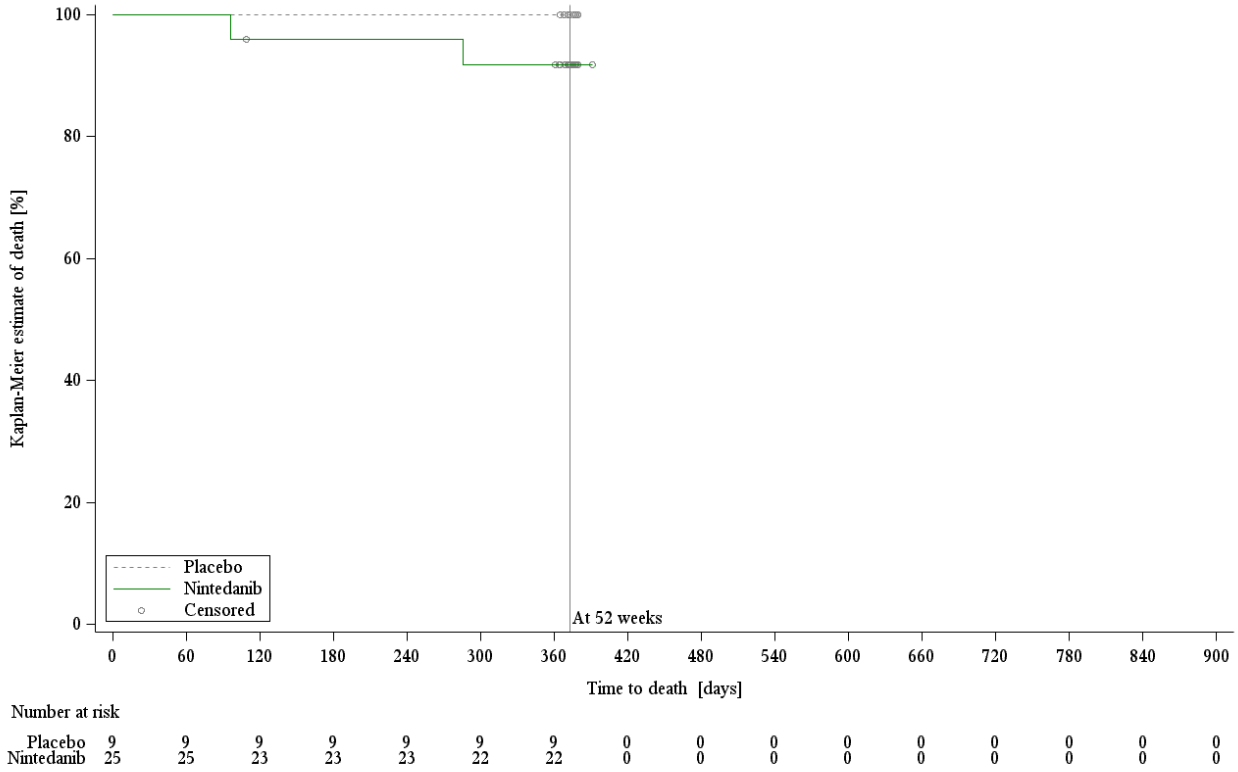

Figure 2.2.2 Kaplan Meier Plot of time to death over the whole trial by age group - Treated set

Age group: <65 years

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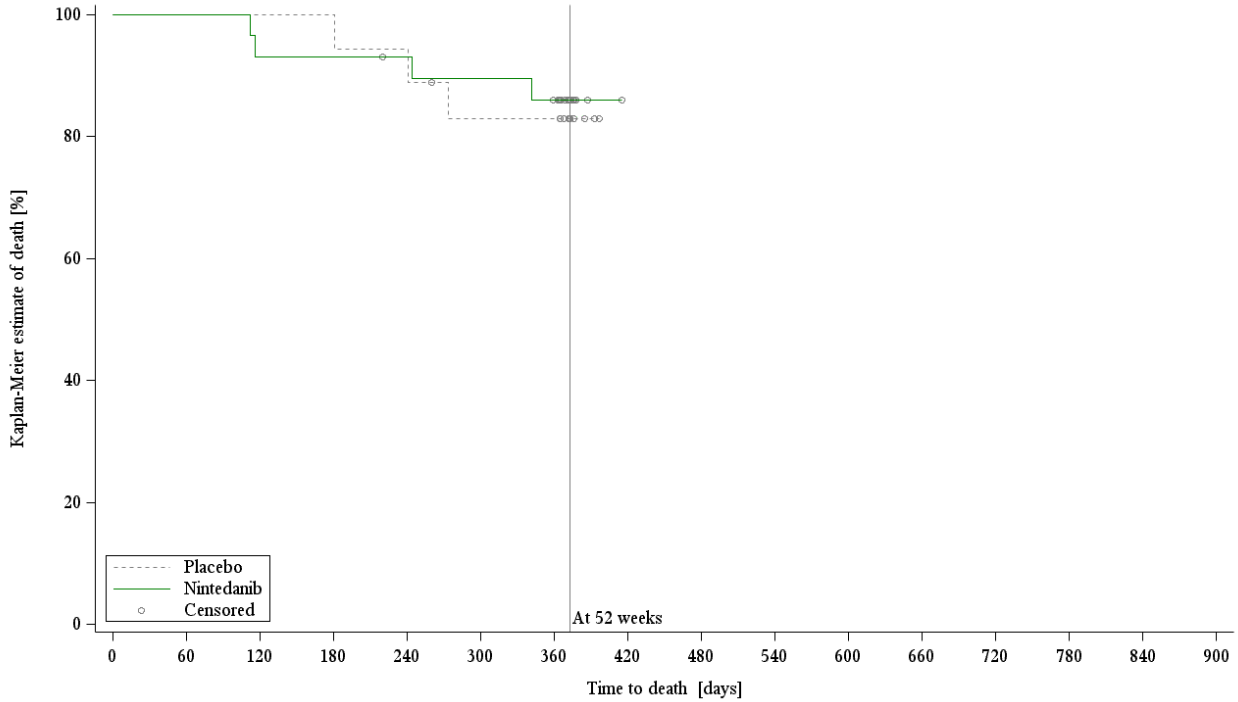

Figure 2.2.2 Kaplan Meier Plot of time to death over the whole trial by age group - Treated set

Age group: >=65 years

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Table 2.2.3 Time to first acute ILD exacerbation or death over the whole trial by age group - Treated Set

Age group/ Treatment	Number at risk [1]	Failure Number Failed	Failure %	Censored Number Censored	Censored %	Probability of survival	Comparison vs Placebo Hazard ratio [2]	95% confidence interval Lower	95% confidence interval Upper	Treatment by subgroup interaction p-value [3]
										0.9199
<65 years										
Placebo	9	3	33.3	6	66.7	0.6667				
Nintedanib	25	5	20.0	20	80.0	0.7930	0.62	0.15	2.61	
>=65 years										
Placebo	18	4	22.2	14	77.8	0.7738				
Nintedanib	29	5	17.2	24	82.8	0.8236	0.74	0.20	2.76	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment stratified by HRCT pattern
[3] Based on a Cox regression model with terms for treatment, subgroup and treatment by subgroup, stratified by HRCT pattern

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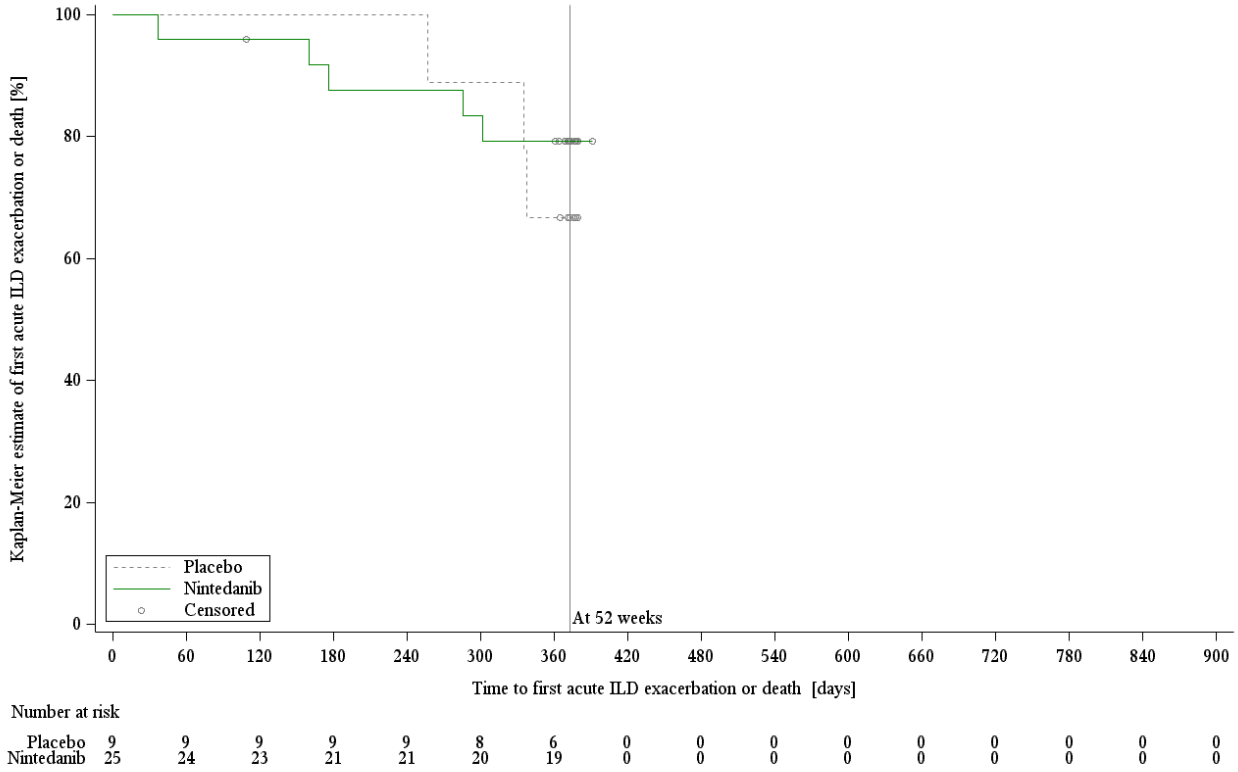

Figure 2.2.4 Kaplan Meier Plot of time to first acute ILD exacerbation or death over the whole trial by age group - Treated Set

Age group: <65 years

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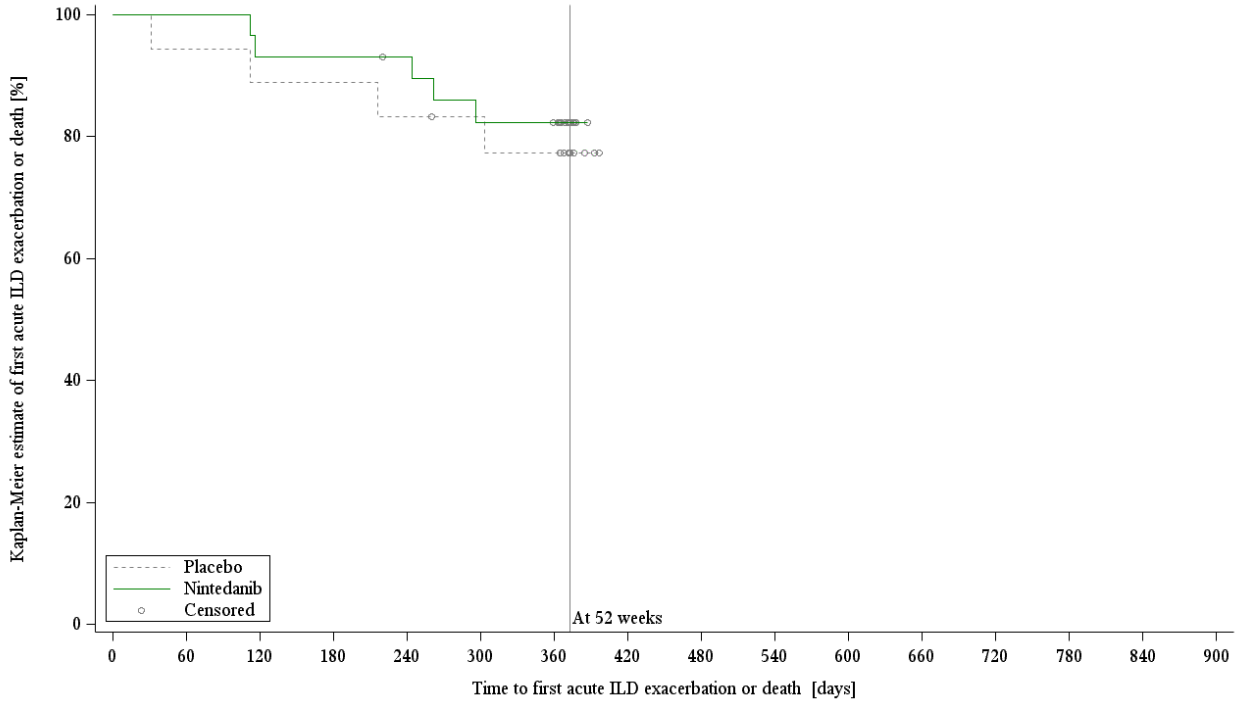

Figure 2.2.4 Kaplan Meier Plot of time to first acute ILD exacerbation or death over the whole trial by age group - Treated Set

Age group: >=65 years

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Table 2.2.5 Time to first acute ILD exacerbation over the whole trial by age group - Treated Set

Age group/ Treatment	Number at risk [1]	Failure: Number Failed	Failure: %	Censored: Number Censored	Censored: %	Probability of survival	Comparison vs Placebo: Hazard ratio [2]	95% confidence interval: Lower	95% confidence interval: Upper	Treatment by subgroup interaction p-value [3]
										0.6300
<65 years										
Placebo	9	3	33.3	6	66.7	0.6667				
Nintedanib	25	4	16.0	21	84.0	0.8327	0.50	0.11	2.23	
>=65 years										
Placebo	18	4	22.2	14	77.8	0.7738				
Nintedanib	29	2	6.9	27	93.1	0.9200	0.31	0.06	1.68	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment stratified by HRCT pattern
[3] Based on a Cox regression model with terms for treatment, subgroup and treatment by subgroup, stratified by HRCT pattern

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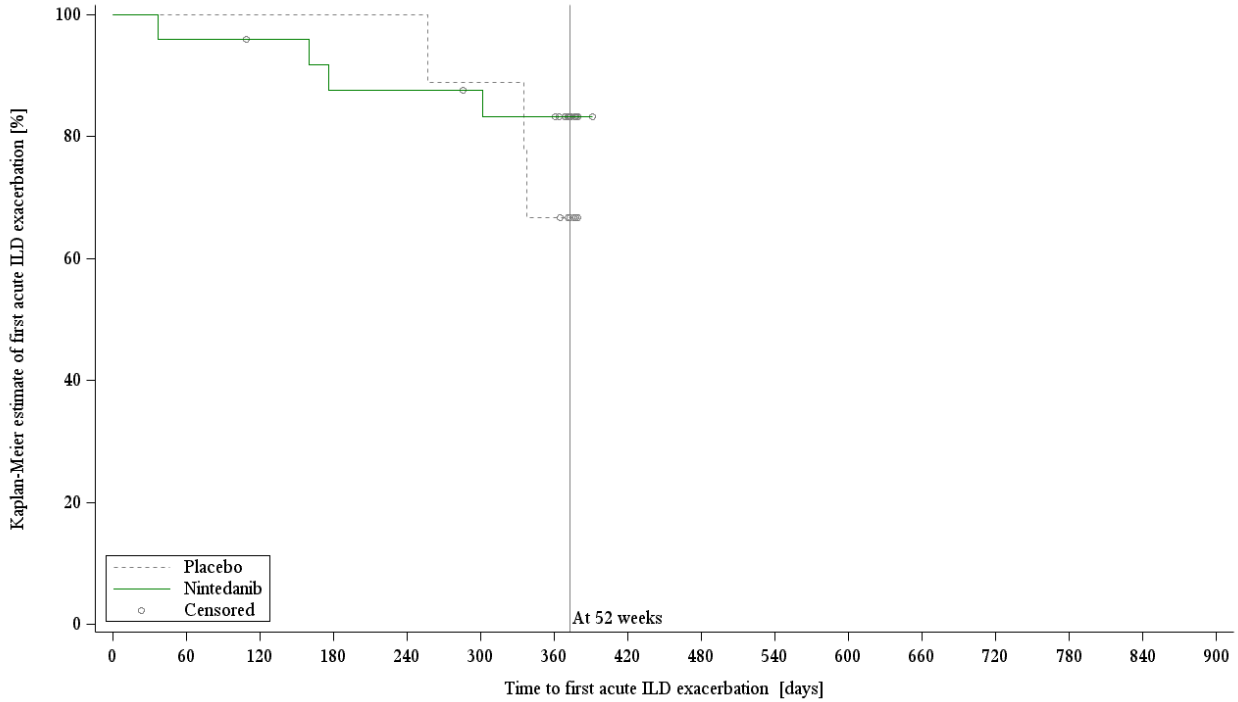

Figure 2.2.6 Kaplan Meier Plot of time to first acute ILD exacerbation over the whole trial by age group - Treated Set

Age group: <65 years

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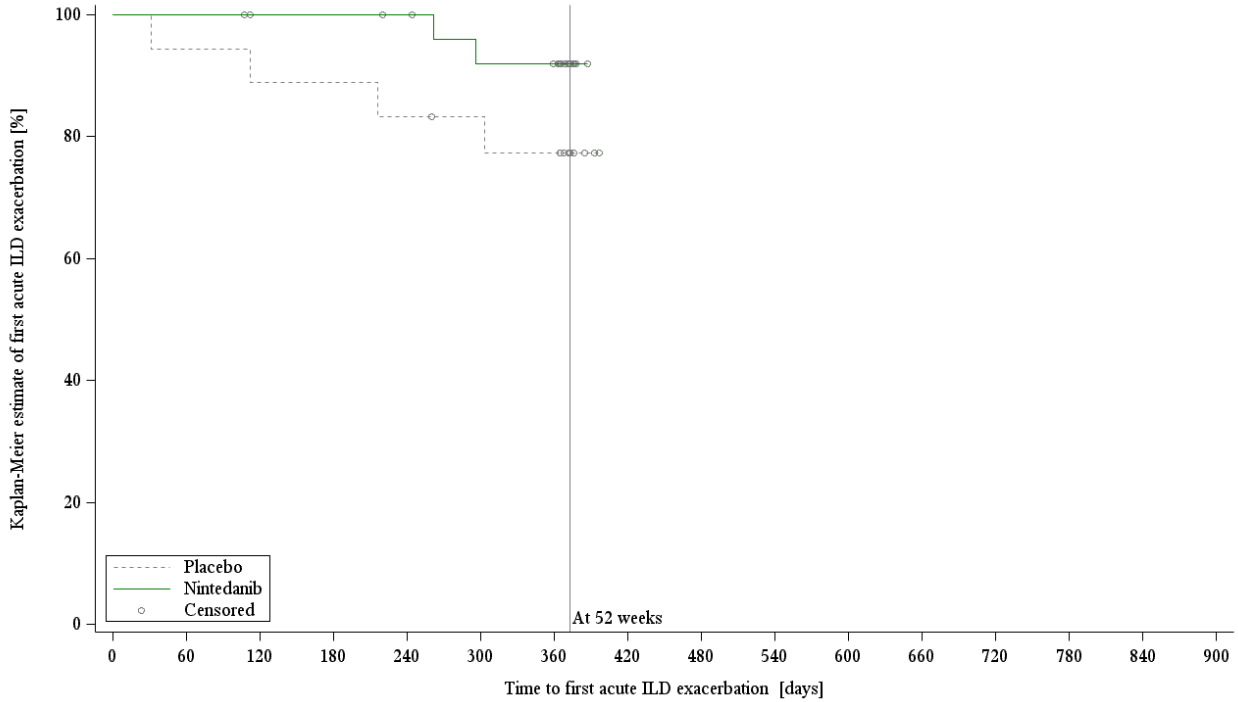

Figure 2.2.6 Kaplan Meier Plot of time to first acute ILD exacerbation over the whole trial by age group - Treated Set

Age group: >=65 years

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1.2.3 Time to event analyses - Subgroup Gender (Male / Female)

Table 2.3.1 Time to death over the whole trial by gender - Treated set

Gender/ Treatment	Number at risk [1]	Failure Number Failed	Failure %	Censored Number Censored	Censored %	Probability of survival	Comparison vs Placebo Hazard ratio [2]	95% confidence interval Lower	95% confidence interval Upper	Treatment by subgroup interaction p-value [3]
										0.4681
Male										
Placebo	11	1	9.1	10	90.9	0.9091				
Nintedanib	26	4	15.4	22	84.6	0.8462	1.85	0.21	16.57	
Female										
Placebo	16	2	12.5	14	87.5	0.8750				
Nintedanib	28	2	7.1	26	92.9	0.9231	0.59	0.08	4.22	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment stratified by HRCT pattern
[3] Based on a Cox regression model with terms for treatment, subgroup and treatment by subgroup, stratified by HRCT pattern

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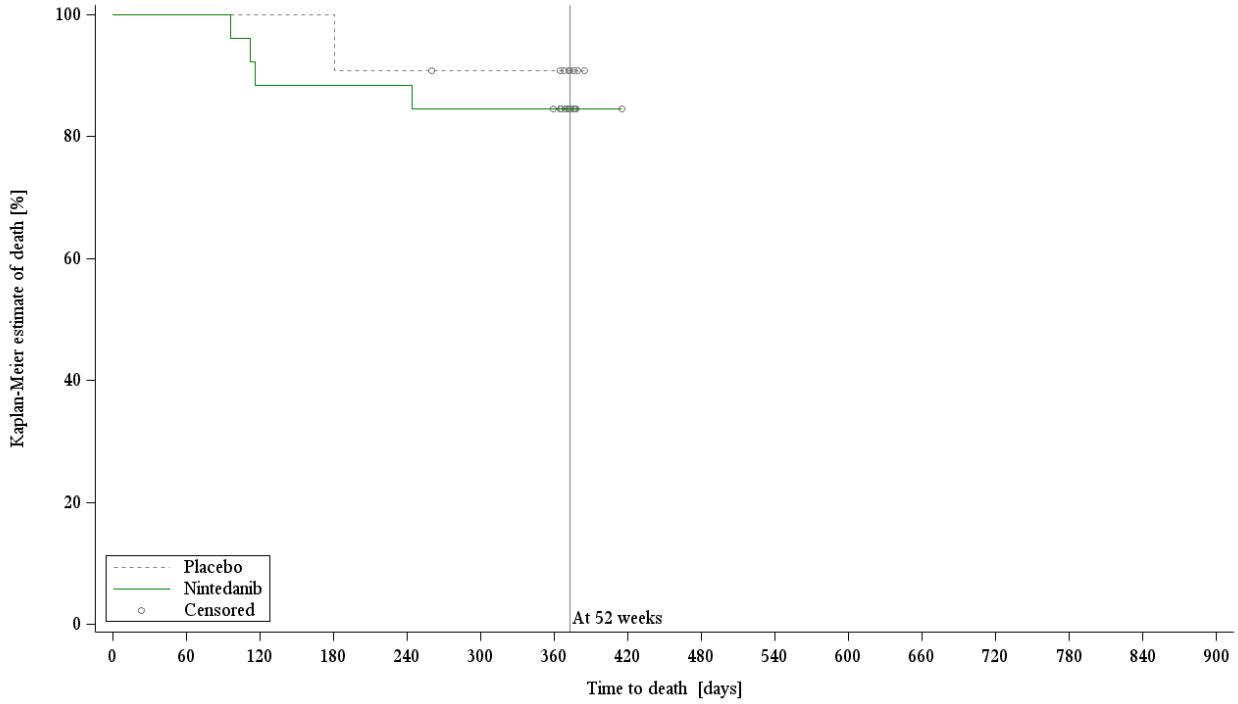

Number at risk

Placebo	11	11	11	11	10	9	9	0	0	0	0	0	0	0	0	0
Nintedanib	26	26	23	23	23	22	21	0	0	0	0	0	0	0	0	0

Figure 2.3.2 Kaplan Meier Plot of time to death over the whole trial by gender - Treated set

Gender: Male

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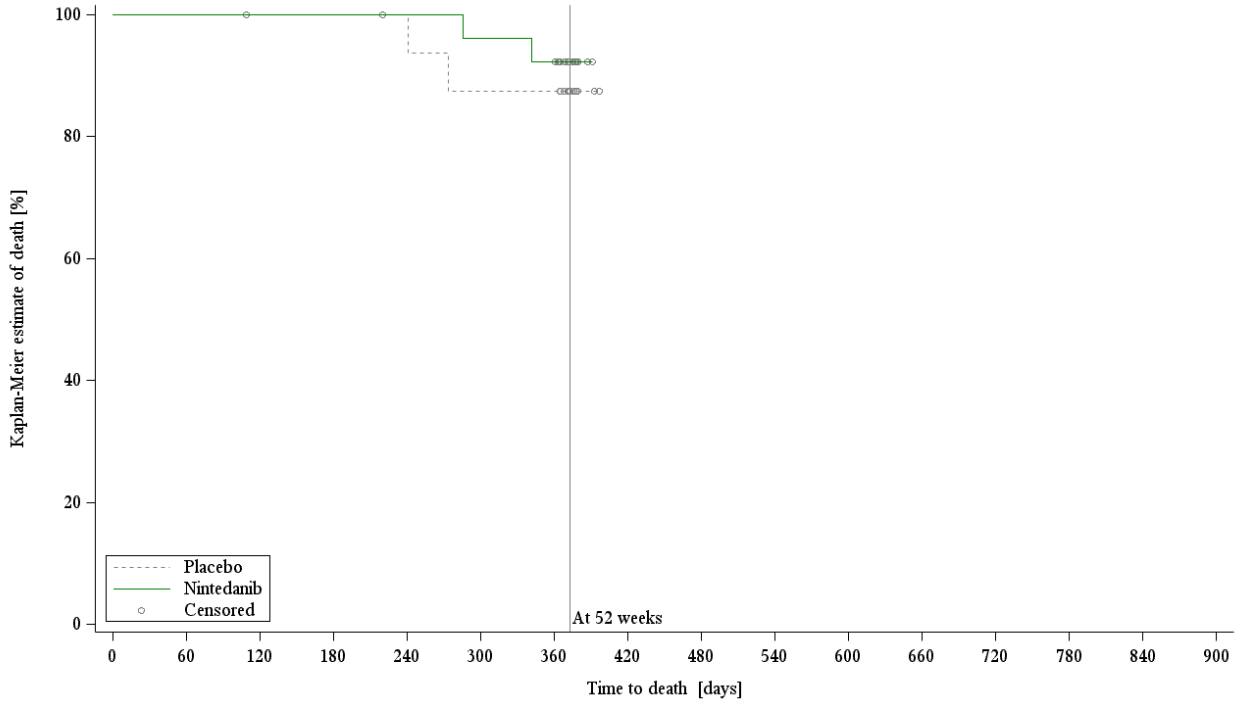

Number at risk

Placebo	16	16	16	16	16	14	14	0	0	0	0	0	0	0	0	0
Nintedanib	28	28	27	27	26	25	24	0	0	0	0	0	0	0	0	0

Figure 2.3.2 Kaplan Meier Plot of time to death over the whole trial by gender - Treated set

Gender: Female

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Table 2.3.3 Time to first acute ILD exacerbation or death over the whole trial by gender - Treated Set

Gender/ Treatment	Number at risk [1]	Failure Number Failed	Failure %	Censored Number Censored	Censored %	Probability of survival	Comparison vs Placebo Hazard ratio [2]	95% confidence interval Lower	95% confidence interval Upper	Treatment by subgroup interaction p-value [3]
										0.1222
Male										
Placebo	11	1	9.1	10	90.9	0.9091				
Nintedanib	26	6	23.1	20	76.9	0.7692	2.61	0.31	21.75	
Female										
Placebo	16	6	37.5	10	62.5	0.6250				
Nintedanib	28	4	14.3	24	85.7	0.8474	0.36	0.10	1.27	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment stratified by HRCT pattern
[3] Based on a Cox regression model with terms for treatment, subgroup and treatment by subgroup, stratified by HRCT pattern

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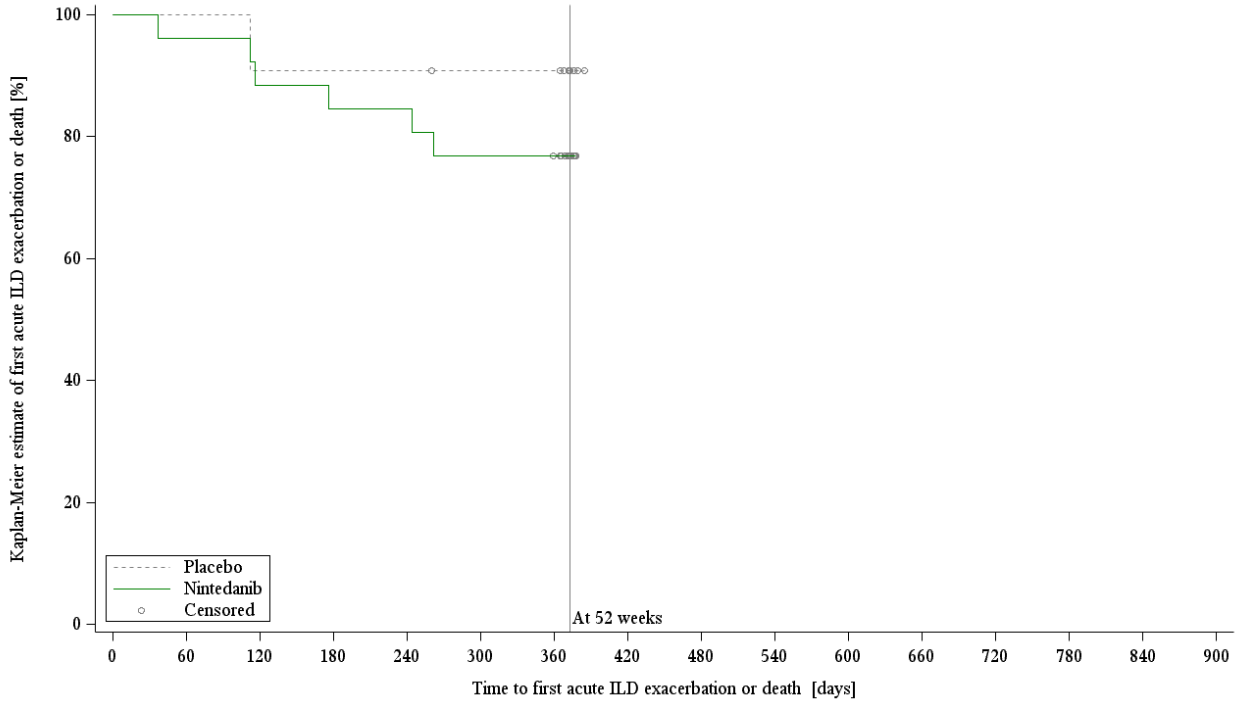

Figure 2.3.4 Kaplan Meier Plot of time to first acute ILD exacerbation or death over the whole trial by gender - Treated Set

Gender: Male

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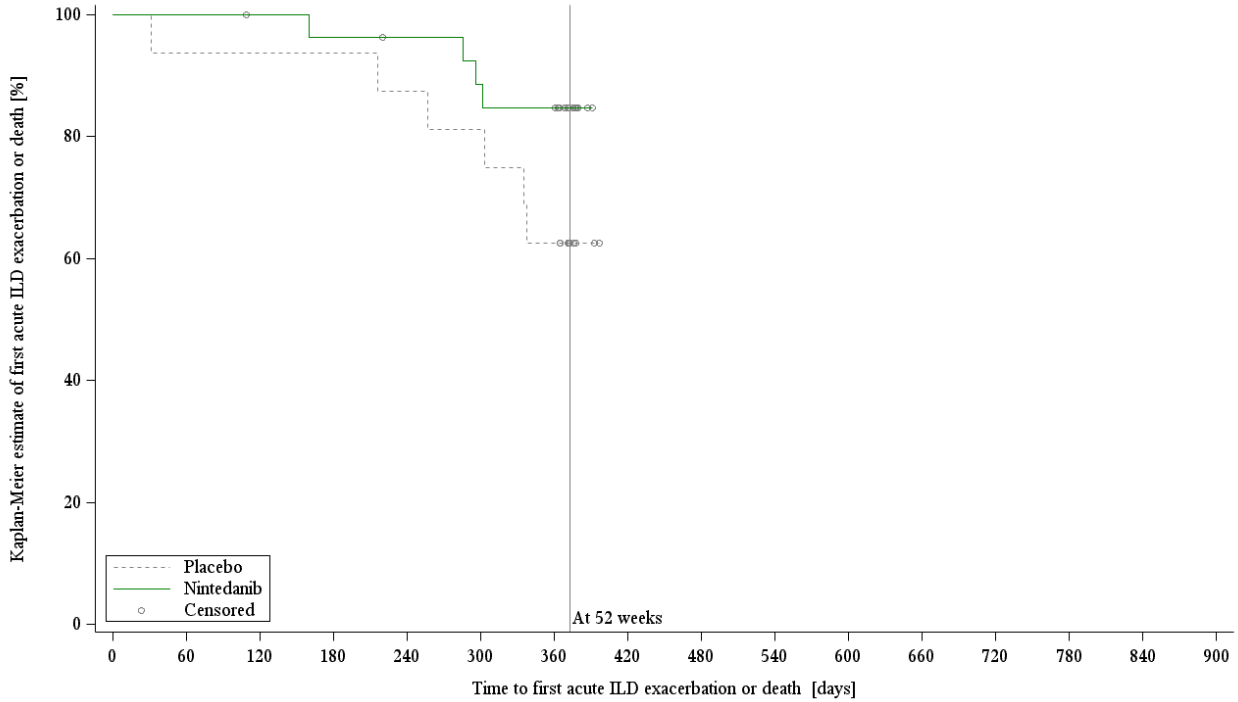

Figure 2.3.4 Kaplan Meier Plot of time to first acute ILD exacerbation or death over the whole trial by gender - Treated Set

Gender: Female

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Table 2.3.5 Time to first acute ILD exacerbation over the whole trial by gender - Treated Set

Gender/ Treatment	Number at risk [1]	Failure: Number Failed	Failure: %	Censored: Number Censored	Censored: %	Probability of survival	Comparison vs Placebo: Hazard ratio [2]	95% confidence interval: Lower	95% confidence interval: Upper	Treatment by subgroup interaction p-value [3]
										0.2571
Male										
Placebo	11	1	9.1	10	90.9	0.9091				
Nintedanib	26	3	11.5	23	88.5	0.8759	1.30	0.13	12.57	
Female										
Placebo	16	6	37.5	10	62.5	0.6250				
Nintedanib	28	3	10.7	25	89.3	0.8827	0.27	0.07	1.08	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment stratified by HRCT pattern
[3] Based on a Cox regression model with terms for treatment, subgroup and treatment by subgroup, stratified by HRCT pattern

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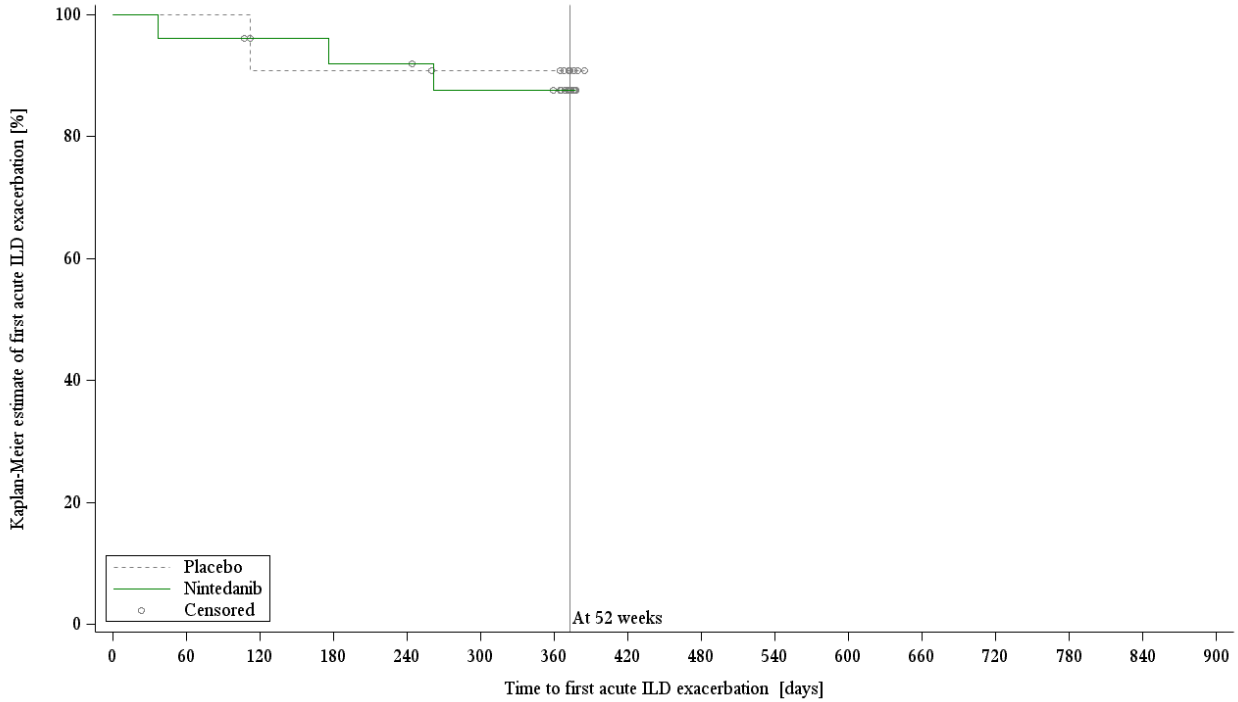

Figure 2.3.6 Kaplan Meier Plot of time to first acute ILD exacerbation over the whole trial by gender - Treated Set

Gender: Male

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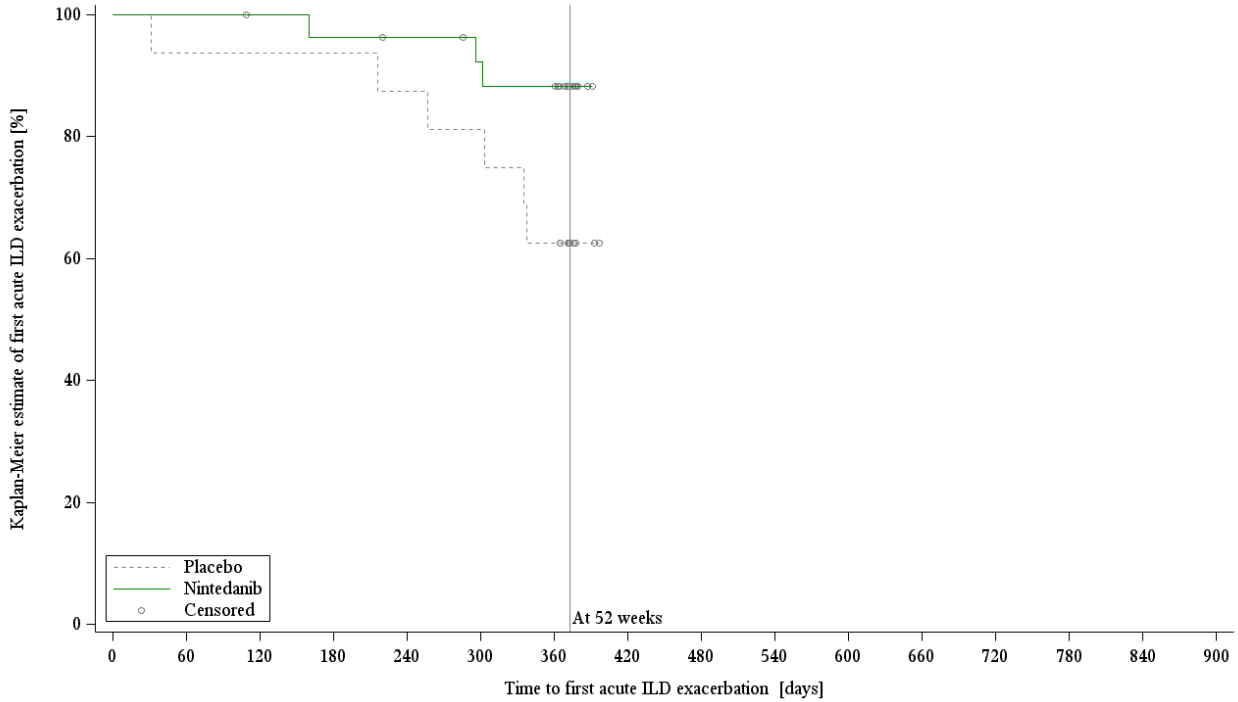

Figure 2.3.6 Kaplan Meier Plot of time to first acute ILD exacerbation over the whole trial by gender - Treated Set

Gender: Female

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1.2.4 Time to event analyses - Subgroup HRCT pattern (UIP-like pattern only / Other fibrotic patterns)

Table 2.4.1 Time to death over the whole trial by HRCT pattern - Treated set

HRCT pattern/ Treatment	Number at risk [1]	Failure: Number Failed	Failure: %	Censored: Number Censored	Censored: %	Probability of survival	Comparison vs Placebo: Hazard ratio [2]	95% confidence interval: Lower	95% confidence interval: Upper	Treatment by subgroup interaction p-value [3]
										1.0000
UIP-like pattern only										
Placebo	23	3	13.0	20	87.0	0.8674				
Nintedanib	45	6	13.3	39	86.7	0.8624	1.05	0.26	4.20	
Other fibrotic patterns										
Placebo	4	0	0.0	4	100.0	1.0000				
Nintedanib	9	0	0.0	9	100.0	1.0000	NC	-	-	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment
[3] Based on a Cox regression model with terms for treatment, subgroup and treatment by subgroup

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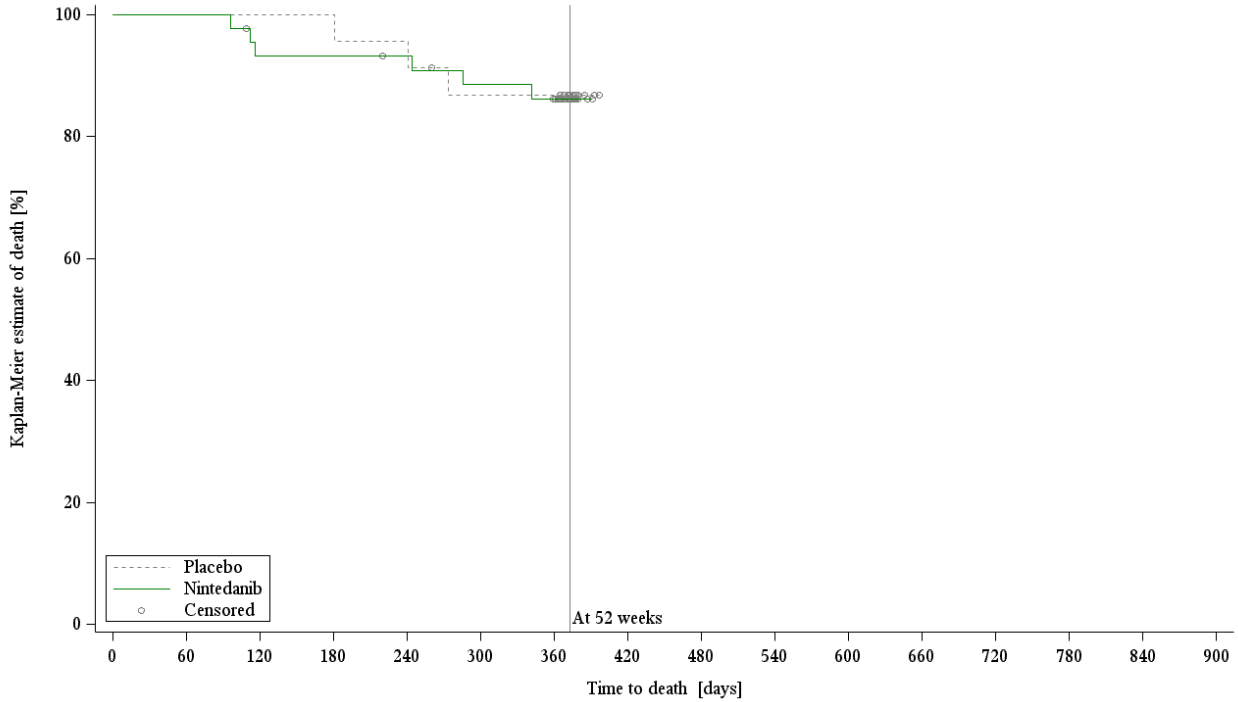

Number at risk

Placebo	23	23	23	23	22	19	19	0	0	0	0	0	0	0	0	0
Nintedanib	45	45	41	41	40	38	36	0	0	0	0	0	0	0	0	0

Figure 2.4.2 Kaplan Meier Plot of time to death over the whole trial by HRCT pattern - Treated set

HRCT pattern: UIP-like pattern only

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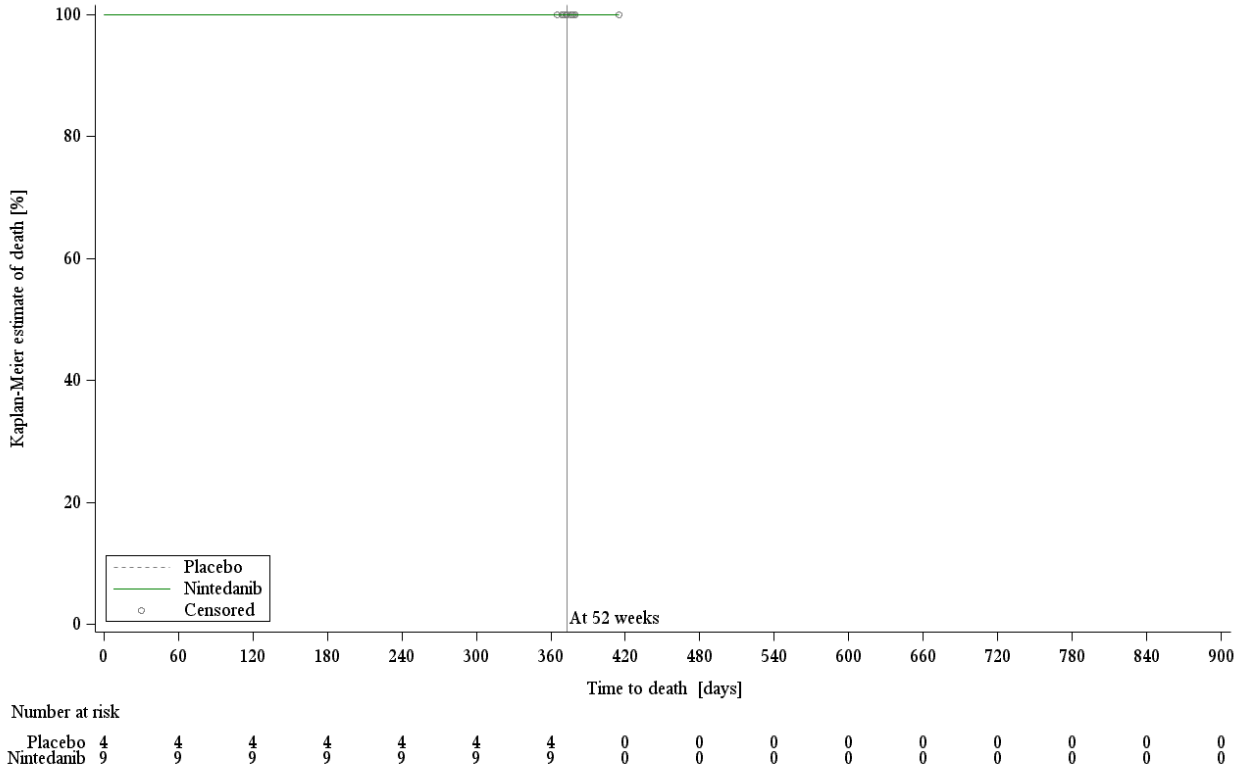

Figure 2.4.2 Kaplan Meier Plot of time to death over the whole trial by HRCT pattern - Treated set

HRCT pattern: Other fibrotic patterns

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Table 2.4.3 Time to first acute ILD exacerbation or death over the whole trial by HRCT pattern - Treated Set

HRCT pattern/ Treatment	Number at risk [1]	Failure: Number Failed	Failure: %	Censored: Number Censored	Censored: %	Probability of survival	Comparison vs Placebo: Hazard ratio [2]	95% confidence interval: Lower	95% confidence interval: Upper	Treatment by subgroup interaction p-value [3]
										0.9933
UIP-like pattern only										
Placebo	23	7	30.4	16	69.6	0.6884				
Nintedanib	45	7	15.6	38	84.4	0.8391	0.49	0.17	1.40	
Other fibrotic patterns										
Placebo	4	0	0.0	4	100.0	1.0000				
Nintedanib	9	3	33.3	6	66.7	0.6667	NC	-	-	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment
[3] Based on a Cox regression model with terms for treatment, subgroup and treatment by subgroup

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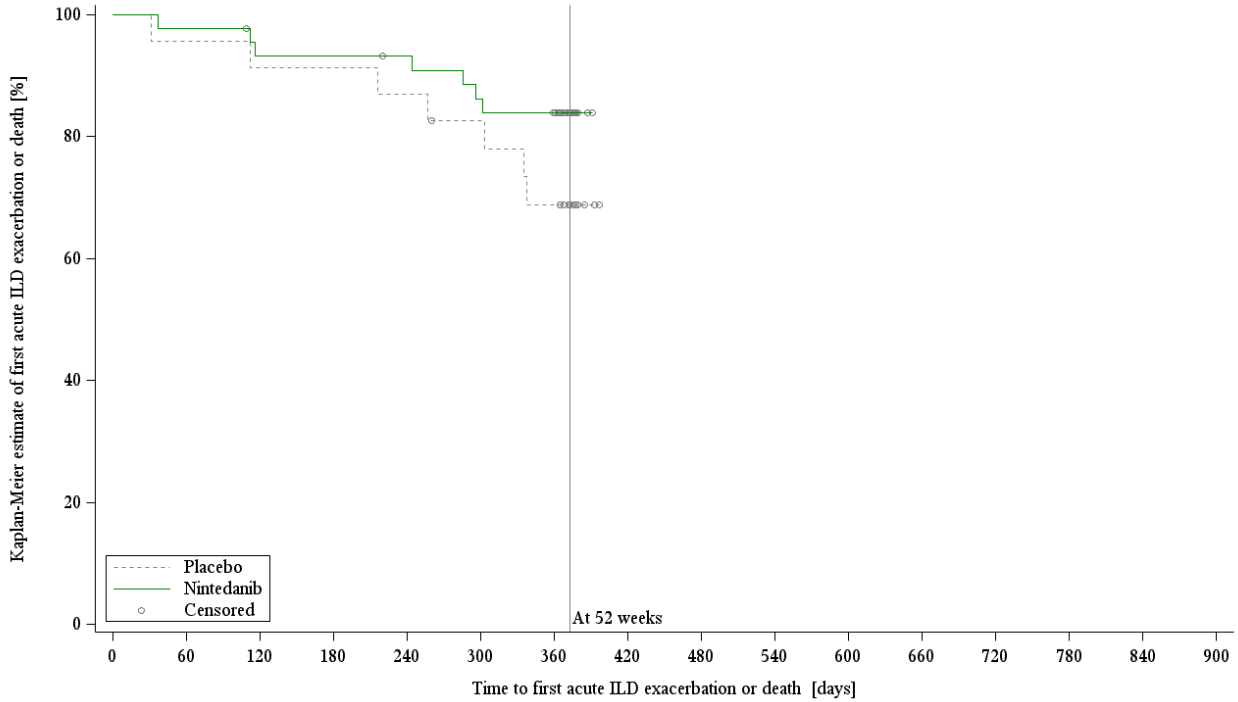

Number at risk

Placebo	23	22	21	21	20	18	15	0	0	0	0	0	0	0	0	0
Nintedanib	45	44	41	41	40	37	35	0	0	0	0	0	0	0	0	0

Figure 2.4.4 Kaplan Meier Plot of time to first acute ILD exacerbation or death over the whole trial by HRCT pattern - Treated Set Overall Population

HRCT pattern: UIP-like pattern only

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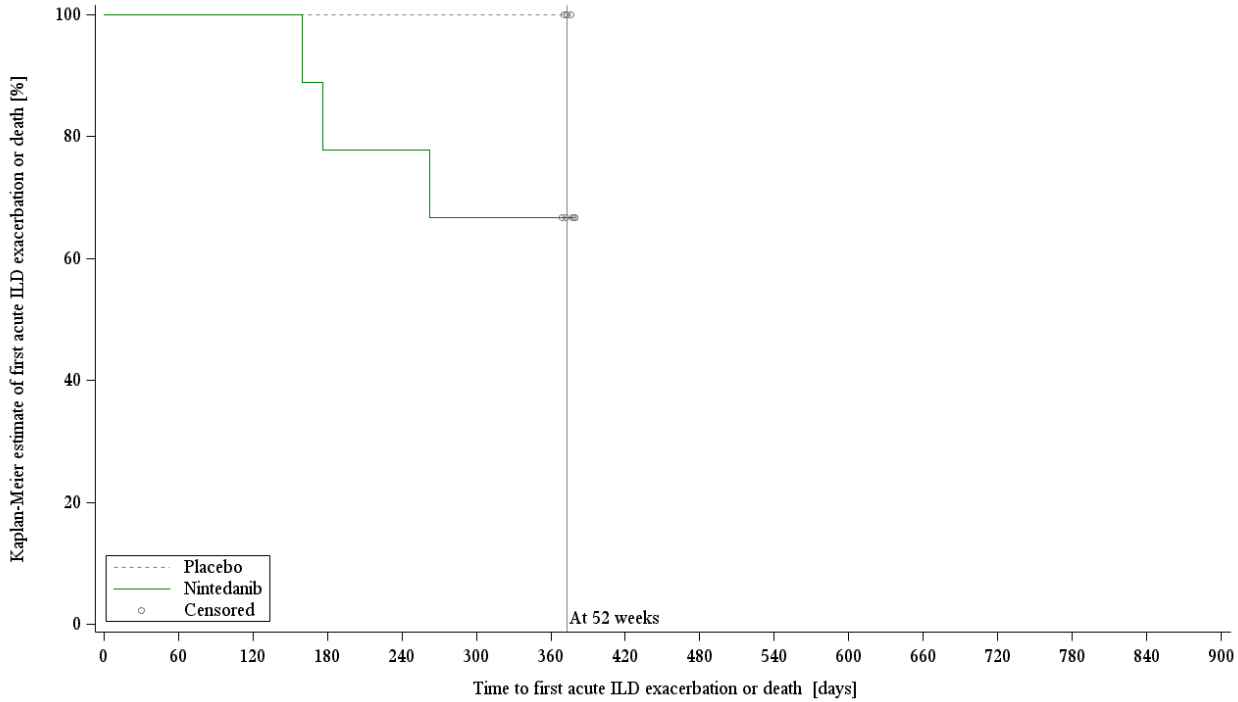

Figure 2.4.4 Kaplan Meier Plot of time to first acute ILD exacerbation or death over the whole trial by HRCT pattern - Treated Set Overall Population

HRCT pattern: Other fibrotic patterns

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Table 2.4.5 Time to first acute ILD exacerbation over the whole trial by HRCT pattern - Treated Set

HRCT pattern/ Treatment	Number at risk [1]	Failure: Number Failed	Failure: %	Censored: Number Censored	Censored: %	Probability of survival	Comparison vs Placebo: Hazard ratio [2]	95% confidence interval: Lower	95% confidence interval: Upper	Treatment by subgroup interaction p-value [3]
										0.9912
UIP-like pattern only										
Placebo	23	7	30.4	16	69.6	0.6884				
Nintedanib	45	3	6.7	42	93.3	0.9263	0.21	0.05	0.82	
Other fibrotic patterns										
Placebo	4	0	0.0	4	100.0	1.0000				
Nintedanib	9	3	33.3	6	66.7	0.6667	NC	-	-	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment
[3] Based on a Cox regression model with terms for treatment, subgroup and treatment by subgroup

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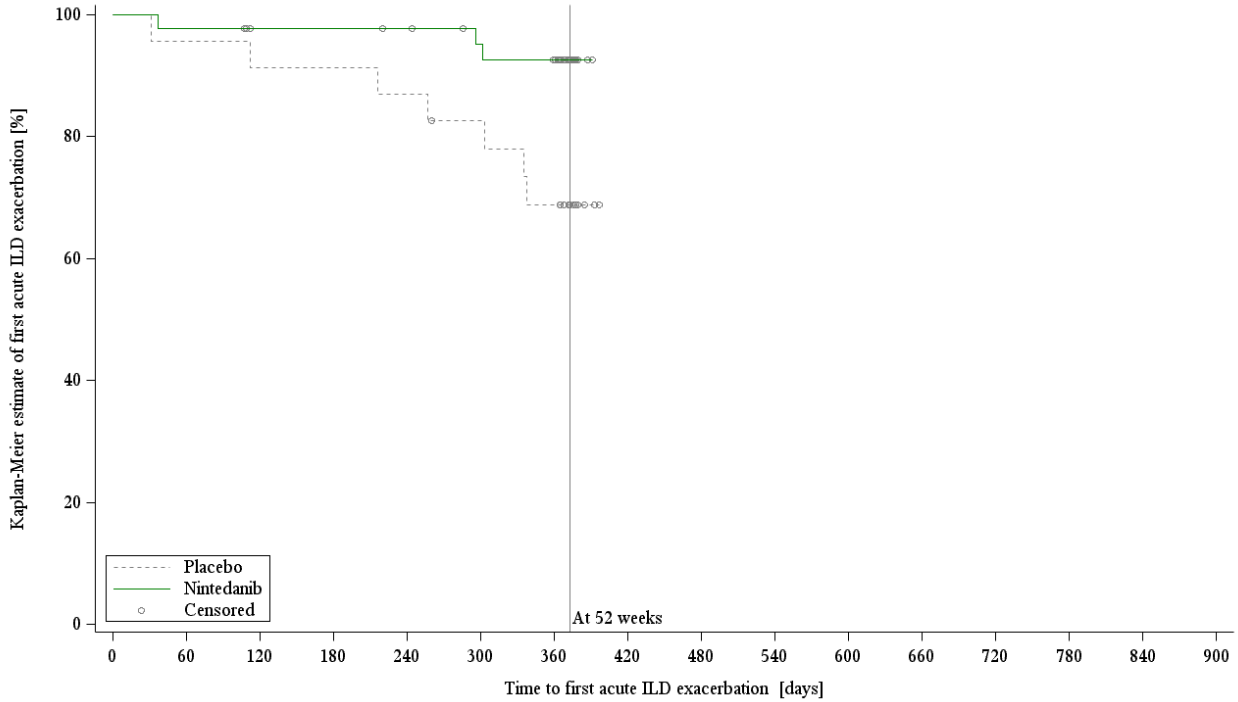

Figure 2.4.6 Kaplan Meier Plot of time to first acute ILD exacerbation over the whole trial by HRCT pattern - Treated Set Overall Population

HRCT pattern: UIP-like pattern only

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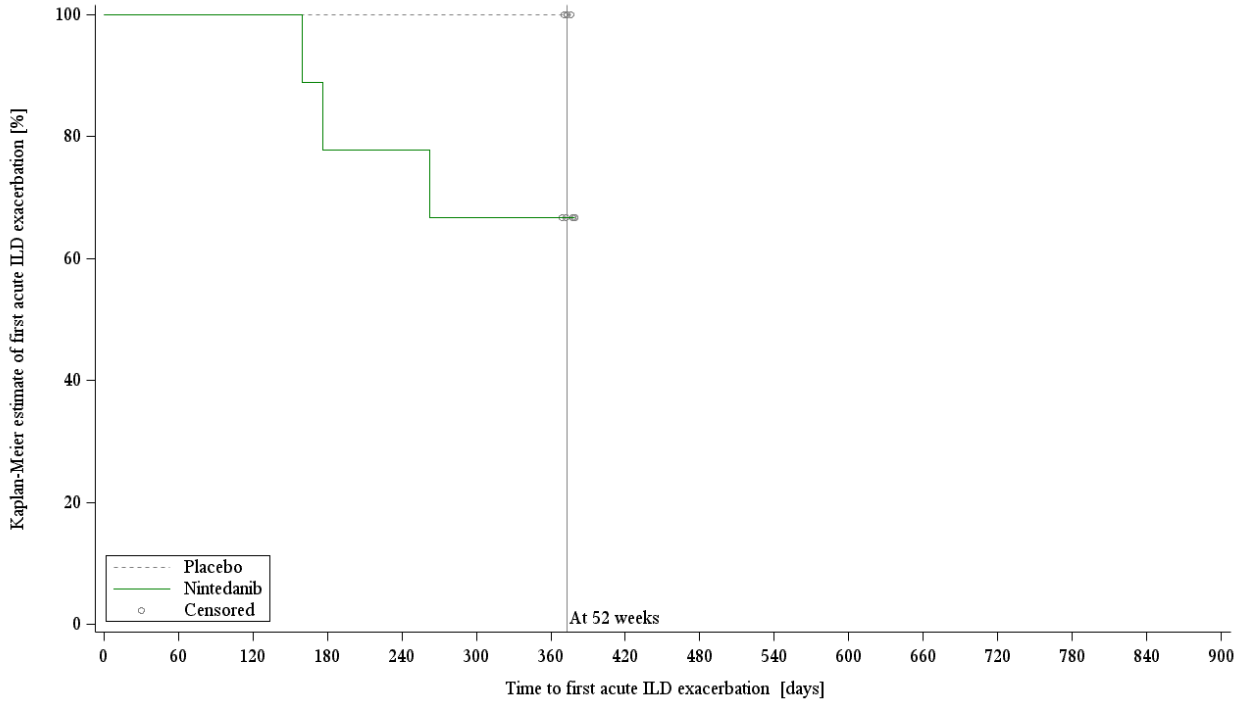

Figure 2.4.6 Kaplan Meier Plot of time to first acute ILD exacerbation over the whole trial by HRCT pattern - Treated Set Overall Population

HRCT pattern: Other fibrotic patterns

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1.2.5 Time to event analyses - Subgroup Baseline FVC % predicted (<=70% / >70%)

Table 2.5.1 Time to death over the whole trial by baseline FVC % predicted - Treated set

Baseline FVC % predicted/ Treatment	Number at risk [1]	Failure Number Failed	Failure %	Censored Number Censored	Censored %	Probability of survival	Comparison vs Placebo Hazard ratio [2]	95% confidence interval Lower	95% confidence interval Upper	Treatment by subgroup interaction p-value [3]
										0.8686
<=70%										
Placebo	10	2	20.0	8	80.0	0.8000				
Nintedanib	17	4	23.5	13	76.5	0.7647	0.87	0.16	4.77	
>70%										
Placebo	17	1	5.9	16	94.1	0.9412				
Nintedanib	37	2	5.4	35	94.6	0.9436	1.13	0.10	12.41	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment stratified by HRCT pattern
[3] Based on a Cox regression model with terms for treatment, subgroup and treatment by subgroup, stratified by HRCT pattern

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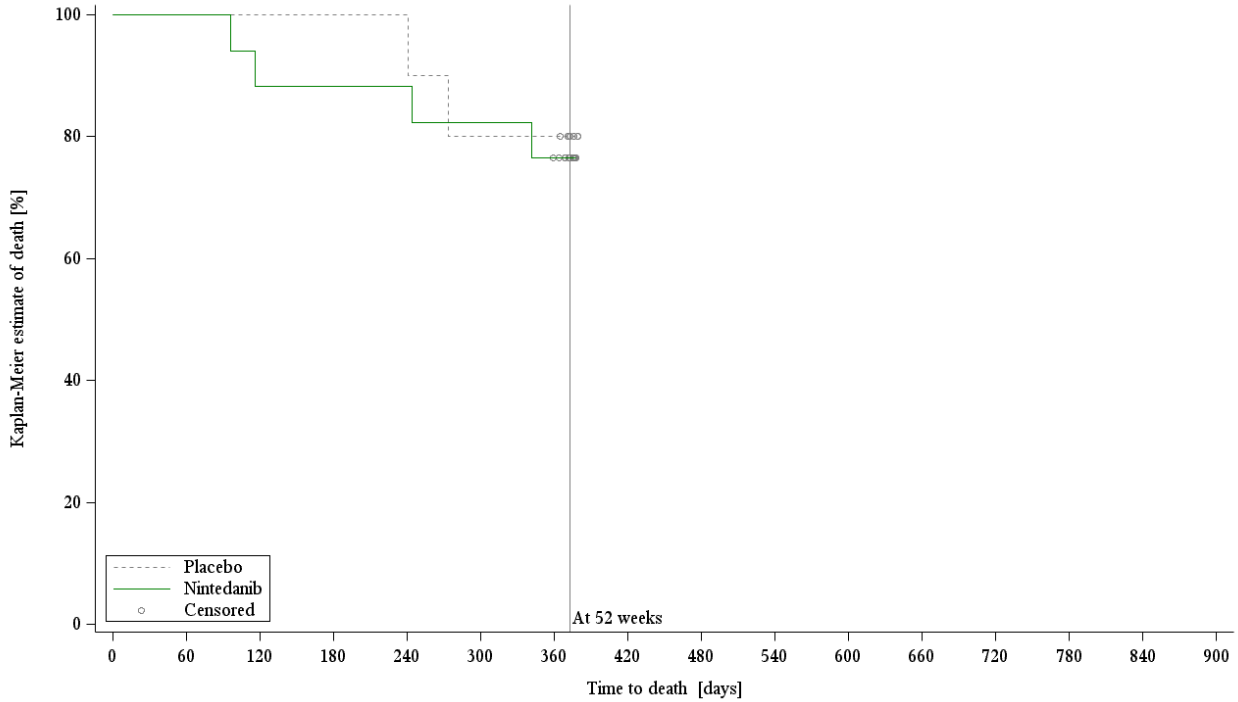

Figure 2.5.2 Kaplan Meier Plot of time to death over the whole trial by baseline FVC % predicted - Treated set

Baseline FVC % predicted: <=70%

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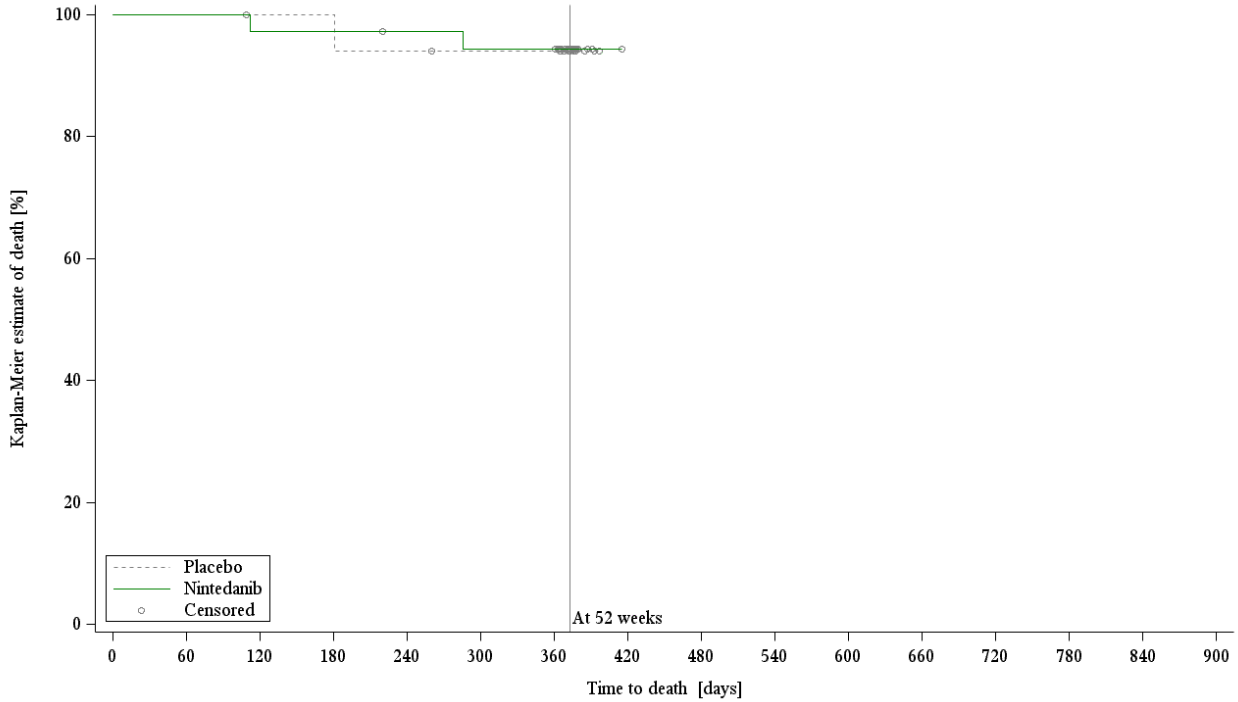

Number at risk

Placebo	17	17	17	17	16	15	15	0	0	0	0	0	0	0	0	0
Nintedanib	37	37	35	35	34	33	33	0	0	0	0	0	0	0	0	0

Figure 2.5.2 Kaplan Meier Plot of time to death over the whole trial by baseline FVC % predicted - Treated set

Baseline FVC % predicted: >70%

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Table 2.5.3 Time to first acute ILD exacerbation or death over the whole trial by baseline FVC % predicted - Treated Set

Baseline FVC % predicted/ Treatment	Number at risk [1]	Failure: Number Failed	Failure: %	Censored: Number Censored	Censored: %	Probability of survival	Comparison vs Placebo: Hazard ratio [2]	95% confidence interval: Lower	95% confidence interval: Upper	Treatment by subgroup interaction p-value [3]
										0.8590
<=70%										
Placebo	10	4	40.0	6	60.0	0.6000				
Nintedanib	17	6	35.3	11	64.7	0.6471	0.60	0.17	2.20	
>70%										
Placebo	17	3	17.6	14	82.4	0.8157				
Nintedanib	37	4	10.8	33	89.2	0.8872	0.37	0.06	2.19	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment stratified by HRCT pattern
[3] Based on a Cox regression model with terms for treatment, subgroup and treatment by subgroup, stratified by HRCT pattern

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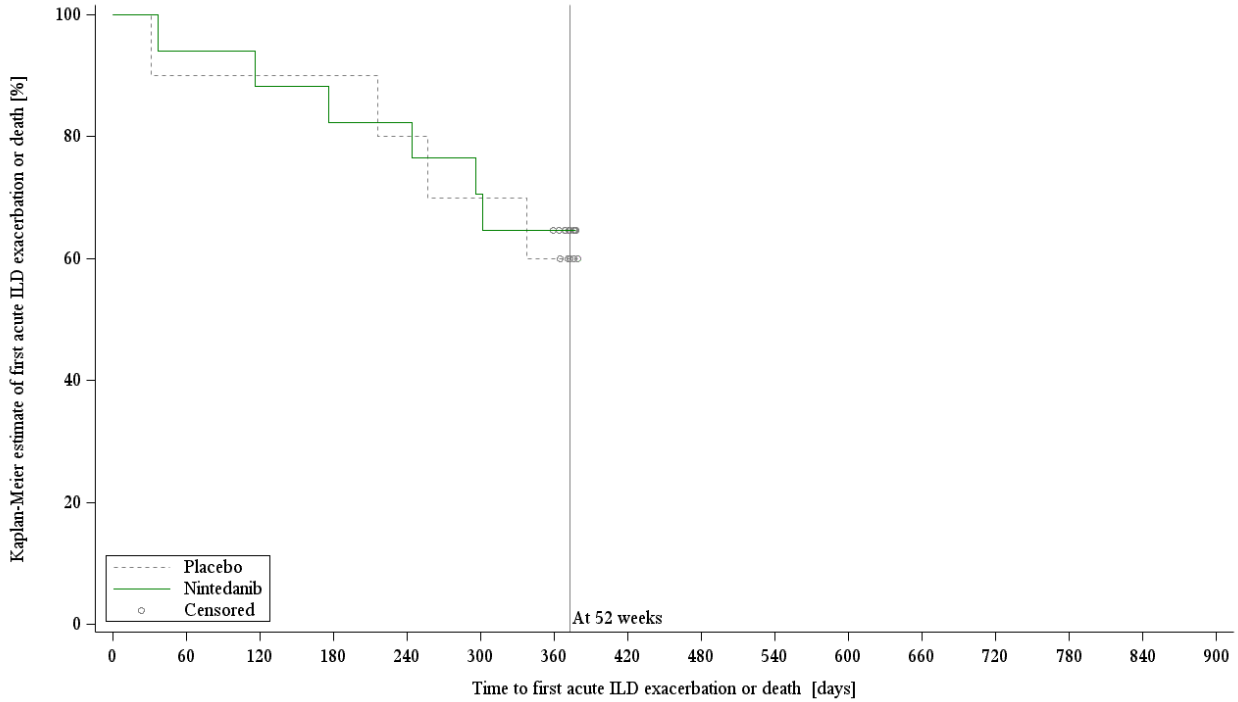

Number at risk

Placebo	10	9	9	9	8	7	6	0	0	0	0	0	0	0	0	0
Nintedanib	17	16	15	14	14	12	10	0	0	0	0	0	0	0	0	0

Figure 2.5.4 Kaplan Meier Plot of time to first acute ILD exacerbation or death over the whole trial by baseline FVC % predicted - Treated Set

Baseline FVC % predicted: <=70%

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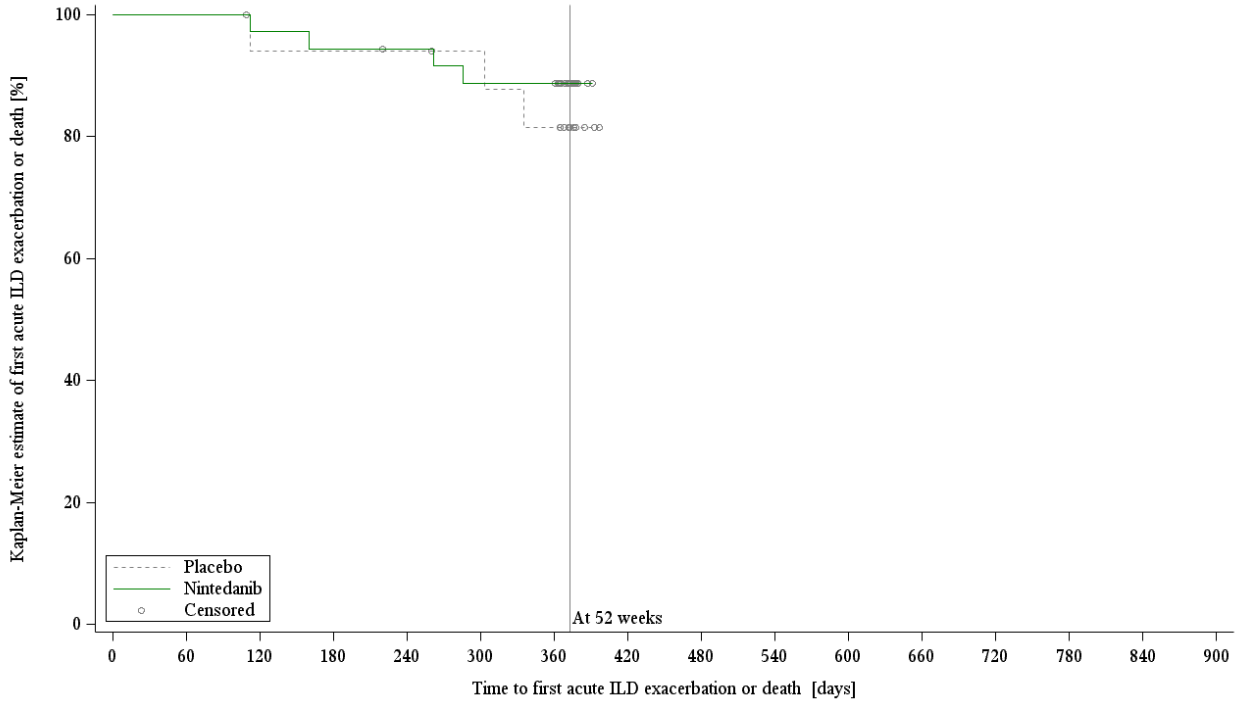

Number at risk

Placebo	17	17	16	16	16	15	13	0	0	0	0	0	0	0	0	0
Nintedanib	37	37	35	34	33	31	31	0	0	0	0	0	0	0	0	0

Figure 2.5.4 Kaplan Meier Plot of time to first acute ILD exacerbation or death over the whole trial by baseline FVC % predicted - Treated Set

Baseline FVC % predicted: >70%

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Table 2.5.5 Time to first acute ILD exacerbation over the whole trial by baseline FVC % predicted - Treated Set

Baseline FVC % predicted/ Treatment	Number at risk [1]	Failure Number Failed	Failure %	Censored Number Censored	Censored %	Probability of survival	Comparison vs Placebo Hazard ratio [2]	95% confidence interval Lower	95% confidence interval Upper	Treatment by subgroup interaction p-value [3]
										0.6111
<=70%										
Placebo	10	4	40.0	6	60.0	0.6000				
Nintedanib	17	4	23.5	13	76.5	0.7433	0.41	0.10	1.68	
>70%										
Placebo	17	3	17.6	14	82.4	0.8157				
Nintedanib	37	2	5.4	35	94.6	0.9420	NC	-	-	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment stratified by HRCT pattern
[3] Based on a Cox regression model with terms for treatment, subgroup and treatment by subgroup, stratified by HRCT pattern

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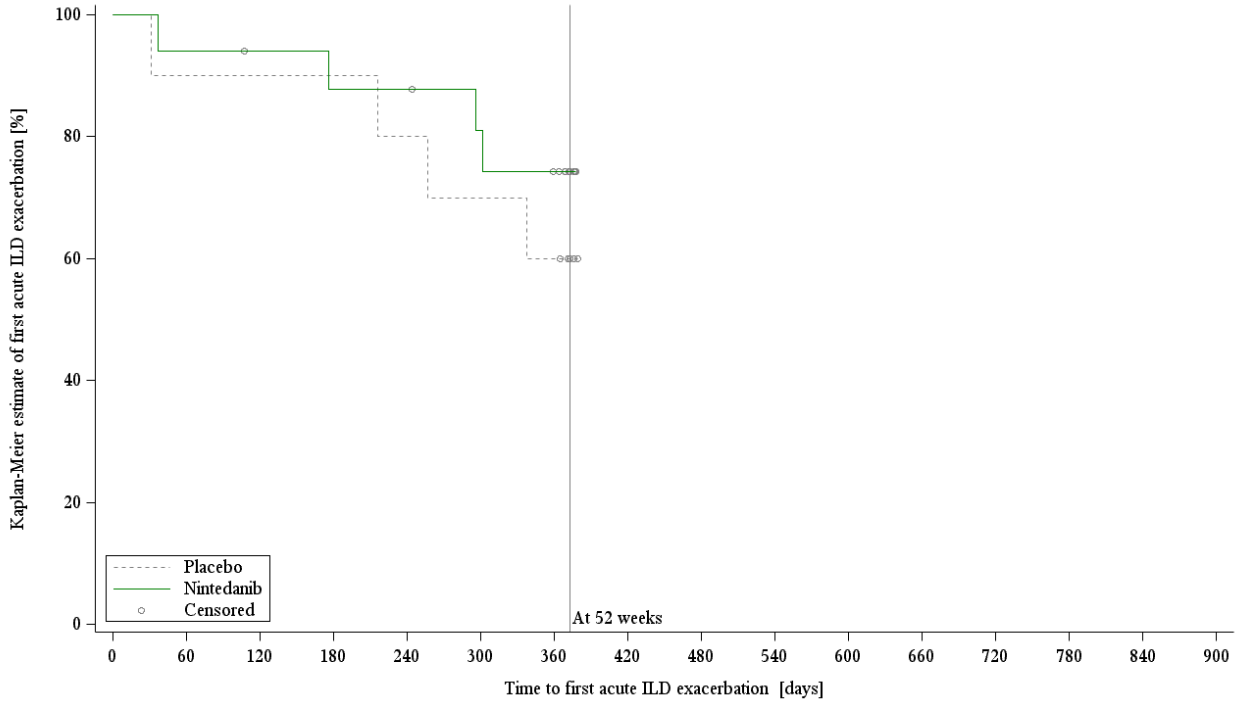

Figure 2.5.6 Kaplan Meier Plot of time to first acute ILD exacerbation over the whole trial by baseline FVC % predicted - Treated Set

Baseline FVC % predicted: <=70%

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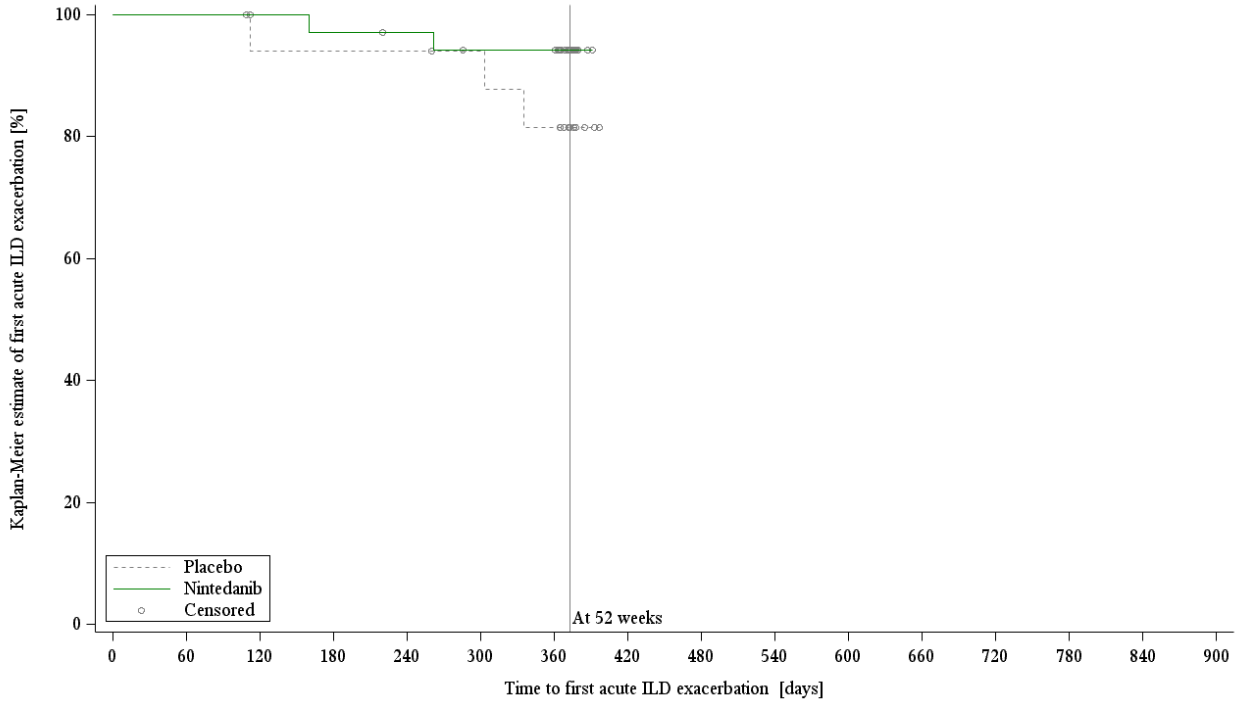

Figure 2.5.6 Kaplan Meier Plot of time to first acute ILD exacerbation over the whole trial by baseline FVC % predicted - Treated Set

Baseline FVC % predicted: >70%

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1.2.6 Time to event analyses - Subgroup Underlying clinical ILD diagnosis

Table 2.6.1 Time to death over the whole trial by underlying ILD diagnosis - Treated set

Underlying ILD Diagnosis in Groups/ Treatment	Number at risk [1]	Failure Number Failed	Failure %	Censored Number Censored	Censored %	Probability of survival	Comparison vs Placebo Hazard ratio [2]	95% confidence interval Lower	95% confidence interval Upper	Treatment by subgroup interaction p-value [3]
										1.0000
Hypersensitivity pneumonitis										
Placebo	0									
Nintedanib	1	0	0.0	1	100.0	1.0000	NC	-	-	
Idiopathic nonspecific interstitial pneumonia										
Placebo	7	1	14.3	6	85.7	0.8333				
Nintedanib	11	2	18.2	9	81.8	0.8182	1.19	0.11	13.16	
Unclassifiable idiopathic interstitial pneumonia										
Placebo	3	1	33.3	2	66.7	0.6667				
Nintedanib	2	0	0.0	2	100.0	1.0000	NC	-	-	
Autoimmune ILDs										
Placebo	12	0	0.0	12	100.0	1.0000				
Nintedanib	34	4	11.8	30	88.2	0.8768	NC	-	-	
Other ILDs										
Placebo	5	1	20.0	4	80.0	0.8000				
Nintedanib	6	0	0.0	6	100.0	1.0000	NC	-	-	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment stratified by HRCT pattern
[3] Based on a Cox regression model with terms for treatment, subgroup and treatment by subgroup, stratified by HRCT pattern

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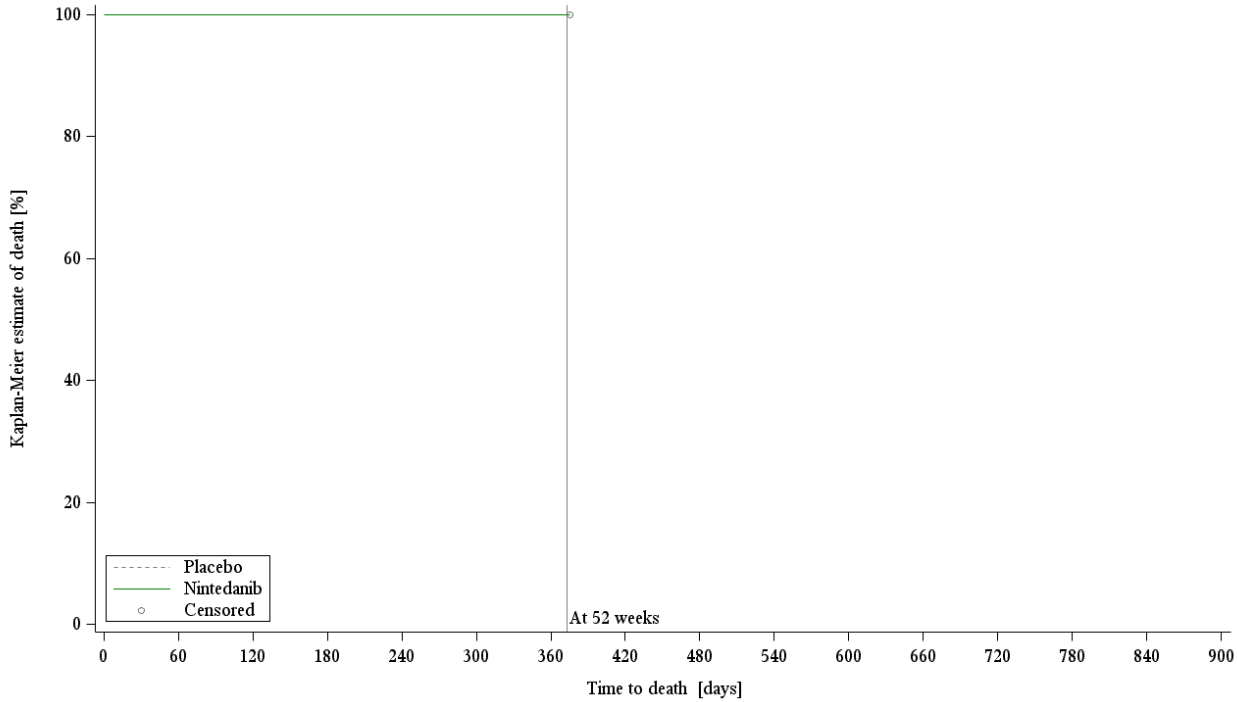

Figure 2.6.2 Kaplan Meier Plot of time to death over the whole trial by underlying ILD diagnosis - Treated set

Underlying ILD Diagnosis in Groups: Hypersensitivity pneumonitis

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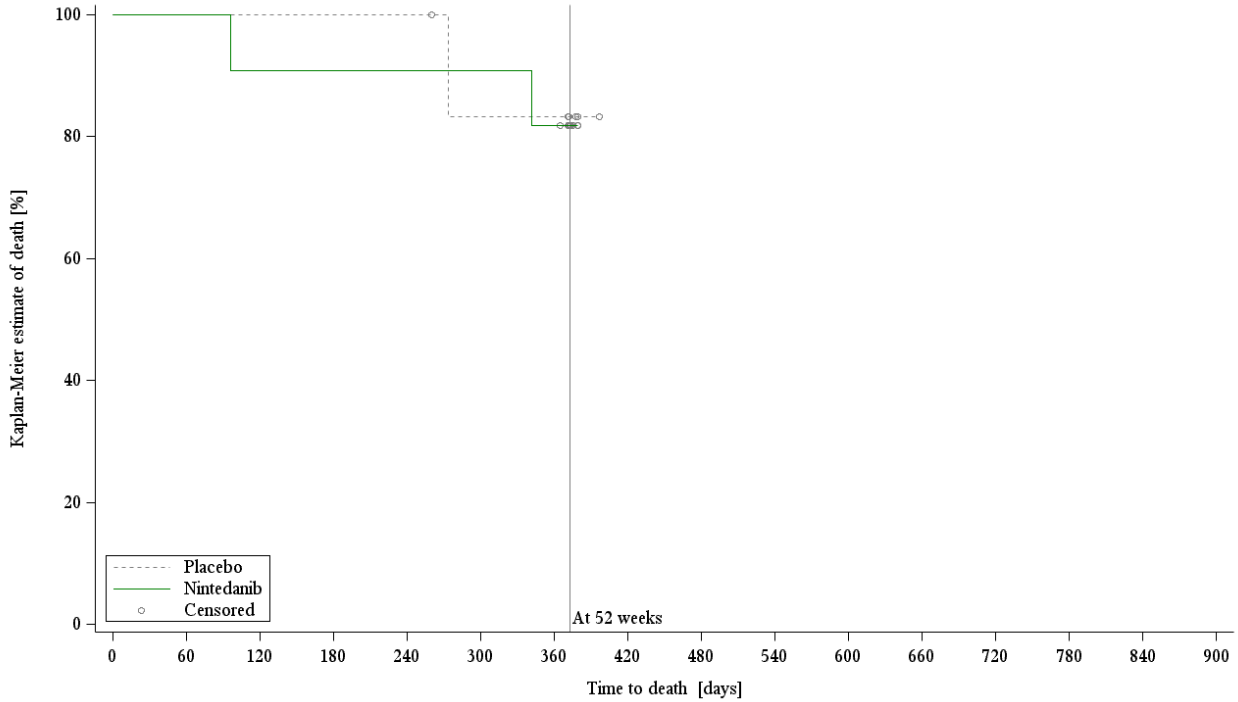

Figure 2.6.2 Kaplan Meier Plot of time to death over the whole trial by underlying ILD diagnosis - Treated set

Underlying ILD Diagnosis in Groups: Idiopathic nonspecific interstitial pneumonia

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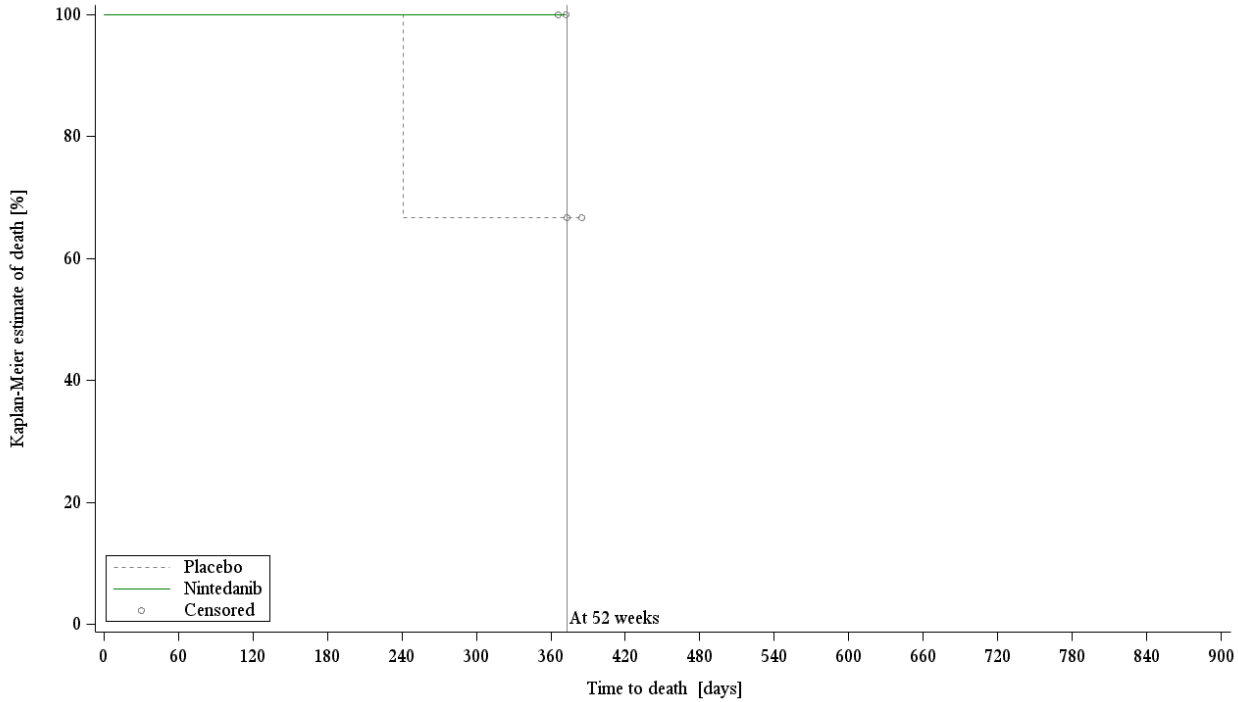

Figure 2.6.2 Kaplan Meier Plot of time to death over the whole trial by underlying ILD diagnosis - Treated set

Underlying ILD Diagnosis in Groups: Unclassifiable idiopathic interstitial pneumonia

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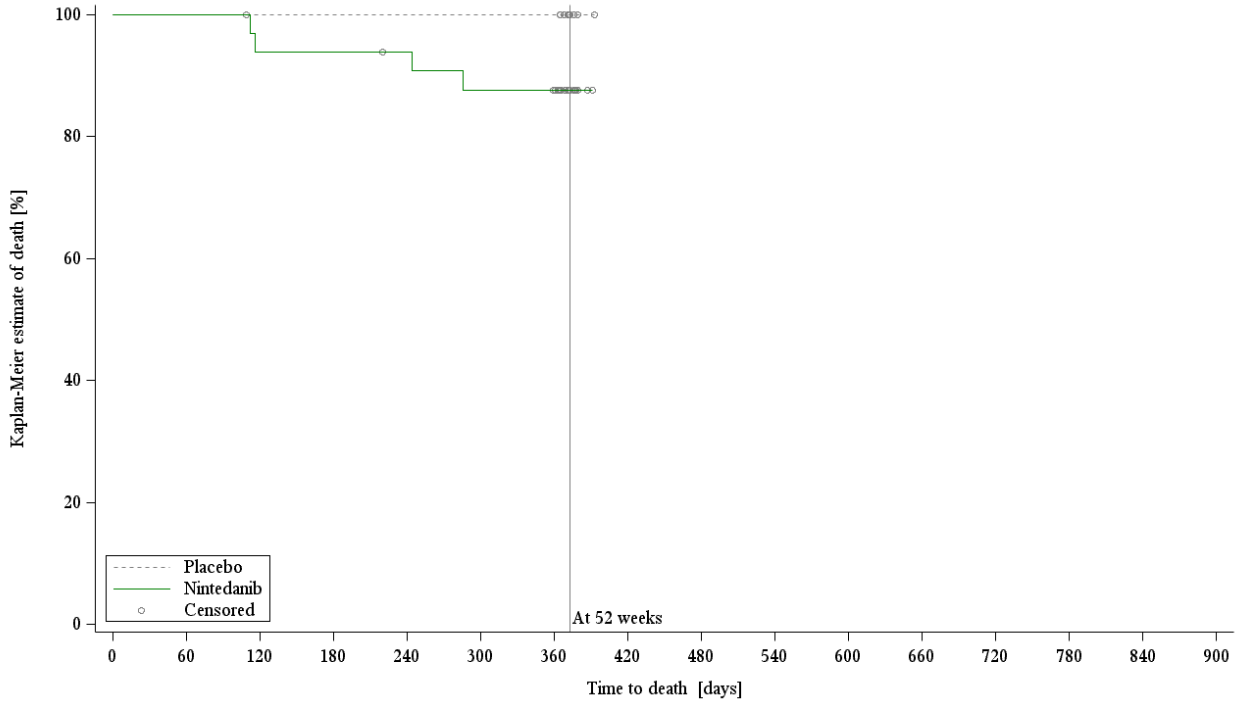

Number at risk

Placebo	12	12	12	12	12	12	12	0	0	0	0	0	0	0	0	0
Nintedanib	34	34	31	31	30	28	27	0	0	0	0	0	0	0	0	0

Figure 2.6.2 Kaplan Meier Plot of time to death over the whole trial by underlying ILD diagnosis - Treated set

Underlying ILD Diagnosis in Groups: Autoimmune ILDs

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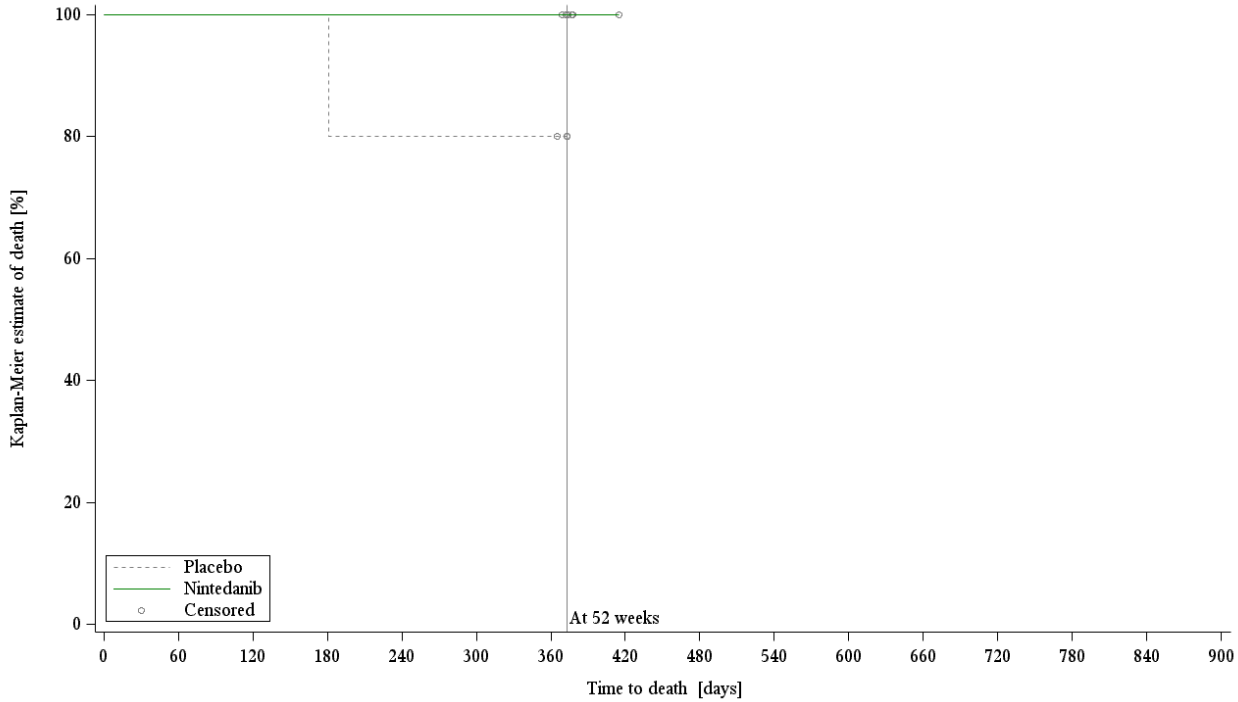

Figure 2.6.2 Kaplan Meier Plot of time to death over the whole trial by underlying ILD diagnosis - Treated set

Underlying ILD Diagnosis in Groups: Other ILDs

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Table 2.6.3 Time to first acute ILD exacerbation or death over the whole trial by underlying ILD diagnosis - Treated Set

Underlying ILD Diagnosis in Groups/ Treatment	Number at risk [1]	Failure Number Failed	Failure %	Censored Number Censored	Censored %	Probability of survival	Comparison vs Placebo Hazard ratio [2]	95% confidence interval Lower	95% confidence interval Upper	Treatment by subgroup interaction p-value [3]
										0.9935
Hypersensitivity pneumonitis										
Placebo	0									
Nintedanib	1	1	100.0	0	0.0	0	NC	-	-	
Idiopathic nonspecific interstitial pneumonia										
Placebo	7	2	28.6	5	71.4	0.6857				
Nintedanib	11	3	27.3	8	72.7	0.7273	0.83	0.14	5.00	
Unclassifiable idiopathic interstitial pneumonia										
Placebo	3	1	33.3	2	66.7	0.6667				
Nintedanib	2	0	0.0	2	100.0	1.0000	NC	-	-	
Autoimmune ILDs										
Placebo	12	3	25.0	9	75.0	0.7500				
Nintedanib	34	5	14.7	29	85.3	0.8464	0.64	0.15	2.72	
Other ILDs										
Placebo	5	1	20.0	4	80.0	0.8000				
Nintedanib	6	1	16.7	5	83.3	0.8333	0.87	0.05	13.95	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment stratified by HRCT pattern
[3] Based on a Cox regression model with terms for treatment, subgroup and treatment by subgroup, stratified by HRCT pattern

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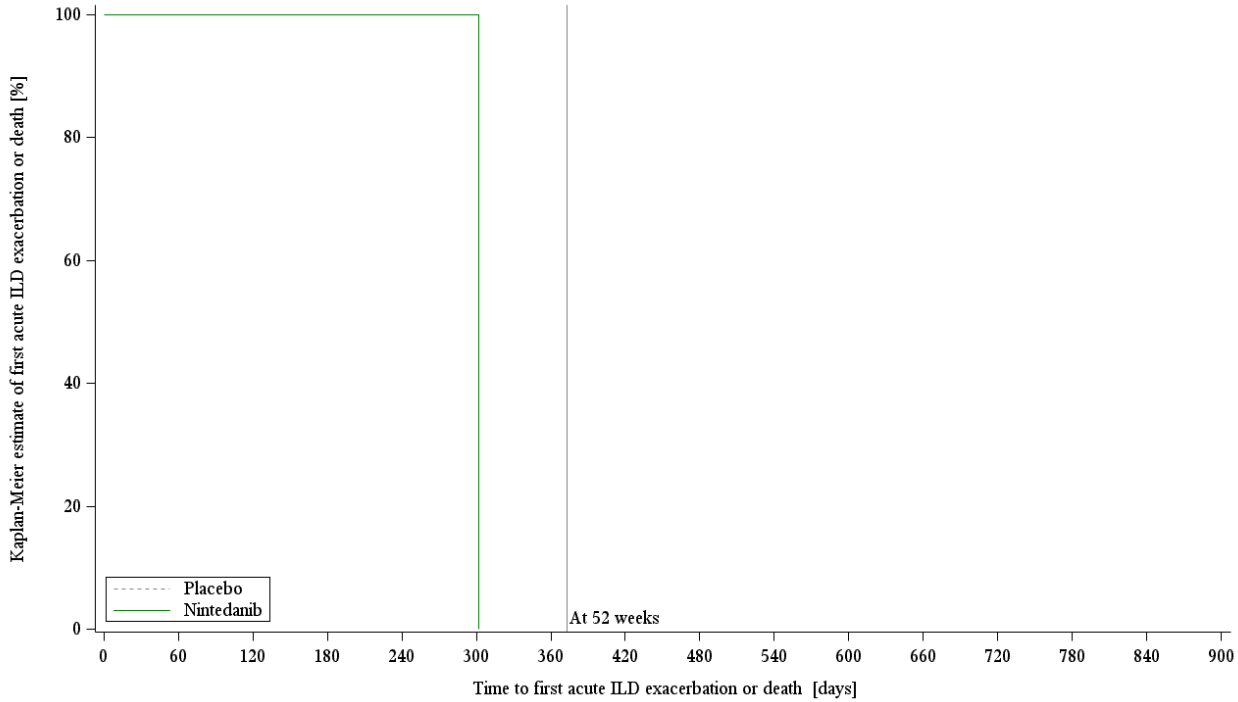

Figure 2.6.4 Kaplan Meier Plot of time to first acute ILD exacerbation or death over the whole trial by underlying ILD diagnosis - Treated Set

Underlying ILD Diagnosis in Groups: Hypersensitivity pneumonitis

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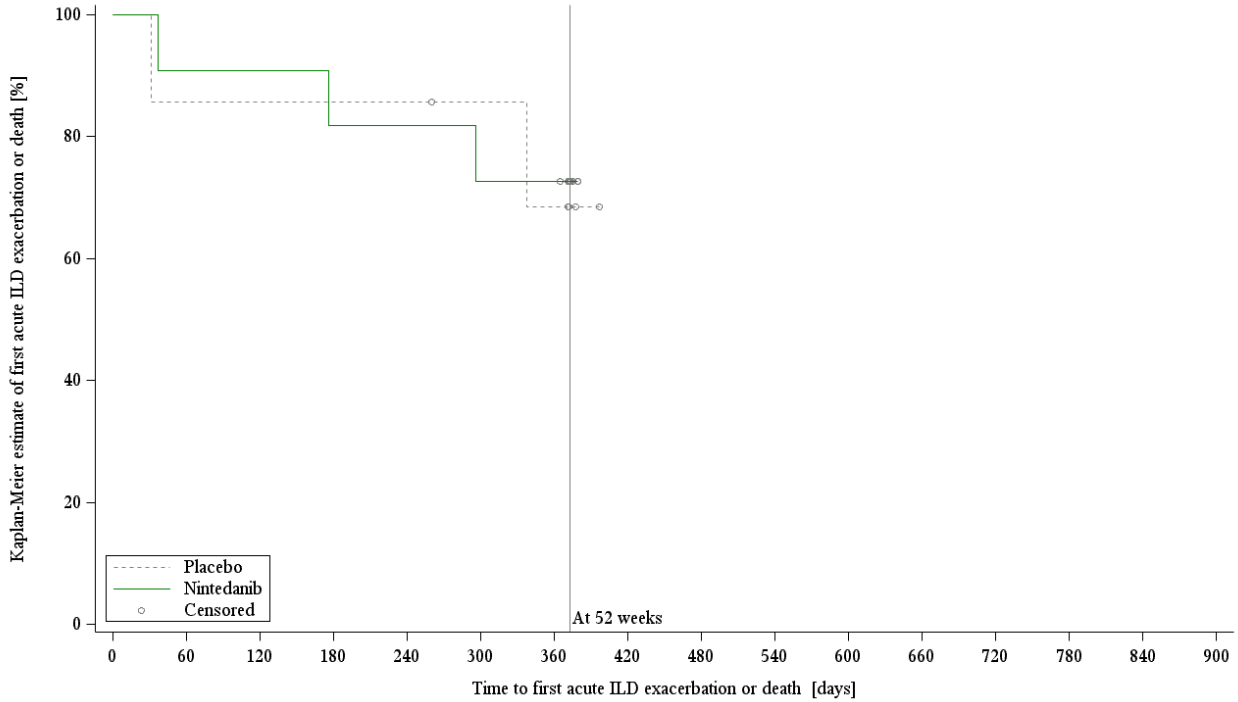

Figure 2.6.4 Kaplan Meier Plot of time to first acute ILD exacerbation or death over the whole trial by underlying ILD diagnosis - Treated Set

Underlying ILD Diagnosis in Groups: Idiopathic nonspecific interstitial pneumonia

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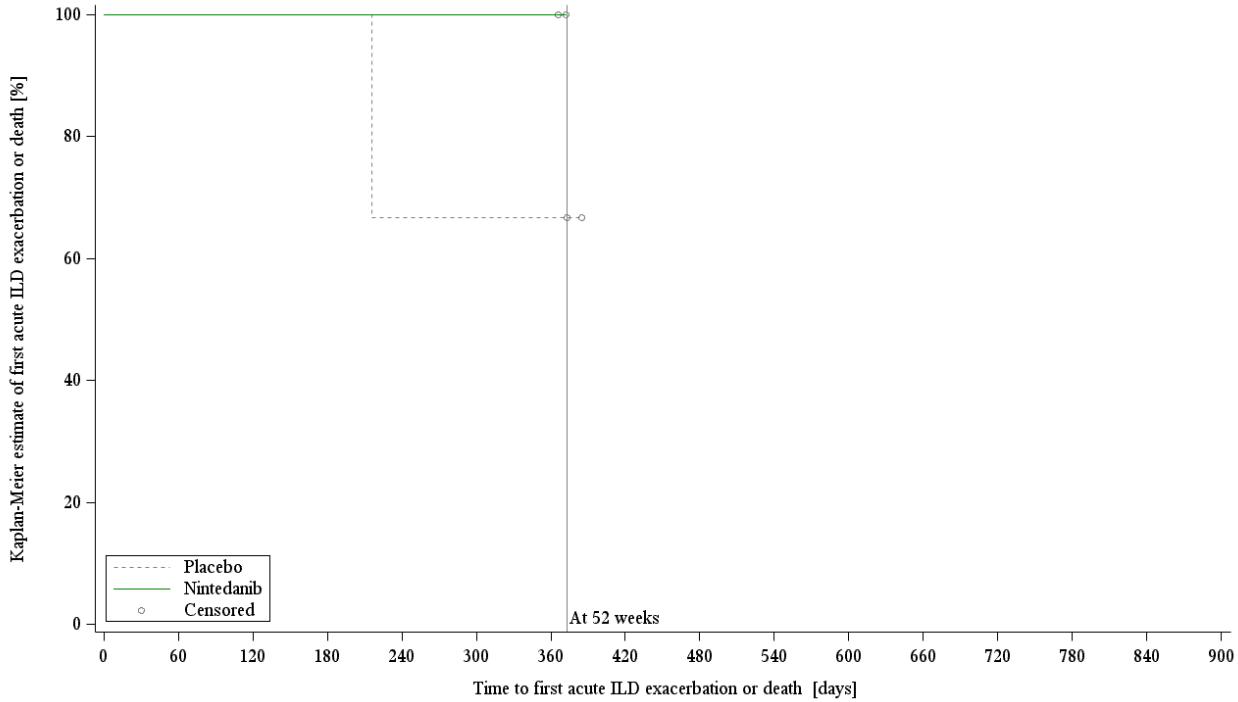

Figure 2.6.4 Kaplan Meier Plot of time to first acute ILD exacerbation or death over the whole trial by underlying ILD diagnosis - Treated Set

Underlying ILD Diagnosis in Groups: Unclassifiable idiopathic interstitial pneumonia

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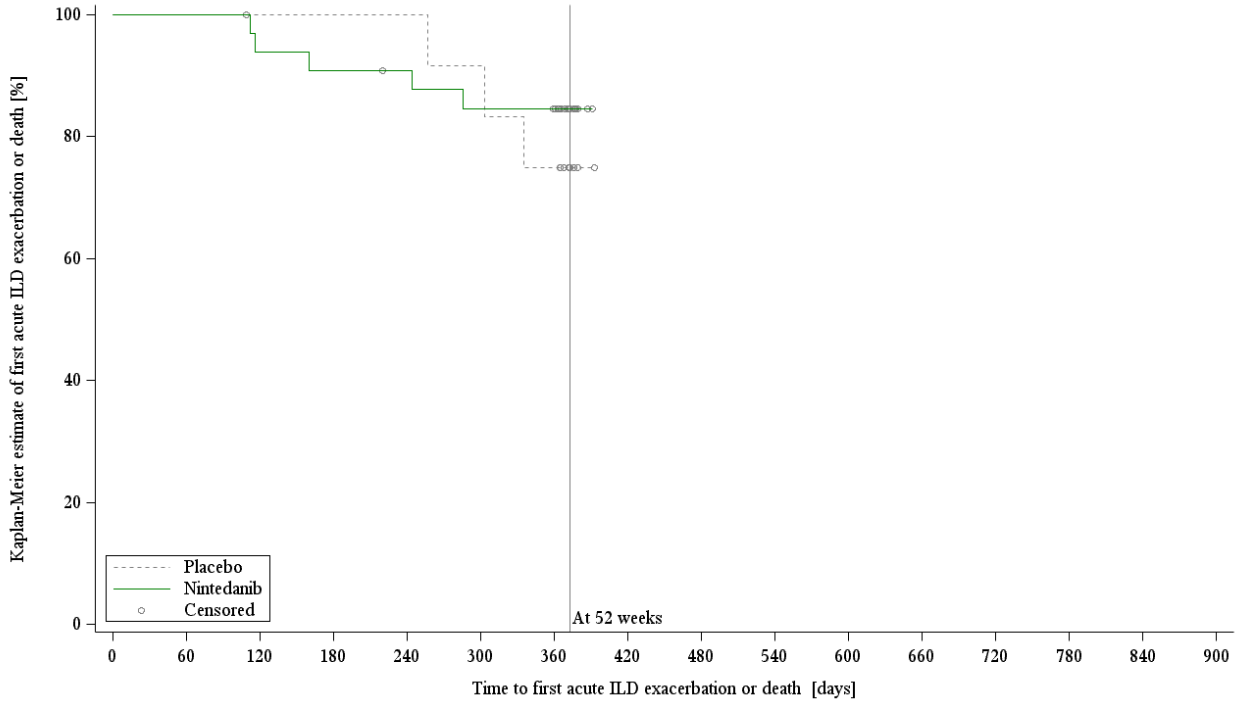

Figure 2.6.4 Kaplan Meier Plot of time to first acute ILD exacerbation or death over the whole trial by underlying ILD diagnosis - Treated Set

Underlying ILD Diagnosis in Groups: Autoimmune ILDs

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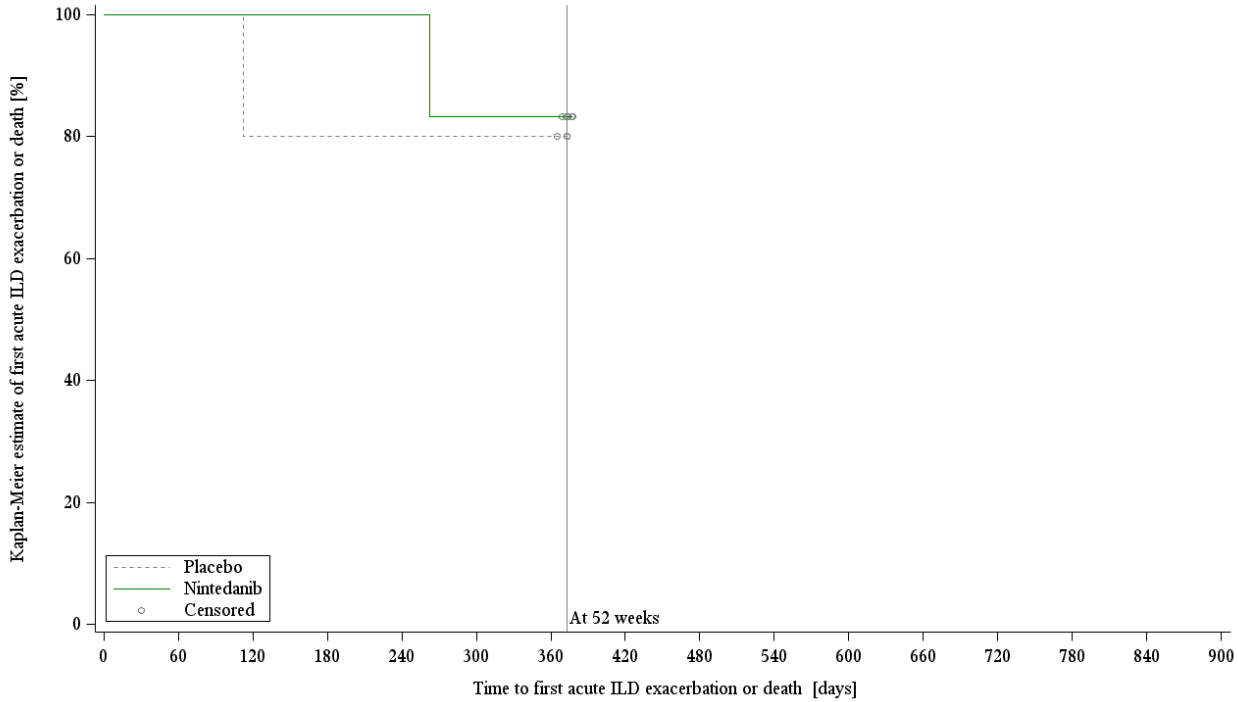

Figure 2.6.4 Kaplan Meier Plot of time to first acute ILD exacerbation or death over the whole trial by underlying ILD diagnosis - Treated Set

Underlying ILD Diagnosis in Groups: Other ILDs

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Table 2.6.5 Time to first acute ILD exacerbation over the whole trial by underlying ILD diagnosis - Treated Set

Underlying ILD Diagnosis in Groups/ Treatment	Number at risk [1]	Failure Number Failed	Failure %	Censored Number Censored	Censored %	Probability of survival	Comparison vs Placebo Hazard ratio [2]	95% confidence interval Lower	95% confidence interval Upper	Treatment by subgroup interaction p-value [3]
										0.5830
Hypersensitivity pneumonitis										
Placebo	0									
Nintedanib	1	1	100.0	0	0.0	0	NC	-	-	
Idiopathic nonspecific interstitial pneumonia										
Placebo	7	2	28.6	5	71.4	0.6857				
Nintedanib	11	3	27.3	8	72.7	0.7273	0.83	0.14	5.00	
Unclassifiable idiopathic interstitial pneumonia										
Placebo	3	1	33.3	2	66.7	0.6667				
Nintedanib	2	0	0.0	2	100.0	1.0000	NC	-	-	
Autoimmune ILDs										
Placebo	12	3	25.0	9	75.0	0.7500				
Nintedanib	34	1	2.9	33	97.1	0.9677	0.11	0.01	1.13	
Other ILDs										
Placebo	5	1	20.0	4	80.0	0.8000				
Nintedanib	6	1	16.7	5	83.3	0.8333	0.87	0.05	13.95	

[1] Cumulative number of patients entering the respective time interval
[2] Based on Cox regression model with terms for treatment stratified by HRCT pattern
[3] Based on a Cox regression model with terms for treatment, subgroup and treatment by subgroup, stratified by HRCT pattern

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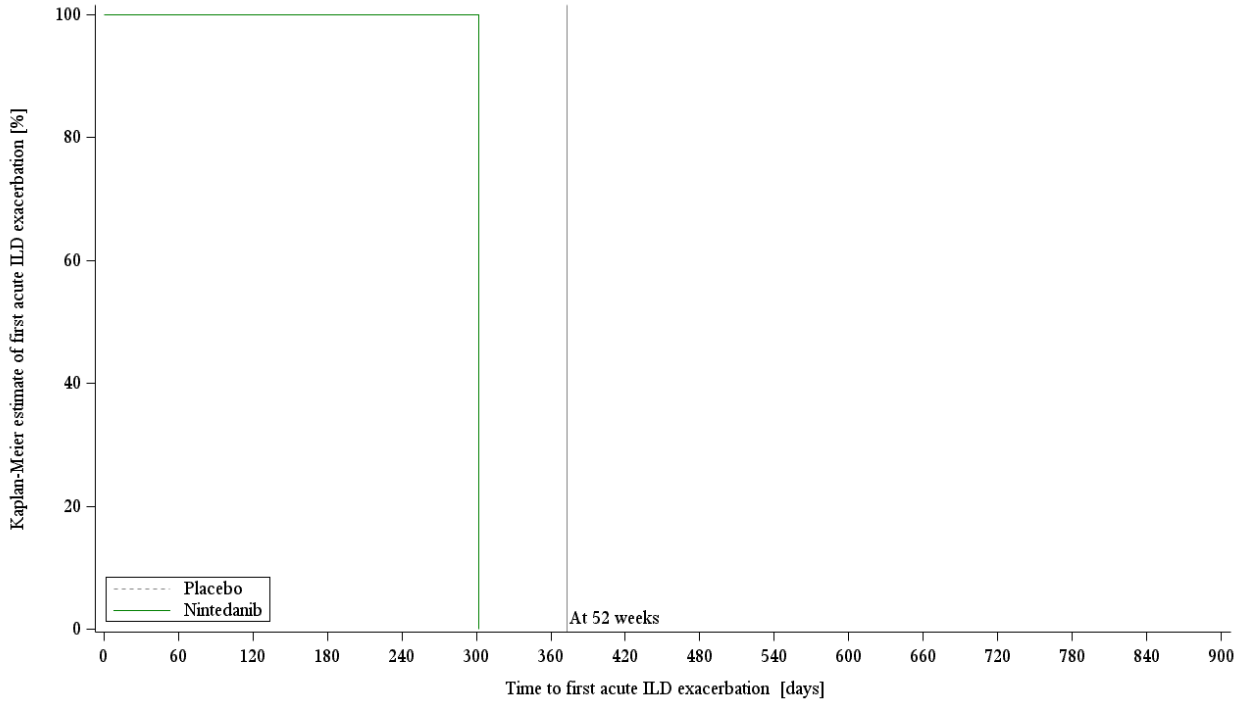

Figure 2.6.6 Kaplan Meier Plot of time to first acute ILD exacerbation over the whole trial by underlying ILD diagnosis - Treated Set

Underlying ILD Diagnosis in Groups: Hypersensitivity pneumonitis

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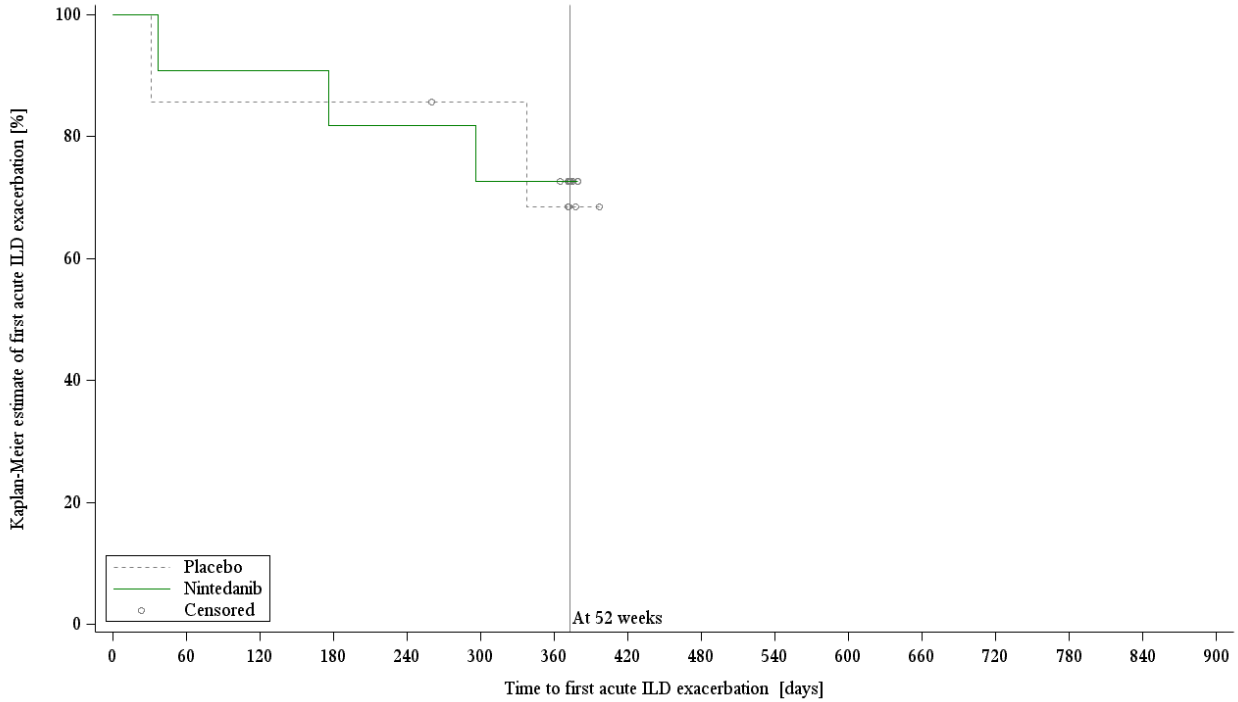

Figure 2.6.6 Kaplan Meier Plot of time to first acute ILD exacerbation over the whole trial by underlying ILD diagnosis - Treated Set

Underlying ILD Diagnosis in Groups: Idiopathic nonspecific interstitial pneumonia

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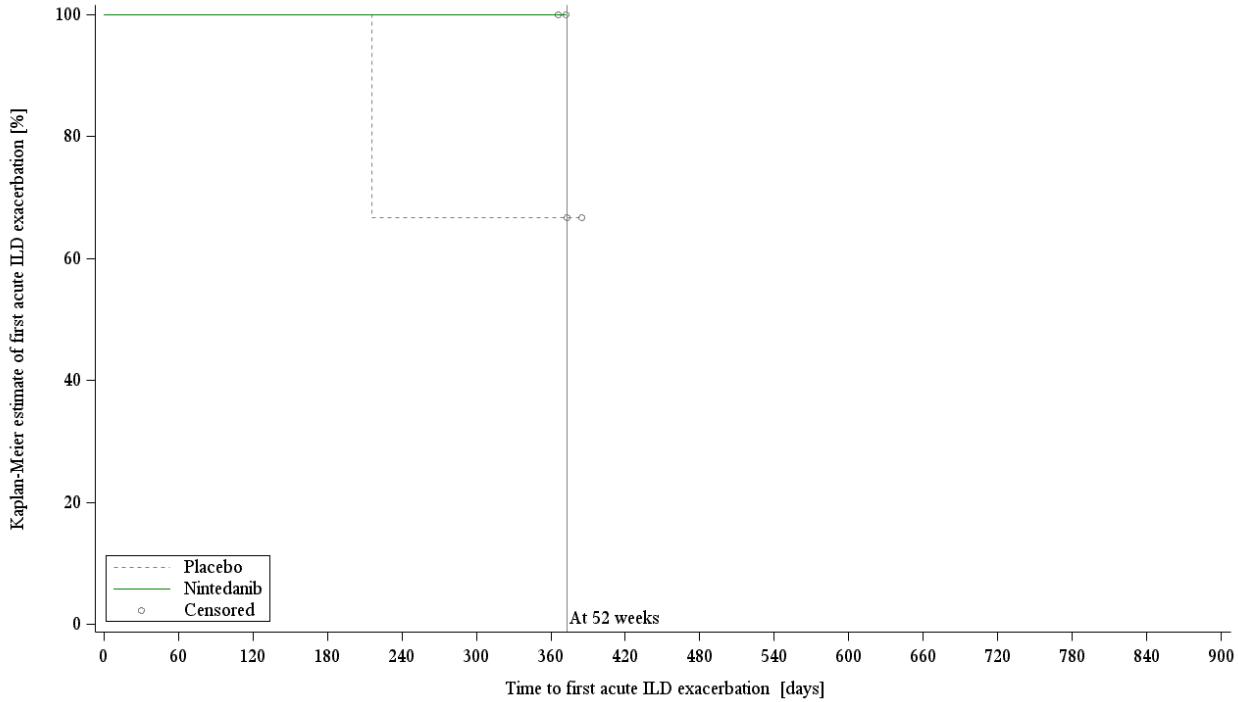

Figure 2.6.6 Kaplan Meier Plot of time to first acute ILD exacerbation over the whole trial by underlying ILD diagnosis - Treated Set

Underlying ILD Diagnosis in Groups: Unclassifiable idiopathic interstitial pneumonia

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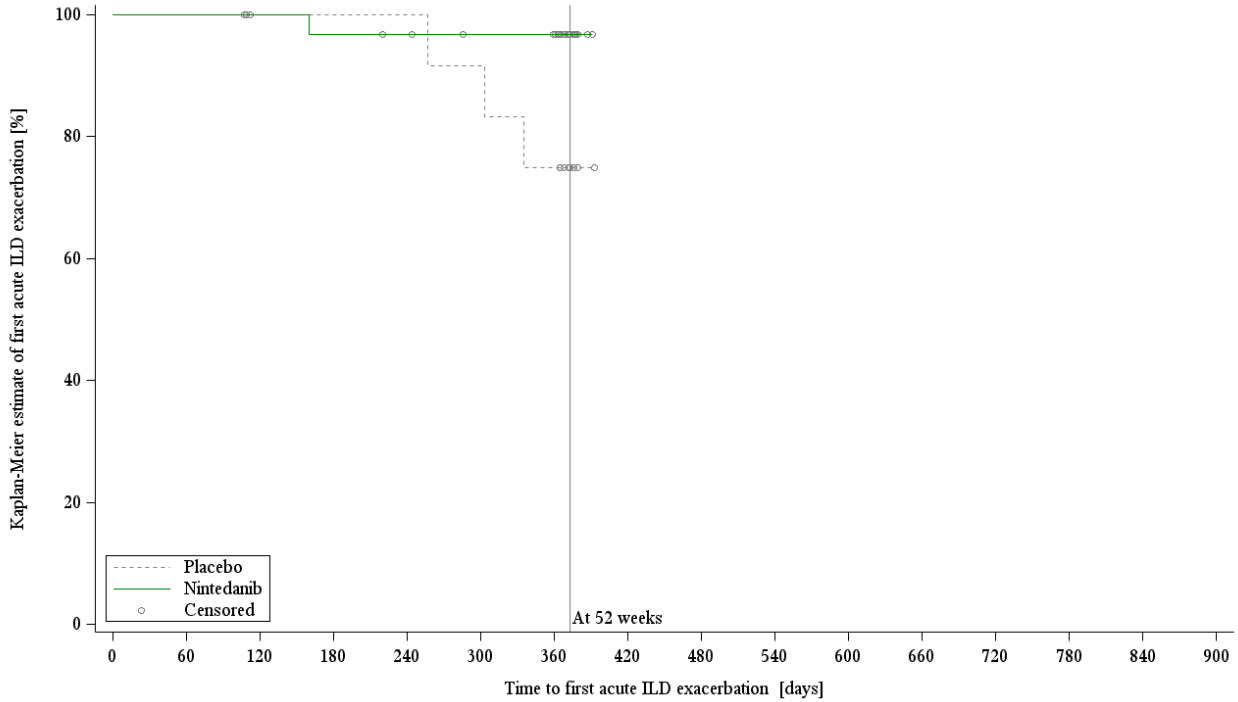

Figure 2.6.6 Kaplan Meier Plot of time to first acute ILD exacerbation over the whole trial by underlying ILD diagnosis - Treated Set

Underlying ILD Diagnosis in Groups: Autoimmune ILDs

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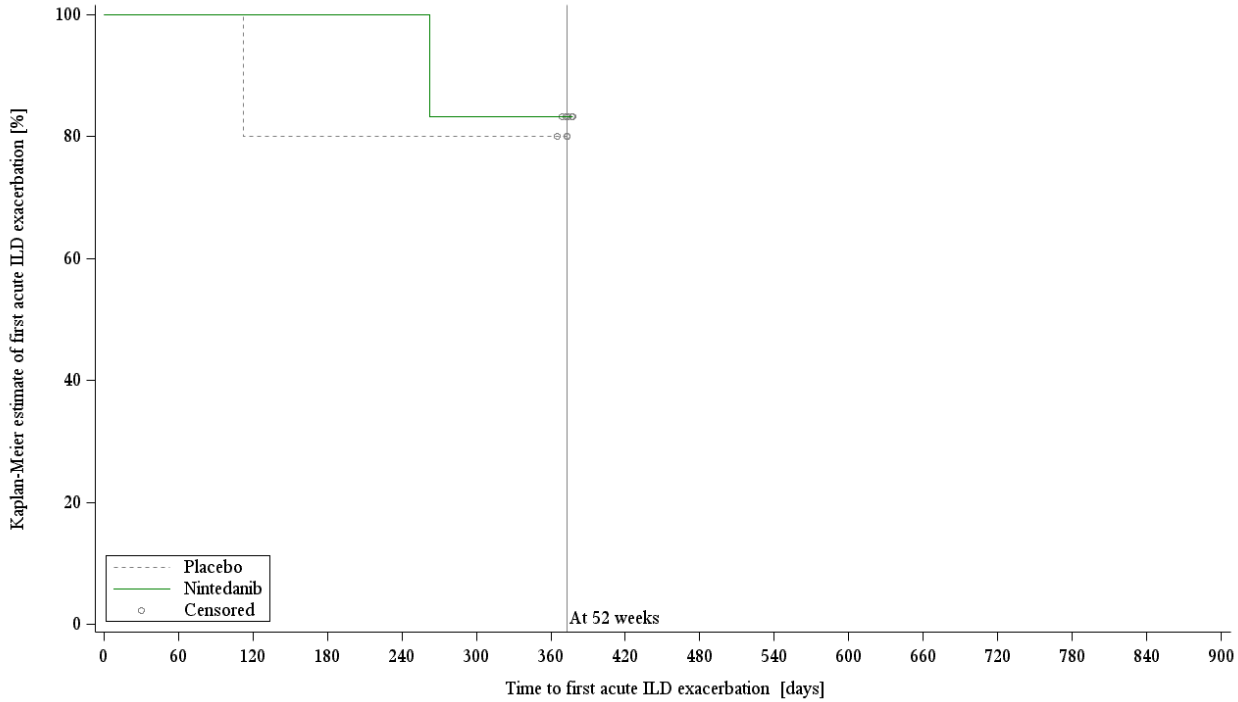

Figure 2.6.6 Kaplan Meier Plot of time to first acute ILD exacerbation over the whole trial by underlying ILD diagnosis - Treated Set

Underlying ILD Diagnosis in Groups: Other ILDs

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1.3 Safety

1.3.1 Adverse events

Table 3.1.1 Proportion of patients with any adverse event over the whole trial by subgroup - Treated Set

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	25	92.6	54	54	100.0	0.043	1.08	(0.97	1.20)				0.07	(-0.02	0.17)	
Age group																	
<65 years	9	8	88.9	25	25	100.0	0.091	1.12	(0.89	1.42)				0.11	(-0.09	0.32)	
>=65 years	18	17	94.4	29	29	100.0	0.199	1.06	(0.95	1.18)				0.06	(-0.05	0.16)	
Gender																	
Male	11	10	90.9	26	26	100.0	0.119	1.10	(0.91	1.33)				0.09	(-0.08	0.26)	
Female	16	15	93.8	28	28	100.0	0.181	1.07	(0.94	1.21)				0.06	(-0.06	0.18)	
HRCT pattern																	
UIP-like pattern only	23	22	95.7	45	45	100.0	0.159	1.05	(0.96	1.14)				0.04	(-0.04	0.13)	
Other fibrotic patterns	4	3	75.0	9	9	100.0	0.118	1.33	(0.76	2.35)				0.25	(-0.17	0.67)	
Baseline FVC % predicted																	
<=70%	10	9	90.0	17	17	100.0	0.184	1.11	(0.90	1.37)				0.10	(-0.09	0.29)	
>70%	17	16	94.1	37	37	100.0	0.136	1.06	(0.94	1.20)				0.06	(-0.05	0.17)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	1	100.0											
Idiopathic nonspecific interstitial pneumonia	7	6	85.7	11	11	100.0	0.197	1.17	(0.86	1.58)				0.14	(-0.12	0.40)	
Unclassifiable idiopathic interstitial pneumonia	3	3	100.0	2	2	100.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	11	91.7	34	34	100.0	0.089	1.09	(0.92	1.29)				0.08	(-0.07	0.24)	
Other ILDs	5	5	100.0	6	6	100.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio is not computed because the data are too sparse.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.

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1.3.2 Serious adverse events

Table 3.2.1 Proportion of patients with any serious adverse event over the whole trial by subgroup - Treated Set

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	12	44.4	54	20	37.0	0.520	0.83	(0.48	1.44)	0.74	(0.29	1.88)	-0.07	(-0.30	0.15)	
Age group																	0.707
<65 years	9	3	33.3	25	6	24.0	0.586	0.72	(0.23	2.29)	0.63	(0.12	3.33)	-0.09	(-0.44	0.26)	
>=65 years	18	9	50.0	29	14	48.3	0.908	0.97	(0.53	1.75)	0.93	(0.29	3.03)	-0.02	(-0.31	0.28)	
Gender																	0.160
Male	11	5	45.5	26	14	53.8	0.641	1.18	(0.57	2.48)	1.40	(0.34	5.76)	0.08	(-0.27	0.44)	
Female	16	7	43.8	28	6	21.4	0.118	0.49	(0.20	1.21)	0.35	(0.09	1.34)	-0.22	(-0.51	0.06)	
HRCT pattern																	0.913
UIP-like pattern only	23	11	47.8	45	18	40.0	0.537	0.84	(0.48	1.46)	0.73	(0.26	2.00)	-0.08	(-0.33	0.17)	
Other fibrotic patterns	4	1	25.0	9	2	22.2	0.913	0.89	(0.11	7.20)	0.86	(0.05	13.48)	-0.03	(-0.53	0.48)	
Baseline FVC % predicted																	0.860
<=70%	10	4	40.0	17	6	35.3	0.807	0.88	(0.33	2.39)	0.82	(0.16	4.09)	-0.05	(-0.43	0.33)	
>70%	17	8	47.1	37	14	37.8	0.522	0.80	(0.42	1.54)	0.68	(0.21	2.19)	-0.09	(-0.38	0.19)	
Underlying ILD Diagnosis in Groups																	0.152
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	2	28.6	11	5	45.5	0.474	1.59	(0.42	6.07)	2.08	(0.28	15.77)	0.17	(-0.28	0.61)	
Unclassifiable idiopathic interstitial pneumonia	3	1	33.3	2	0	0.0	0.361	0.00			0.00			-0.33	(-0.87	0.20)	
Autoimmune ILDs	12	5	41.7	34	14	41.2	0.976	0.99	(0.45	2.16)	0.98	(0.26	3.73)	-0.00	(-0.33	0.32)	
Other ILDs	5	4	80.0	6	1	16.7	0.036	0.21	(0.03	1.31)	0.05	(0.00	1.07)	-0.63	(-1.09	-0.17)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.

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1.3.3 Adverse events leading to treatment discontinuation

Table 3.3.1 Proportion of patients with any adverse event leading to treatment discontinuation over the whole trial by subgroup - Treated Set

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	10	18.5	0.067	5.00	(0.67	37.06)	5.91	(0.71	48.84)	0.15	(0.02	0.27)	
Age group																	0.724
<65 years	9	0	0.0	25	2	8.0	0.382							0.08	(-0.03 | 0.19)	
>=65 years	18	1	5.6	29	8	27.6	0.062	4.97	(0.68	36.47)	6.48	(0.74	57.00)	0.22	(0.03	0.41)	
Gender																	0.049
Male	11	1	9.1	26	2	7.7	0.887	0.85	(0.09	8.39)	0.83	(0.07	10.27)	-0.01	(-0.21	0.18)	
Female	16	0	0.0	28	8	28.6	0.018							0.29	(0.12 | 0.45)	
HRCT pattern																	0.763
UIP-like pattern only	23	1	4.3	45	9	20.0	0.085	4.60	(0.62	34.12)	5.50	(0.65	46.42)	0.16	(0.01	0.30)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09 | 0.32)	
Baseline FVC % predicted																	0.361
<=70%	10	0	0.0	17	4	23.5	0.097							0.24	(0.03 | 0.44)	
>70%	17	1	5.9	37	6	16.2	0.294	2.76	(0.36	21.15)	3.10	(0.34	27.98)	0.10	(-0.06	0.27)	
Underlying ILD Diagnosis in Groups																	0.518
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	2	18.2	0.231							0.18	(-0.05 | 0.41)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	8	23.5	0.254	2.82	(0.39	20.29)	3.38	(0.38	30.40)	0.15	(-0.06	0.36)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.

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1.3.4 Adverse events by CTCAE-Grade

Table 3.4.1 Proportion of patients with Diarrhoea CTCAE-Grade >= 3 over the whole trial by subgroup - Treated Set

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	-0.02	0.05	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	0.00	0.00	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	-0.03	0.10	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	-0.04	0.11	
Female	16	0	0.0	28	0	0.0								0.00	0.00	0.00	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	-0.02	0.07	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	0.00	0.00	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	-0.05	0.17	
>70%	17	0	0.0	37	0	0.0								0.00	0.00	0.00	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	0.00	0.00	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	0.00	0.00	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	-0.03	0.09	
Other ILDs	5	0	0.0	6	0	0.0								0.00	0.00	0.00	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio is not computed because the data are too sparse.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
Each patient is considered only once with the worst grade for the analysis of patients with Diarrhoea CTCAE-Grade <3 and >=3.
A missing CTCAE-Grade is considered as CTCAE-Grade>=3.

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Table 3.4.2 Proportion of patients with Diarrhoea CTCAE-Grade < 3 over the whole trial by subgroup - Treated Set

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	4	14.8	54	18	33.3	0.077	2.25	(0.84	5.99)	2.88	(0.86	9.58)	0.19	(0.00	0.37)	
Age group																	0.606
<65 years	9	1	11.1	25	5	20.0	0.549	1.80	(0.24	13.40)	2.00	(0.20	19.91)	0.09	(-0.17	0.35)	
>=65 years	18	3	16.7	29	13	44.8	0.048	2.69	(0.89	8.15)	4.06	(0.96	17.14)	0.28	(0.03	0.53)	
Gender																	0.181
Male	11	0	0.0	26	7	26.9	0.056							0.27	(0.10	0.44)	
Female	16	4	25.0	28	11	39.3	0.336	1.57	(0.60	4.13)	1.94	(0.50	7.58)	0.14	(-0.14	0.42)	
HRCT pattern																	0.337
UIP-like pattern only	23	3	13.0	45	16	35.6	0.050	2.73	(0.88	8.41)	3.68	(0.95	14.31)	0.23	(0.03	0.42)	
Other fibrotic patterns	4	1	25.0	9	2	22.2	0.913	0.89	(0.11	7.20)	0.86	(0.05	13.48)	-0.03	(-0.53	0.48)	
Baseline FVC % predicted																	0.775
<=70%	10	1	10.0	17	5	29.4	0.241	2.94	(0.40	21.73)	3.75	(0.37	37.95)	0.19	(-0.09	0.48)	
>70%	17	3	17.6	37	13	35.1	0.191	1.99	(0.65	6.08)	2.53	(0.61	10.44)	0.17	(-0.06	0.41)	
Underlying ILD Diagnosis in Groups																	0.165
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	7	63.6	0.040	4.45	(0.69	28.87)	10.50	(0.91	>99.99)	0.49	(0.11	0.88)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	1	50.0	0.171							0.50	(-0.19	1.19)	
Autoimmune ILDs	12	1	8.3	34	9	26.5	0.190	3.18	(0.45	22.51)	3.96	(0.45	35.18)	0.18	(-0.03	0.40)	
Other ILDs	5	2	40.0	6	1	16.7	0.387	0.42	(0.05	3.36)	0.30	(0.02	4.91)	-0.23	(-0.76	0.29)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
Each patient is considered only once with the worst grade for the analysis of patients with Diarrhoea CTCAE-Grade <3 and >=3.
A missing CTCAE-Grade is considered as CTCAE-Grade>=3.

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1.3.5 Adverse events excluding disease-related events

Table 3.5.1 Proportion of patients with any adverse event excluding acute ILD exacerbation over the whole trial by subgroup - Treated Set

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	25	92.6	54	54	100.0	0.043	1.08	(0.97	1.20)				0.07	(-0.02	0.17)	
Age group																	
<65 years	9	8	88.9	25	25	100.0	0.091	1.12	(0.89	1.42)				0.11	(-0.09	0.32)	
>=65 years	18	17	94.4	29	29	100.0	0.199	1.06	(0.95	1.18)				0.06	(-0.05	0.16)	
Gender																	
Male	11	10	90.9	26	26	100.0	0.119	1.10	(0.91	1.33)				0.09	(-0.08	0.26)	
Female	16	15	93.8	28	28	100.0	0.181	1.07	(0.94	1.21)				0.06	(-0.06	0.18)	
HRCT pattern																	
UIP-like pattern only	23	22	95.7	45	45	100.0	0.159	1.05	(0.96	1.14)				0.04	(-0.04	0.13)	
Other fibrotic patterns	4	3	75.0	9	9	100.0	0.118	1.33	(0.76	2.35)				0.25	(-0.17	0.67)	
Baseline FVC % predicted																	
<=70%	10	9	90.0	17	17	100.0	0.184	1.11	(0.90	1.37)				0.10	(-0.09	0.29)	
>70%	17	16	94.1	37	37	100.0	0.136	1.06	(0.94	1.20)				0.06	(-0.05	0.17)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	1	100.0											
Idiopathic nonspecific interstitial pneumonia	7	6	85.7	11	11	100.0	0.197	1.17	(0.86	1.58)				0.14	(-0.12	0.40)	
Unclassifiable idiopathic interstitial pneumonia	3	3	100.0	2	2	100.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	11	91.7	34	34	100.0	0.089	1.09	(0.92	1.29)				0.08	(-0.07	0.24)	
Other ILDs	5	5	100.0	6	6	100.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio is not computed because the data are too sparse.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.

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Table 3.5.2 Proportion of patients with any serious adverse event excluding acute ILD exacerbation over the whole trial by subgroup - Treated Set

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	12	44.4	54	20	37.0	0.520	0.83	(0.48	1.44)	0.74	(0.29	1.88)	-0.07	(-0.30	0.15)	
Age group																	0.707
<65 years	9	3	33.3	25	6	24.0	0.586	0.72	(0.23	2.29)	0.63	(0.12	3.33)	-0.09	(-0.44	0.26)	
>=65 years	18	9	50.0	29	14	48.3	0.908	0.97	(0.53	1.75)	0.93	(0.29	3.03)	-0.02	(-0.31	0.28)	
Gender																	0.160
Male	11	5	45.5	26	14	53.8	0.641	1.18	(0.57	2.48)	1.40	(0.34	5.76)	0.08	(-0.27	0.44)	
Female	16	7	43.8	28	6	21.4	0.118	0.49	(0.20	1.21)	0.35	(0.09	1.34)	-0.22	(-0.51	0.06)	
HRCT pattern																	0.913
UIP-like pattern only	23	11	47.8	45	18	40.0	0.537	0.84	(0.48	1.46)	0.73	(0.26	2.00)	-0.08	(-0.33	0.17)	
Other fibrotic patterns	4	1	25.0	9	2	22.2	0.913	0.89	(0.11	7.20)	0.86	(0.05	13.48)	-0.03	(-0.53	0.48)	
Baseline FVC % predicted																	0.860
<=70%	10	4	40.0	17	6	35.3	0.807	0.88	(0.33	2.39)	0.82	(0.16	4.09)	-0.05	(-0.43	0.33)	
>70%	17	8	47.1	37	14	37.8	0.522	0.80	(0.42	1.54)	0.68	(0.21	2.19)	-0.09	(-0.38	0.19)	
Underlying ILD Diagnosis in Groups																	0.152
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	2	28.6	11	5	45.5	0.474	1.59	(0.42	6.07)	2.08	(0.28	15.77)	0.17	(-0.28	0.61)	
Unclassifiable idiopathic interstitial pneumonia	3	1	33.3	2	0	0.0	0.361	0.00			0.00			-0.33	(-0.87	0.20)	
Autoimmune ILDs	12	5	41.7	34	14	41.2	0.976	0.99	(0.45	2.16)	0.98	(0.26	3.73)	-0.00	(-0.33	0.32)	
Other ILDs	5	4	80.0	6	1	16.7	0.036	0.21	(0.03	1.31)	0.05	(0.00	1.07)	-0.63	(-1.09	-0.17)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.

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Table 3.5.3 Proportion of patients with any adverse event leading to treatment discontinuation excluding acute ILD exacerbation over the whole trial by subgroup - Treated Set

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	10	18.5	0.067	5.00	(0.67	37.06)	5.91	(0.71	48.84)	0.15	(0.02	0.27)	
Age group																	0.724
<65 years	9	0	0.0	25	2	8.0	0.382							0.08	(-0.03	0.19)	
>=65 years	18	1	5.6	29	8	27.6	0.062	4.97	(0.68	36.47)	6.48	(0.74	57.00)	0.22	(0.03	0.41)	
Gender																	0.049
Male	11	1	9.1	26	2	7.7	0.887	0.85	(0.09	8.39)	0.83	(0.07	10.27)	-0.01	(-0.21	0.18)	
Female	16	0	0.0	28	8	28.6	0.018							0.29	(0.12	0.45)	
HRCT pattern																	0.763
UIP-like pattern only	23	1	4.3	45	9	20.0	0.085	4.60	(0.62	34.12)	5.50	(0.65	46.42)	0.16	(0.01	0.30)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	0.361
<=70%	10	0	0.0	17	4	23.5	0.097							0.24	(0.03	0.44)	
>70%	17	1	5.9	37	6	16.2	0.294	2.76	(0.36	21.15)	3.10	(0.34	27.98)	0.10	(-0.06	0.27)	
Underlying ILD Diagnosis in Groups																	0.518
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	2	18.2	0.231							0.18	(-0.05	0.41)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	8	23.5	0.254	2.82	(0.39	20.29)	3.38	(0.38	30.40)	0.15	(-0.06	0.36)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.

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1.3.6 Adverse events on SOC level

Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Blood and lymphatic system disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	4	14.8	54	3	5.6	0.162	0.38	(0.09	1.56)	0.34	(0.07	1.64)	-0.09	(-0.24	0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	4	22.2	29	3	10.3	0.266	0.47	(0.12	1.84)	0.40	(0.08	2.07)	-0.12	(-0.34	0.10)	
Gender																	0.200
Male	11	2	18.2	26	3	11.5	0.589	0.63	(0.12	3.29)	0.59	(0.08	4.12)	-0.07	(-0.33	0.19)	
Female	16	2	12.5	28	0	0.0	0.056	0.00			0.00			-0.13	(-0.29	0.04)	
HRCT pattern																	0.215
UIP-like pattern only	23	4	17.4	45	2	4.4	0.075	0.26	(0.05	1.29)	0.22	(0.04	1.31)	-0.13	(-0.30	0.04)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	0.141
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05	0.17)	
>70%	17	4	23.5	37	2	5.4	0.049	0.23	(0.05	1.13)	0.19	(0.03	1.14)	-0.18	(-0.40	0.03)	
Underlying ILD Diagnosis in Groups																	0.630
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	0	0.0	0.197	0.00			0.00			-0.14	(-0.40	0.12)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	2	5.9	0.768	0.71	(0.07	7.10)	0.69	(0.06	8.34)	-0.02	(-0.20	0.15)	
Other ILDs	5	2	40.0	6	1	16.7	0.387	0.42	(0.05	3.36)	0.30	(0.02	4.91)	-0.23	(-0.76	0.29)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Cardiac disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	8	14.8	0.134	4.00	(0.53	30.36)	4.52	(0.54	38.19)	0.11	(-0.01	0.23)	
Age group																	0.558
<65 years	9	0	0.0	25	3	12.0	0.276							0.12	(-0.01 | 0.25)	
>=65 years	18	1	5.6	29	5	17.2	0.243	3.10	(0.39	24.47)	3.54	(0.38	33.11)	0.12	(-0.06	0.29)	
Gender																	0.399
Male	11	1	9.1	26	5	19.2	0.444	2.12	(0.28	16.07)	2.38	(0.24	23.17)	0.10	(-0.13	0.33)	
Female	16	0	0.0	28	3	10.7	0.175							0.11	(-0.01 | 0.22)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	8	17.8	0.122	4.09	(0.54	30.74)	4.76	(0.56	40.62)	0.13	(-0.01	0.27)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	0.392
<=70%	10	0	0.0	17	3	17.6	0.159							0.18	(-0.00 | 0.36)	
>70%	17	1	5.9	37	5	13.5	0.407	2.30	(0.29	18.18)	2.50	(0.27	23.23)	0.08	(-0.08	0.23)	
Underlying ILD Diagnosis in Groups																	0.062
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	7	20.6	0.088							0.21	(0.07 | 0.34)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Ear and labyrinth disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01 | 0.09)	
Age group																	
<65 years	9	0	0.0	25	2	8.0	0.382							0.08	(-0.03 | 0.19)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	2	7.7	0.344							0.08	(-0.03 | 0.18)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02 | 0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	2	5.4	0.329							0.05	(-0.02 | 0.13)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	2	5.9	0.390							0.06	(-0.02 | 0.14)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Endocrine disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	8	29.6	54	35	64.8	0.003	2.19	(1.18	4.04)	4.38	(1.61	11.86)	0.35	(0.14	0.57)	
Age group																	0.347
<65 years	9	3	33.3	25	14	56.0	0.244	1.68	(0.63	4.51)	2.55	(0.52	12.55)	0.23	(-0.14	0.59)	
>=65 years	18	5	27.8	29	21	72.4	0.003	2.61	(1.20	5.68)	6.83	(1.83	25.40)	0.45	(0.18	0.71)	
Gender																	0.291
Male	11	3	27.3	26	13	50.0	0.202	1.83	(0.65	5.18)	2.67	(0.58	12.36)	0.23	(-0.10	0.55)	
Female	16	5	31.3	28	22	78.6	0.002	2.51	(1.19	5.33)	8.07	(2.01	32.39)	0.47	(0.20	0.75)	
HRCT pattern																	0.482
UIP-like pattern only	23	6	26.1	45	29	64.4	0.003	2.47	(1.20	5.08)	5.14	(1.69	15.63)	0.38	(0.16	0.61)	
Other fibrotic patterns	4	2	50.0	9	6	66.7	0.569	1.33	(0.45	3.94)	2.00	(0.18	22.06)	0.17	(-0.41	0.75)	
Baseline FVC % predicted																	0.070
<=70%	10	4	40.0	17	8	47.1	0.722	1.18	(0.47	2.93)	1.33	(0.27	6.50)	0.07	(-0.31	0.46)	
>70%	17	4	23.5	37	27	73.0	<.001	3.10	(1.29	7.47)	8.78	(2.31	33.35)	0.49	(0.25	0.74)	
Underlying ILD Diagnosis in Groups																	0.132
Hypersensitivity pneumonitis	0	0	0.0	1	1	100.0											
Idiopathic nonspecific interstitial pneumonia	7	2	28.6	11	8	72.7	0.066	2.55	(0.75	8.67)	6.67	(0.81	54.96)	0.44	(0.02	0.87)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	2	100.0	0.025							1.00	(1.00	1.00)	
Autoimmune ILDs	12	2	16.7	34	20	58.8	0.012	3.53	(0.97	12.90)	7.14	(1.35	37.74)	0.42	(0.15	0.69)	
Other ILDs	5	4	80.0	6	4	66.7	0.621	0.83	(0.41	1.70)	0.50	(0.03	7.99)	-0.13	(-0.65	0.38)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: General disorders and administration site conditions

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	5	18.5	54	12	22.2	0.700	1.20	(0.47	3.06)	1.26	(0.39	4.03)	0.04	(-0.15	0.22)	
Age group																	0.451
<65 years	9	1	11.1	25	6	24.0	0.412	2.16	(0.30	15.57)	2.53	(0.26	24.51)	0.13	(-0.14	0.39)	
>=65 years	18	4	22.2	29	6	20.7	0.901	0.93	(0.30	2.85)	0.91	(0.22	3.81)	-0.02	(-0.26	0.23)	
Gender																	0.401
Male	11	2	18.2	26	8	30.8	0.431	1.69	(0.43	6.73)	2.00	(0.35	11.44)	0.13	(-0.16	0.41)	
Female	16	3	18.8	28	4	14.3	0.697	0.76	(0.19	2.98)	0.72	(0.14	3.73)	-0.04	(-0.28	0.19)	
HRCT pattern																	0.046
UIP-like pattern only	23	5	21.7	45	7	15.6	0.527	0.72	(0.25	2.01)	0.66	(0.18	2.38)	-0.06	(-0.26	0.14)	
Other fibrotic patterns	4	0	0.0	9	5	55.6	0.057							0.56	(0.23	0.88)	
Baseline FVC % predicted																	0.232
<=70%	10	1	10.0	17	5	29.4	0.241	2.94	(0.40	21.73)	3.75	(0.37	37.95)	0.19	(-0.09	0.48)	
>70%	17	4	23.5	37	7	18.9	0.696	0.80	(0.27	2.38)	0.76	(0.19	3.05)	-0.05	(-0.28	0.19)	
Underlying ILD Diagnosis in Groups																	0.088
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	4	36.4	0.070							0.36	(0.08	0.65)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	4	33.3	34	6	17.6	0.257	0.53	(0.18	1.56)	0.43	(0.10	1.90)	-0.16	(-0.45	0.14)	
Other ILDs	5	1	20.0	6	2	33.3	0.621	1.67	(0.21	13.43)	2.00	(0.13	31.98)	0.13	(-0.38	0.65)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Hepatobiliary disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	18	33.3	0.011	4.50	(1.13	17.99)	6.25	(1.33	29.37)	0.26	(0.10	0.42)	
Age group																	0.264
<65 years	9	0	0.0	25	9	36.0	0.036							0.36	(0.17	0.55)	
>=65 years	18	2	11.1	29	9	31.0	0.117	2.79	(0.68	11.50)	3.60	(0.68	19.07)	0.20	(-0.02	0.42)	
Gender																	0.051
Male	11	2	18.2	26	7	26.9	0.571	1.48	(0.36	6.03)	1.66	(0.29	9.64)	0.09	(-0.20	0.37)	
Female	16	0	0.0	28	11	39.3	0.004							0.39	(0.21	0.57)	
HRCT pattern																	0.546
UIP-like pattern only	23	2	8.7	45	15	33.3	0.026	3.83	(0.96	15.35)	5.25	(1.08	25.42)	0.25	(0.07	0.43)	
Other fibrotic patterns	4	0	0.0	9	3	33.3	0.188							0.33	(0.03	0.64)	
Baseline FVC % predicted																	0.191
<=70%	10	0	0.0	17	7	41.2	0.018							0.41	(0.18	0.65)	
>70%	17	2	11.8	37	11	29.7	0.152	2.53	(0.63	10.18)	3.17	(0.62	16.28)	0.18	(-0.03	0.39)	
Underlying ILD Diagnosis in Groups																	0.022
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	4	36.4	0.308	2.55	(0.35	18.36)	3.43	(0.30	39.64)	0.22	(-0.16	0.61)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	14	41.2	0.008							0.41	(0.25	0.58)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Immune system disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01	0.09)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03	0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04	0.11)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03	0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02	0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	2	11.8	0.260							0.12	(-0.04	0.27)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00	0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	2	5.9	0.390							0.06	(-0.02	0.14)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	17	63.0	54	29	53.7	0.428	0.85	(0.58	1.25)	0.68	(0.26	1.76)	-0.09	(-0.32	0.13)	
Age group																	0.209
<65 years	9	5	55.6	25	16	64.0	0.655	1.15	(0.60	2.22)	1.42	(0.30	6.69)	0.08	(-0.29	0.46)	
>=65 years	18	12	66.7	29	13	44.8	0.145	0.67	(0.40	1.13)	0.41	(0.12	1.38)	-0.22	(-0.50	0.06)	
Gender																	0.565
Male	11	7	63.6	26	16	61.5	0.904	0.97	(0.56	1.66)	0.91	(0.21	3.94)	-0.02	(-0.36	0.32)	
Female	16	10	62.5	28	13	46.4	0.305	0.74	(0.43	1.29)	0.52	(0.15	1.82)	-0.16	(-0.46	0.14)	
HRCT pattern																	0.331
UIP-like pattern only	23	15	65.2	45	23	51.1	0.268	0.78	(0.52	1.18)	0.56	(0.20	1.57)	-0.14	(-0.38	0.10)	
Other fibrotic patterns	4	2	50.0	9	6	66.7	0.569	1.33	(0.45	3.94)	2.00	(0.18	22.06)	0.17	(-0.41	0.75)	
Baseline FVC % predicted																	0.603
<=70%	10	7	70.0	17	9	52.9	0.384	0.76	(0.41	1.38)	0.48	(0.09	2.52)	-0.17	(-0.54	0.20)	
>70%	17	10	58.8	37	20	54.1	0.743	0.92	(0.56	1.51)	0.82	(0.26	2.63)	-0.05	(-0.33	0.24)	
Underlying ILD Diagnosis in Groups																	0.701
Hypersensitivity pneumonitis	0	0	0.0	1	1	100.0											
Idiopathic nonspecific interstitial pneumonia	7	4	57.1	11	6	54.5	0.914	0.95	(0.41	2.21)	0.90	(0.13	6.08)	-0.03	(-0.50	0.44)	
Unclassifiable idiopathic interstitial pneumonia	3	2	66.7	2	2	100.0	0.361	1.50	(0.67	3.34)				0.33	(-0.20	0.87)	
Autoimmune ILDs	12	8	66.7	34	17	50.0	0.319	0.75	(0.44	1.26)	0.50	(0.13	1.98)	-0.17	(-0.48	0.15)	
Other ILDs	5	3	60.0	6	3	50.0	0.740	0.83	(0.28	2.44)	0.67	(0.06	7.35)	-0.10	(-0.69	0.49)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Injury, poisoning and procedural complications

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	2	3.7	0.468	0.50	(0.07	3.36)	0.48	(0.06	3.61)	-0.04	(-0.15	0.07)	
Age group																	0.335
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	2	11.1	29	1	3.4	0.296	0.31	(0.03	3.18)	0.29	(0.02	3.40)	-0.08	(-0.24	0.08)	
Gender																	0.026
Male	11	2	18.2	26	0	0.0	0.025	0.00			0.00			-0.18	(-0.41	0.05)	
Female	16	0	0.0	28	2	7.1	0.274							0.07	(-0.02	0.17)	
HRCT pattern																	0.199
UIP-like pattern only	23	1	4.3	45	2	4.4	0.985	1.02	(0.10	10.69)	1.02	(0.09	11.92)	0.00	(-0.10	0.10)	
Other fibrotic patterns	4	1	25.0	9	0	0.0	0.118	0.00			0.00			-0.25	(-0.67	0.17)	
Baseline FVC % predicted																	0.285
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29	0.09)	
>70%	17	1	5.9	37	2	5.4	0.943	0.92	(0.09	9.45)	0.91	(0.08	10.83)	-0.00	(-0.14	0.13)	
Underlying ILD Diagnosis in Groups																	0.078
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	2	5.9	0.390							0.06	(-0.02	0.14)	
Other ILDs	5	2	40.0	6	0	0.0	0.087	0.00			0.00			-0.40	(-0.83	0.03)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Investigations

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	8	29.6	54	29	53.7	0.040	1.81	(0.96	3.41)	2.76	(1.03	7.37)	0.24	(0.02	0.46)	
Age group																	0.692
<65 years	9	2	22.2	25	13	52.0	0.123	2.34	(0.65	8.41)	3.79	(0.65	21.96)	0.30	(-0.04	0.63)	
>=65 years	18	6	33.3	29	16	55.2	0.145	1.66	(0.80	3.44)	2.46	(0.72	8.36)	0.22	(-0.06	0.50)	
Gender																	0.224
Male	11	2	18.2	26	15	57.7	0.028	3.17	(0.87	11.60)	6.14	(1.10	34.21)	0.40	(0.10	0.69)	
Female	16	6	37.5	28	14	50.0	0.423	1.33	(0.64	2.78)	1.67	(0.48	5.84)	0.13	(-0.18	0.43)	
HRCT pattern																	0.470
UIP-like pattern only	23	6	26.1	45	24	53.3	0.032	2.04	(0.98	4.29)	3.24	(1.08	9.72)	0.27	(0.04	0.50)	
Other fibrotic patterns	4	2	50.0	9	5	55.6	0.853	1.11	(0.36	3.48)	1.25	(0.12	13.24)	0.06	(-0.53	0.64)	
Baseline FVC % predicted																	0.345
<=70%	10	3	30.0	17	12	70.6	0.040	2.35	(0.87	6.37)	5.60	(1.01	30.90)	0.41	(0.05	0.76)	
>70%	17	5	29.4	37	17	45.9	0.251	1.56	(0.69	3.53)	2.04	(0.60	6.96)	0.17	(-0.10	0.43)	
Underlying ILD Diagnosis in Groups																	0.446
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	2	28.6	11	5	45.5	0.474	1.59	(0.42	6.07)	2.08	(0.28	15.77)	0.17	(-0.28	0.61)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	1	50.0	0.171							0.50	(-0.19	1.19)	
Autoimmune ILDs	12	3	25.0	34	20	58.8	0.044	2.35	(0.85	6.52)	4.29	(0.98	18.72)	0.34	(0.04	0.63)	
Other ILDs	5	3	60.0	6	3	50.0	0.740	0.83	(0.28	2.44)	0.67	(0.06	7.35)	-0.10	(-0.69	0.49)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Metabolism and nutrition disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	5	18.5	54	14	25.9	0.458	1.40	(0.56	3.48)	1.54	(0.49	4.84)	0.07	(-0.11	0.26)	
Age group																	0.124
<65 years	9	2	22.2	25	3	12.0	0.458	0.54	(0.11	2.73)	0.48	(0.07	3.46)	-0.10	(-0.40	0.20)	
>=65 years	18	3	16.7	29	11	37.9	0.121	2.28	(0.73	7.07)	3.06	(0.72	13.01)	0.21	(-0.03	0.46)	
Gender																	0.050
Male	11	1	9.1	26	10	38.5	0.074	4.23	(0.61	29.18)	6.25	(0.69	56.53)	0.29	(0.04	0.55)	
Female	16	4	25.0	28	4	14.3	0.375	0.57	(0.16	1.98)	0.50	(0.11	2.35)	-0.11	(-0.36	0.14)	
HRCT pattern																	0.567
UIP-like pattern only	23	5	21.7	45	13	28.9	0.527	1.33	(0.54	3.27)	1.46	(0.45	4.77)	0.07	(-0.14	0.29)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	0.104
<=70%	10	1	10.0	17	7	41.2	0.087	4.12	(0.59	28.78)	6.30	(0.64	61.63)	0.31	(0.01	0.61)	
>70%	17	4	23.5	37	7	18.9	0.696	0.80	(0.27	2.38)	0.76	(0.19	3.05)	-0.05	(-0.28	0.19)	
Underlying ILD Diagnosis in Groups																	0.515
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	2	18.2	0.231							0.18	(-0.05	0.41)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	3	25.0	34	10	29.4	0.770	1.18	(0.39	3.57)	1.25	(0.28	5.60)	0.04	(-0.24	0.33)	
Other ILDs	5	2	40.0	6	2	33.3	0.819	0.83	(0.18	3.96)	0.75	(0.06	8.83)	-0.07	(-0.64	0.50)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Musculoskeletal and connective tissue disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	3	11.1	54	6	11.1	1.000	1.00	(0.27	3.69)	1.00	(0.23	4.35)	0.00	(-0.15	0.15)	
Age group																	0.688
<65 years	9	2	22.2	25	4	16.0	0.675	0.72	(0.16	3.28)	0.67	(0.10	4.46)	-0.06	(-0.37	0.25)	
>=65 years	18	1	5.6	29	2	6.9	0.855	1.24	(0.12	12.72)	1.26	(0.11	14.98)	0.01	(-0.13	0.15)	
Gender																	0.302
Male	11	0	0.0	26	2	7.7	0.344							0.08	(-0.03	0.18)	
Female	16	3	18.8	28	4	14.3	0.697	0.76	(0.19	2.98)	0.72	(0.14	3.73)	-0.04	(-0.28	0.19)	
HRCT pattern																	0.463
UIP-like pattern only	23	3	13.0	45	5	11.1	0.815	0.85	(0.22	3.25)	0.83	(0.18	3.84)	-0.02	(-0.18	0.15)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	0.029
<=70%	10	2	20.0	17	0	0.0	0.055	0.00			0.00			-0.20	(-0.45	0.05)	
>70%	17	1	5.9	37	6	16.2	0.294	2.76	(0.36	21.15)	3.10	(0.34	27.98)	0.10	(-0.06	0.27)	
Underlying ILD Diagnosis in Groups																	0.237
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	2	18.2	0.231							0.18	(-0.05	0.41)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	2	16.7	34	4	11.8	0.665	0.71	(0.15	3.37)	0.67	(0.11	4.21)	-0.05	(-0.29	0.19)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	0	0.0	0.197	0.00			0.00			-0.14	(-0.40 | 0.12)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Nervous system disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	9	16.7	0.252	2.25	(0.52	9.70)	2.50	(0.50	12.49)	0.09	(-0.05	0.23)	
Age group																	0.454
<65 years	9	0	0.0	25	3	12.0	0.276							0.12	(-0.01	0.25)	
>=65 years	18	2	11.1	29	6	20.7	0.396	1.86	(0.42	8.25)	2.09	(0.37	11.69)	0.10	(-0.11	0.30)	
Gender																	0.404
Male	11	0	0.0	26	3	11.5	0.240							0.12	(-0.01	0.24)	
Female	16	2	12.5	28	6	21.4	0.460	1.71	(0.39	7.51)	1.91	(0.34	10.82)	0.09	(-0.13	0.31)	
HRCT pattern																	
UIP-like pattern only	23	2	8.7	45	9	20.0	0.231	2.30	(0.54	9.78)	2.63	(0.52	13.32)	0.11	(-0.05	0.28)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.271
<=70%	10	0	0.0	17	3	17.6	0.159							0.18	(-0.00	0.36)	
>70%	17	2	11.8	37	6	16.2	0.669	1.38	(0.31	6.14)	1.45	(0.26	8.07)	0.04	(-0.15	0.24)	
Underlying ILD Diagnosis in Groups																	0.204
Hypersensitivity pneumonitis	0	0	0.0	1	1	100.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	2	18.2	0.231							0.18	(-0.05	0.41)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	6	17.6	0.440	2.12	(0.28	15.84)	2.36	(0.25	21.90)	0.09	(-0.11	0.30)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Psychiatric disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	1	1.9	0.613	0.50	(0.03	7.69)	0.49	(0.03	8.16)	-0.02	(-0.10	0.06)	
Age group																	0.211
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16	0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	1	6.3	28	1	3.6	0.682	0.57	(0.04	8.53)	0.56	(0.03	9.54)	-0.03	(-0.16	0.11)	
HRCT pattern																	0.166
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13	0.04)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	1	5.9	37	1	2.7	0.566	0.46	(0.03	6.92)	0.44	(0.03	7.56)	-0.03	(-0.16	0.09)	
Underlying ILD Diagnosis in Groups																	0.095
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24	0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Renal and urinary disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	3	11.1	54	6	11.1	1.000	1.00	(0.27	3.69)	1.00	(0.23	4.35)	0.00	(-0.15	0.15)	
Age group																	0.330
<65 years	9	1	11.1	25	1	4.0	0.437	0.36	(0.03	5.17)	0.33	(0.02	5.97)	-0.07	(-0.29	0.15)	
>=65 years	18	2	11.1	29	5	17.2	0.566	1.55	(0.34	7.17)	1.67	(0.29	9.66)	0.06	(-0.14	0.26)	
Gender																	0.071
Male	11	0	0.0	26	4	15.4	0.168							0.15	(0.02	0.29)	
Female	16	3	18.8	28	2	7.1	0.243	0.38	(0.07	2.04)	0.33	(0.05	2.25)	-0.12	(-0.33	0.10)	
HRCT pattern																	
UIP-like pattern only	23	3	13.0	45	6	13.3	0.973	1.02	(0.28	3.72)	1.03	(0.23	4.54)	0.00	(-0.17	0.17)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.386
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05	0.17)	
>70%	17	3	17.6	37	5	13.5	0.691	0.77	(0.21	2.84)	0.73	(0.15	3.48)	-0.04	(-0.25	0.17)	
Underlying ILD Diagnosis in Groups																	0.267
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	3	25.0	34	4	11.8	0.272	0.47	(0.12	1.81)	0.40	(0.08	2.13)	-0.13	(-0.40	0.14)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13	0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	13	48.1	54	15	27.8	0.069	0.58	(0.32	1.03)	0.41	(0.16	1.08)	-0.20	(-0.43	0.02)	
Age group																	0.151
<65 years	9	6	66.7	25	6	24.0	0.022	0.36	(0.16	0.83)	0.16	(0.03	0.83)	-0.43	(-0.78	-0.08)	
>=65 years	18	7	38.9	29	9	31.0	0.581	0.80	(0.36	1.76)	0.71	(0.21	2.42)	-0.08	(-0.36	0.20)	
Gender																	0.143
Male	11	4	36.4	26	9	34.6	0.919	0.95	(0.37	2.45)	0.93	(0.21	4.03)	-0.02	(-0.36	0.32)	
Female	16	9	56.3	28	6	21.4	0.019	0.38	(0.17	0.87)	0.21	(0.06	0.81)	-0.35	(-0.63	-0.06)	
HRCT pattern																	0.533
UIP-like pattern only	23	11	47.8	45	11	24.4	0.051	0.51	(0.26	1.00)	0.35	(0.12	1.02)	-0.23	(-0.47	0.01)	
Other fibrotic patterns	4	2	50.0	9	4	44.4	0.853	0.89	(0.26	3.02)	0.80	(0.08	8.47)	-0.06	(-0.64	0.53)	
Baseline FVC % predicted																	0.676
<=70%	10	5	50.0	17	4	23.5	0.159	0.47	(0.16	1.36)	0.31	(0.06	1.64)	-0.26	(-0.63	0.11)	
>70%	17	8	47.1	37	11	29.7	0.216	0.63	(0.31	1.28)	0.48	(0.15	1.56)	-0.17	(-0.45	0.11)	
Underlying ILD Diagnosis in Groups																	0.796
Hypersensitivity pneumonitis	0	0	0.0	1	1	100.0											
Idiopathic nonspecific interstitial pneumonia	7	4	57.1	11	2	18.2	0.087	0.32	(0.08	1.30)	0.17	(0.02	1.42)	-0.39	(-0.82	0.04)	
Unclassifiable idiopathic interstitial pneumonia	3	2	66.7	2	1	50.0	0.709	0.75	(0.15	3.72)	0.50	(0.01	19.56)	-0.17	(-1.04	0.71)	
Autoimmune ILDs	12	5	41.7	34	9	26.5	0.325	0.64	(0.27	1.52)	0.50	(0.13	2.00)	-0.15	(-0.47	0.16)	
Other ILDs	5	2	40.0	6	2	33.3	0.819	0.83	(0.18	3.96)	0.75	(0.06	8.83)	-0.07	(-0.64	0.50)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Skin and subcutaneous tissue disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	4	14.8	54	3	5.6	0.162	0.38	(0.09	1.56)	0.34	(0.07	1.64)	-0.09	(-0.24	0.05)	
Age group																	0.242
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32	0.09)	
>=65 years	18	3	16.7	29	3	10.3	0.528	0.62	(0.14	2.75)	0.58	(0.10	3.23)	-0.06	(-0.27	0.14)	
Gender																	0.917
Male	11	1	9.1	26	1	3.8	0.519	0.42	(0.03	6.17)	0.40	(0.02	7.03)	-0.05	(-0.24	0.13)	
Female	16	3	18.8	28	2	7.1	0.243	0.38	(0.07	2.04)	0.33	(0.05	2.25)	-0.12	(-0.33	0.10)	
HRCT pattern																	
UIP-like pattern only	23	4	17.4	45	3	6.7	0.169	0.38	(0.09	1.57)	0.34	(0.07	1.67)	-0.11	(-0.28	0.06)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.670
<=70%	10	1	10.0	17	1	5.9	0.693	0.59	(0.04	8.41)	0.56	(0.03	10.12)	-0.04	(-0.26	0.18)	
>70%	17	3	17.6	37	2	5.4	0.149	0.31	(0.06	1.67)	0.27	(0.04	1.77)	-0.12	(-0.32	0.07)	
Underlying ILD Diagnosis in Groups																	0.525
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	3	25.0	34	3	8.8	0.153	0.35	(0.08	1.52)	0.29	(0.05	1.69)	-0.16	(-0.42	0.10)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.6.1 Proportion of patients with adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup - Treated Set

Body System or Organ Class: Vascular disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	4	7.4	0.514	2.00	(0.23	17.03)	2.08	(0.22	19.58)	0.04	(-0.06	0.14)	
Age group																	0.251
<65 years	9	1	11.1	25	2	8.0	0.778	0.72	(0.07	7.01)	0.70	(0.06	8.75)	-0.03	(-0.26	0.20)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02	0.16)	
Gender																	0.412
Male	11	0	0.0	26	2	7.7	0.344							0.08	(-0.03	0.18)	
Female	16	1	6.3	28	2	7.1	0.910	1.14	(0.11	11.64)	1.15	(0.10	13.82)	0.01	(-0.14	0.16)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	4	8.9	0.497	2.04	(0.24	17.25)	2.15	(0.23	20.40)	0.05	(-0.07	0.16)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.035
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29	0.09)	
>70%	17	0	0.0	37	4	10.8	0.159							0.11	(0.01	0.21)	
Underlying ILD Diagnosis in Groups																	0.477
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	2	18.2	0.829	1.27	(0.14	11.55)	1.33	(0.10	18.19)	0.04	(-0.31	0.38)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	2	5.9	0.390							0.06	(-0.02	0.14)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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1.3.7 Serious adverse events on SOC level

Table 3.7.1 Proportion of patients with serious adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup
Treated Set

Body System or Organ Class: Cardiac disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	4	7.4	0.514	2.00	(0.23	17.03)	2.08	(0.22	19.58)	0.04	(-0.06	0.14)	
Age group																	0.666
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	1	5.6	29	3	10.3	0.567	1.86	(0.21	16.56)	1.96	(0.19	20.45)	0.05	(-0.11	0.20)	
Gender																	0.297
Male	11	1	9.1	26	2	7.7	0.887	0.85	(0.09	8.39)	0.83	(0.07	10.27)	-0.01	(-0.21	0.18)	
Female	16	0	0.0	28	2	7.1	0.274							0.07	(-0.02	0.17)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	4	8.9	0.497	2.04	(0.24	17.25)	2.15	(0.23	20.40)	0.05	(-0.07	0.16)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.529
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05	0.17)	
>70%	17	1	5.9	37	3	8.1	0.772	1.38	(0.15	12.31)	1.41	(0.14	14.65)	0.02	(-0.12	0.16)	
Underlying ILD Diagnosis in Groups																	0.176
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	3	8.8	0.287							0.09	(-0.01	0.18)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.7.1 Proportion of patients with serious adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup
Treated Set

Body System or Organ Class: Ear and labyrinth disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.7.1 Proportion of patients with serious adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup
Treated Set

Body System or Organ Class: Gastrointestinal disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.7.1 Proportion of patients with serious adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup
Treated Set

Body System or Organ Class: General disorders and administration site conditions

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26 | 0.08)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.7.1 Proportion of patients with serious adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup
Treated Set

Body System or Organ Class: Immune system disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.7.1 Proportion of patients with serious adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup
Treated Set

Body System or Organ Class: Infections and infestations

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	5	18.5	54	12	22.2	0.700	1.20	(0.47	3.06)	1.26	(0.39	4.03)	0.04	(-0.15	0.22)	
Age group																	0.206
<65 years	9	2	22.2	25	3	12.0	0.458	0.54	(0.11	2.73)	0.48	(0.07	3.46)	-0.10	(-0.40	0.20)	
>=65 years	18	3	16.7	29	9	31.0	0.272	1.86	(0.58	5.98)	2.25	(0.52	9.77)	0.14	(-0.10	0.38)	
Gender																	0.678
Male	11	3	27.3	26	9	34.6	0.663	1.27	(0.42	3.81)	1.41	(0.30	6.68)	0.07	(-0.25	0.39)	
Female	16	2	12.5	28	3	10.7	0.858	0.86	(0.16	4.60)	0.84	(0.13	5.64)	-0.02	(-0.22	0.18)	
HRCT pattern																	0.327
UIP-like pattern only	23	5	21.7	45	10	22.2	0.964	1.02	(0.40	2.64)	1.03	(0.31	3.47)	0.00	(-0.20	0.21)	
Other fibrotic patterns	4	0	0.0	9	2	22.2	0.305							0.22	(-0.05	0.49)	
Baseline FVC % predicted																	0.409
<=70%	10	1	10.0	17	4	23.5	0.382	2.35	(0.30	18.23)	2.77	(0.26	29.05)	0.14	(-0.14	0.41)	
>70%	17	4	23.5	37	8	21.6	0.876	0.92	(0.32	2.64)	0.90	(0.23	3.52)	-0.02	(-0.26	0.22)	
Underlying ILD Diagnosis in Groups																	0.127
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	4	36.4	0.070							0.36	(0.08	0.65)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	3	25.0	34	7	20.6	0.750	0.82	(0.25	2.68)	0.78	(0.17	3.66)	-0.04	(-0.32	0.24)	
Other ILDs	5	2	40.0	6	1	16.7	0.387	0.42	(0.05	3.36)	0.30	(0.02	4.91)	-0.23	(-0.76	0.29)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.7.1 Proportion of patients with serious adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup
Treated Set

Body System or Organ Class: Injury, poisoning and procedural complications

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.7.1 Proportion of patients with serious adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup
Treated Set

Body System or Organ Class: Investigations

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.7.1 Proportion of patients with serious adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup
Treated Set

Body System or Organ Class: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	0	0.0	0.197	0.00			0.00			-0.14	(-0.40 | 0.12)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.7.1 Proportion of patients with serious adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup
Treated Set

Body System or Organ Class: Nervous system disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02	0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03	0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04	0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00	0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.7.1 Proportion of patients with serious adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup
Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	7	25.9	54	5	9.3	0.047	0.36	(0.12	1.02)	0.29	(0.08	1.03)	-0.17	(-0.35	0.02)	
Age group																	0.294
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32	0.09)	
>=65 years	18	6	33.3	29	5	17.2	0.205	0.52	(0.18	1.45)	0.42	(0.11	1.65)	-0.16	(-0.42	0.10)	
Gender																	0.019
Male	11	2	18.2	26	5	19.2	0.941	1.06	(0.24	4.65)	1.07	(0.17	6.59)	0.01	(-0.26	0.28)	
Female	16	5	31.3	28	0	0.0	0.002	0.00			0.00			-0.31	(-0.54	-0.09)	
HRCT pattern																	0.859
UIP-like pattern only	23	6	26.1	45	4	8.9	0.058	0.34	(0.11	1.09)	0.28	(0.07	1.11)	-0.17	(-0.37	0.03)	
Other fibrotic patterns	4	1	25.0	9	1	11.1	0.522	0.44	(0.04	5.46)	0.38	(0.02	8.10)	-0.14	(-0.61	0.33)	
Baseline FVC % predicted																	0.113
<=70%	10	3	30.0	17	0	0.0	0.017	0.00			0.00			-0.30	(-0.58	-0.02)	
>70%	17	4	23.5	37	5	13.5	0.359	0.57	(0.18	1.87)	0.51	(0.12	2.20)	-0.10	(-0.33	0.13)	
Underlying ILD Diagnosis in Groups																	0.915
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	2	28.6	11	1	9.1	0.280	0.32	(0.04	2.89)	0.25	(0.02	3.47)	-0.19	(-0.57	0.18)	
Unclassifiable idiopathic interstitial pneumonia	3	1	33.3	2	0	0.0	0.361	0.00			0.00			-0.33	(-0.87	0.20)	
Autoimmune ILDs	12	2	16.7	34	3	8.8	0.453	0.53	(0.10	2.79)	0.48	(0.07	3.32)	-0.08	(-0.31	0.15)	
Other ILDs	5	2	40.0	6	1	16.7	0.387	0.42	(0.05	3.36)	0.30	(0.02	4.91)	-0.23	(-0.76	0.29)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.7.1 Proportion of patients with serious adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup
Treated Set

Body System or Organ Class: Skin and subcutaneous tissue disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24 | 0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.7.1 Proportion of patients with serious adverse events on SOC level over the whole trial by treatment and primary SOC and by subgroup
Treated Set

Body System or Organ Class: Vascular disorders

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	2	3.7	1.000	1.00	(0.09	10.54)	1.00	(0.09	11.54)	0.00	(-0.09	0.09)	
Age group																	0.040
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32	0.09)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02	0.16)	
Gender																	0.435
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04	0.11)	
Female	16	1	6.3	28	1	3.6	0.682	0.57	(0.04	8.53)	0.56	(0.03	9.54)	-0.03	(-0.16	0.11)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	2	4.4	0.985	1.02	(0.10	10.69)	1.02	(0.09	11.92)	0.00	(-0.10	0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.099
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29	0.09)	
>70%	17	0	0.0	37	2	5.4	0.329							0.05	(-0.02	0.13)	
Underlying ILD Diagnosis in Groups																	0.485
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	1	9.1	0.732	0.64	(0.05	8.61)	0.60	(0.03	11.47)	-0.05	(-0.36	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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1.3.8 Adverse events on SOC and PT level

Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Blood and lymphatic system disorders
Dictionary-Derived Term: Anaemia

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	1	1.9	0.613	0.50	(0.03	7.69)	0.49	(0.03	8.16)	-0.02	(-0.10	0.06)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	1	5.6	29	1	3.4	0.728	0.62	(0.04	9.32)	0.61	(0.04	10.36)	-0.02	(-0.15	0.10)	
Gender																	
Male	11	1	9.1	26	1	3.8	0.519	0.42	(0.03	6.17)	0.40	(0.02	7.03)	-0.05	(-0.24	0.13)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00	0.00)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	1	2.2	0.624	0.51	(0.03	7.80)	0.50	(0.03	8.38)	-0.02	(-0.12	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	1	5.9	37	1	2.7	0.566	0.46	(0.03	6.92)	0.44	(0.03	7.56)	-0.03	(-0.16	0.09)	
Underlying ILD Diagnosis in Groups																	0.234
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Blood and lymphatic system disorders
Dictionary-Derived Term: Coagulopathy

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26 | 0.08)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Blood and lymphatic system disorders
Dictionary-Derived Term: Leukocytosis

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
							p-value	Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	0	0.0	0.043	0.00			0.00			-0.07	(-0.17 | 0.02)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	2	11.1	29	0	0.0	0.067	0.00			0.00			-0.11	(-0.26 | 0.03)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	2	12.5	28	0	0.0	0.056	0.00			0.00			-0.13	(-0.29 | 0.04)	
HRCT pattern																	
UIP-like pattern only	23	2	8.7	45	0	0.0	0.045	0.00			0.00			-0.09	(-0.20 | 0.03)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	2	11.8	37	0	0.0	0.033	0.00			0.00			-0.12	(-0.27 | 0.04)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24 | 0.07)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Blood and lymphatic system disorders
Dictionary-Derived Term: Lymphopenia

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02	0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03	0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04	0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00	0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00	0.00)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00	0.00)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13	0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Blood and lymphatic system disorders
Dictionary-Derived Term: Neutrophilia

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
							p-value	Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Blood and lymphatic system disorders
Dictionary-Derived Term: Thrombocytopenia

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	1	1.9	0.613	0.50	(0.03	7.69)	0.49	(0.03	8.16)	-0.02	(-0.10	0.06)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	1	5.6	29	1	3.4	0.728	0.62	(0.04	9.32)	0.61	(0.04	10.36)	-0.02	(-0.15	0.10)	
Gender																	
Male	11	1	9.1	26	1	3.8	0.519	0.42	(0.03	6.17)	0.40	(0.02	7.03)	-0.05	(-0.24	0.13)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00	0.00)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	1	2.2	0.624	0.51	(0.03	7.80)	0.50	(0.03	8.38)	-0.02	(-0.12	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.127
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05	0.17)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17	0.05)	
Underlying ILD Diagnosis in Groups																	0.209
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	0	0.0	0.197	0.00			0.00			-0.14	(-0.40	0.12)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Cardiac disorders
Dictionary-Derived Term: Angina unstable

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Cardiac disorders
Dictionary-Derived Term: Arteriosclerosis coronary artery

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01 | 0.09)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02 | 0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	2	5.9	0.390							0.06	(-0.02 | 0.14)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Cardiac disorders
Dictionary-Derived Term: Atrial fibrillation

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01 | 0.09)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02 | 0.16)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02 | 0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	2	5.4	0.329							0.05	(-0.02 | 0.13)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	2	5.9	0.390							0.06	(-0.02 | 0.14)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Cardiac disorders
Dictionary-Derived Term: Cardiac disorder

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Cardiac disorders
Dictionary-Derived Term: Cardiac failure

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	1	1.9	0.613	0.50	(0.03	7.69)	0.49	(0.03	8.16)	-0.02	(-0.10	0.06)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	1	5.6	29	1	3.4	0.728	0.62	(0.04	9.32)	0.61	(0.04	10.36)	-0.02	(-0.15	0.10)	
Gender																	
Male	11	1	9.1	26	1	3.8	0.519	0.42	(0.03	6.17)	0.40	(0.02	7.03)	-0.05	(-0.24	0.13)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00	0.00)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	1	2.2	0.624	0.51	(0.03	7.80)	0.50	(0.03	8.38)	-0.02	(-0.12	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	1	5.9	37	1	2.7	0.566	0.46	(0.03	6.92)	0.44	(0.03	7.56)	-0.03	(-0.16	0.09)	
Underlying ILD Diagnosis in Groups																	0.234
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Cardiac disorders
Dictionary-Derived Term: Coronary artery disease

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Cardiac disorders
Dictionary-Derived Term: Palpitations

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Ear and labyrinth disorders
Dictionary-Derived Term: Vertigo

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Ear and labyrinth disorders
Dictionary-Derived Term: Vertigo positional

	Placebo			Nintedanib				Nintedanib vs Placebo [2]							
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02	0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00	0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04	0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00	0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Endocrine disorders
Dictionary-Derived Term: Hypothyroidism

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Abdominal discomfort

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	7	13.0	0.188	3.50	(0.45	27.02)	3.87	(0.45	33.22)	0.09	(-0.02	0.21)	
Age group																	0.299
<65 years	9	1	11.1	25	4	16.0	0.723	1.44	(0.18	11.24)	1.52	(0.15	15.78)	0.05	(-0.20	0.30)	
>=65 years	18	0	0.0	29	3	10.3	0.158							0.10	(-0.01	0.21)	
Gender																	0.115
Male	11	1	9.1	26	2	7.7	0.887	0.85	(0.09	8.39)	0.83	(0.07	10.27)	-0.01	(-0.21	0.18)	
Female	16	0	0.0	28	5	17.9	0.073							0.18	(0.04	0.32)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	7	15.6	0.175	3.58	(0.47	27.36)	4.05	(0.47	35.14)	0.11	(-0.02	0.25)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.008
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29	0.09)	
>70%	17	0	0.0	37	7	18.9	0.055							0.19	(0.06	0.32)	
Underlying ILD Diagnosis in Groups																	0.692
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	5	14.7	0.573	1.76	(0.23	13.62)	1.90	(0.20	18.11)	0.06	(-0.13	0.26)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13	0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Abdominal pain

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	4	7.4	0.147							0.07	(0.00 | 0.14)	
Age group																	
<65 years	9	0	0.0	25	2	8.0	0.382							0.08	(-0.03 | 0.19)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02 | 0.16)	
Gender																	
Male	11	0	0.0	26	2	7.7	0.344							0.08	(-0.03 | 0.18)	
Female	16	0	0.0	28	2	7.1	0.274							0.07	(-0.02 | 0.17)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	3	6.7	0.205							0.07	(-0.01 | 0.14)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09 | 0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	4	10.8	0.159							0.11	(0.01 | 0.21)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	3	27.3	0.130							0.27	(0.01 | 0.54)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Abdominal pain upper

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	5	9.3	0.103							0.09	(0.02	0.17)	
Age group																	
<65 years	9	0	0.0	25	3	12.0	0.276							0.12	(-0.01	0.25)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02	0.16)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04	0.11)	
Female	16	0	0.0	28	4	14.3	0.113							0.14	(0.01	0.27)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	3	6.7	0.205							0.07	(-0.01	0.14)	
Other fibrotic patterns	4	0	0.0	9	2	22.2	0.305							0.22	(-0.05	0.49)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	5	13.5	0.112							0.14	(0.02	0.25)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	3	8.8	0.287							0.09	(-0.01	0.18)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13	0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Chronic gastritis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01 | 0.09)	
Age group																	
<65 years	9	0	0.0	25	2	8.0	0.382							0.08	(-0.03 | 0.19)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	2	7.1	0.274							0.07	(-0.02 | 0.17)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	0	0.0	9	2	22.2	0.305							0.22	(-0.05 | 0.49)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	2	5.4	0.329							0.05	(-0.02 | 0.13)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Constipation

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	3	5.6	0.744	0.75	(0.13	4.22)	0.74	(0.12	4.69)	-0.02	(-0.13	0.10)	
Age group																	0.061
<65 years	9	2	22.2	25	1	4.0	0.098	0.18	(0.02	1.75)	0.15	(0.01	1.86)	-0.18	(-0.46	0.10)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02	0.16)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	2	12.5	28	3	10.7	0.858	0.86	(0.16	4.60)	0.84	(0.13	5.64)	-0.02	(-0.22	0.18)	
HRCT pattern																	
UIP-like pattern only	23	2	8.7	45	3	6.7	0.762	0.77	(0.14	4.27)	0.75	(0.12	4.84)	-0.02	(-0.16	0.12)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.802
<=70%	10	1	10.0	17	1	5.9	0.693	0.59	(0.04	8.41)	0.56	(0.03	10.12)	-0.04	(-0.26	0.18)	
>70%	17	1	5.9	37	2	5.4	0.943	0.92	(0.09	9.45)	0.91	(0.08	10.83)	-0.00	(-0.14	0.13)	
Underlying ILD Diagnosis in Groups																	0.067
Hypersensitivity pneumonitis	0	0	0.0	1	1	100.0											
Idiopathic nonspecific interstitial pneumonia	7	2	28.6	11	0	0.0	0.060	0.00			0.00			-0.29	(-0.62	0.05)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	2	5.9	0.390							0.06	(-0.02	0.14)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Diarrhoea

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	4	14.8	54	19	35.2	0.055	2.38	(0.90	6.29)	3.12	(0.94	10.36)	0.20	(0.02	0.39)	
Age group																	0.536
<65 years	9	1	11.1	25	5	20.0	0.549	1.80	(0.24	13.40)	2.00	(0.20	19.91)	0.09	(-0.17	0.35)	
>=65 years	18	3	16.7	29	14	48.3	0.028	2.90	(0.96	8.70)	4.67	(1.11	19.65)	0.32	(0.07	0.57)	
Gender																	0.149
Male	11	0	0.0	26	8	30.8	0.038							0.31	(0.13	0.49)	
Female	16	4	25.0	28	11	39.3	0.336	1.57	(0.60	4.13)	1.94	(0.50	7.58)	0.14	(-0.14	0.42)	
HRCT pattern																	0.303
UIP-like pattern only	23	3	13.0	45	17	37.8	0.034	2.90	(0.95	8.88)	4.05	(1.04	15.69)	0.25	(0.05	0.44)	
Other fibrotic patterns	4	1	25.0	9	2	22.2	0.913	0.89	(0.11	7.20)	0.86	(0.05	13.48)	-0.03	(-0.53	0.48)	
Baseline FVC % predicted																	0.627
<=70%	10	1	10.0	17	6	35.3	0.148	3.53	(0.49	25.25)	4.91	(0.50	48.62)	0.25	(-0.04	0.55)	
>70%	17	3	17.6	37	13	35.1	0.191	1.99	(0.65	6.08)	2.53	(0.61	10.44)	0.17	(-0.06	0.41)	
Underlying ILD Diagnosis in Groups																	0.158
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	7	63.6	0.040	4.45	(0.69	28.87)	10.50	(0.91	>99.99)	0.49	(0.11	0.88)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	1	50.0	0.171							0.50	(-0.19	1.19)	
Autoimmune ILDs	12	1	8.3	34	10	29.4	0.141	3.53	(0.50	24.74)	4.58	(0.52	40.38)	0.21	(-0.01	0.43)	
Other ILDs	5	2	40.0	6	1	16.7	0.387	0.42	(0.05	3.36)	0.30	(0.02	4.91)	-0.23	(-0.76	0.29)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Dysphagia

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26 | 0.08)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	1	25.0	9	0	0.0	0.118	0.00			0.00			-0.25	(-0.67 | 0.17)	
Baseline FVC % predicted																	
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29 | 0.09)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Enteritis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Flatulence

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	1	25.0	9	0	0.0	0.118	0.00			0.00			-0.25	(-0.67 | 0.17)	
Baseline FVC % predicted																	
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29 | 0.09)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Gastritis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	1	50.0	0.171							0.50	(-0.19 | 1.19)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Gastrointestinal disorder

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Haematochezia

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26 | 0.08)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Haemorrhoids

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	1	1.9	0.613	0.50	(0.03	7.69)	0.49	(0.03	8.16)	-0.02	(-0.10	0.06)	
Age group																	0.098
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32	0.09)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03	0.10)	
Gender																	
Male	11	1	9.1	26	1	3.8	0.519	0.42	(0.03	6.17)	0.40	(0.02	7.03)	-0.05	(-0.24	0.13)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00	0.00)	
HRCT pattern																	0.166
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13	0.04)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	0.175
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29	0.09)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	0.072
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24	0.07)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13	0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Large intestine polyp

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Mouth ulceration

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09 | 0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Nausea

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	1	3.7	54	4	7.4	0.514	2.00	(0.23	17.03)	2.08	(0.22	19.58)	0.04	(-0.06	0.14)	
Age group																	0.459
<65 years	9	0	0.0	25	2	8.0	0.382							0.08	(-0.03 | 0.19)	
>=65 years	18	1	5.6	29	2	6.9	0.855	1.24	(0.12	12.72)	1.26	(0.11	14.98)	0.01	(-0.13	0.15)	
Gender																	0.628
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	1	6.3	28	3	10.7	0.620	1.71	(0.19	15.14)	1.80	(0.17	18.91)	0.04	(-0.12	0.21)	
HRCT pattern																	0.143
UIP-like pattern only	23	0	0.0	45	3	6.7	0.205							0.07	(-0.01 | 0.14)	
Other fibrotic patterns	4	1	25.0	9	1	11.1	0.522	0.44	(0.04	5.46)	0.38	(0.02	8.10)	-0.14	(-0.61	0.33)	
Baseline FVC % predicted																	
<=70%	10	1	10.0	17	4	23.5	0.382	2.35	(0.30	18.23)	2.77	(0.26	29.05)	0.14	(-0.14	0.41)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	0.229
Hypersensitivity pneumonitis	0	0	0.0	1	1	100.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	2	5.9	0.390							0.06	(-0.02 | 0.14)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Oral lichen planus

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	1	25.0	9	0	0.0	0.118	0.00			0.00			-0.25	(-0.67 | 0.17)	
Baseline FVC % predicted																	
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29 | 0.09)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Toothache

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	1	50.0	0.171							0.50	(-0.19 | 1.19)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Vomiting

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	7	13.0	0.188	3.50	(0.45	27.02)	3.87	(0.45	33.22)	0.09	(-0.02	0.21)	
Age group																	0.510
<65 years	9	0	0.0	25	3	12.0	0.276							0.12	(-0.01	0.25)	
>=65 years	18	1	5.6	29	4	13.8	0.373	2.48	(0.30	20.50)	2.72	(0.28	26.49)	0.08	(-0.08	0.25)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	1	6.3	28	7	25.0	0.121	4.00	(0.54	29.65)	5.00	(0.56	45.02)	0.19	(-0.01	0.39)	
HRCT pattern																	0.051
UIP-like pattern only	23	0	0.0	45	6	13.3	0.067							0.13	(0.03	0.23)	
Other fibrotic patterns	4	1	25.0	9	1	11.1	0.522	0.44	(0.04	5.46)	0.38	(0.02	8.10)	-0.14	(-0.61	0.33)	
Baseline FVC % predicted																	0.335
<=70%	10	1	10.0	17	3	17.6	0.589	1.76	(0.21	14.76)	1.93	(0.17	21.54)	0.08	(-0.18	0.34)	
>70%	17	0	0.0	37	4	10.8	0.159							0.11	(0.01	0.21)	
Underlying ILD Diagnosis in Groups																	0.104
Hypersensitivity pneumonitis	0	0	0.0	1	1	100.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	5	14.7	0.159							0.15	(0.03	0.27)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: General disorders and administration site conditions
Dictionary-Derived Term: Chest pain

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	3	5.6	0.744	0.75	(0.13	4.22)	0.74	(0.12	4.69)	-0.02	(-0.13	0.10)	
Age group																	0.944
<65 years	9	1	11.1	25	2	8.0	0.778	0.72	(0.07	7.01)	0.70	(0.06	8.75)	-0.03	(-0.26	0.20)	
>=65 years	18	1	5.6	29	1	3.4	0.728	0.62	(0.04	9.32)	0.61	(0.04	10.36)	-0.02	(-0.15	0.10)	
Gender																	0.580
Male	11	1	9.1	26	1	3.8	0.519	0.42	(0.03	6.17)	0.40	(0.02	7.03)	-0.05	(-0.24	0.13)	
Female	16	1	6.3	28	2	7.1	0.910	1.14	(0.11	11.64)	1.15	(0.10	13.82)	0.01	(-0.14	0.16)	
HRCT pattern																	0.133
UIP-like pattern only	23	2	8.7	45	1	2.2	0.219	0.26	(0.02	2.67)	0.24	(0.02	2.78)	-0.06	(-0.19	0.06)	
Other fibrotic patterns	4	0	0.0	9	2	22.2	0.305							0.22	(-0.05	0.49)	
Baseline FVC % predicted																	0.802
<=70%	10	1	10.0	17	1	5.9	0.693	0.59	(0.04	8.41)	0.56	(0.03	10.12)	-0.04	(-0.26	0.18)	
>70%	17	1	5.9	37	2	5.4	0.943	0.92	(0.09	9.45)	0.91	(0.08	10.83)	-0.00	(-0.14	0.13)	
Underlying ILD Diagnosis in Groups																	0.386
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	2	5.9	0.768	0.71	(0.07	7.10)	0.69	(0.06	8.34)	-0.02	(-0.20	0.15)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: General disorders and administration site conditions
Dictionary-Derived Term: Fatigue

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	4	7.4	0.147							0.07	(0.00	0.14)	
Age group																	
<65 years	9	0	0.0	25	2	8.0	0.382							0.08	(-0.03	0.19)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02	0.16)	
Gender																	
Male	11	0	0.0	26	3	11.5	0.240							0.12	(-0.01	0.24)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03	0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	3	6.7	0.205							0.07	(-0.01	0.14)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	4	23.5	0.097							0.24	(0.03	0.44)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00	0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	3	27.3	0.130							0.27	(0.01	0.54)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: General disorders and administration site conditions
Dictionary-Derived Term: Oedema peripheral

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24 | 0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: General disorders and administration site conditions
Dictionary-Derived Term: Pain

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: General disorders and administration site conditions
Dictionary-Derived Term: Pyrexia

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2] Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	4	7.4	1.000	1.00	(0.20	5.12)	1.00	(0.17	5.84)	0.00	(-0.12	0.12)	
Age group																	0.539
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	2	11.1	29	3	10.3	0.934	0.93	(0.17	5.04)	0.92	(0.14	6.14)	-0.01	(-0.19	0.17)	
Gender																	0.649
Male	11	1	9.1	26	3	11.5	0.827	1.27	(0.15	10.90)	1.30	(0.12	14.12)	0.02	(-0.19	0.23)	
Female	16	1	6.3	28	1	3.6	0.682	0.57	(0.04	8.53)	0.56	(0.03	9.54)	-0.03	(-0.16	0.11)	
HRCT pattern																	0.215
UIP-like pattern only	23	2	8.7	45	2	4.4	0.481	0.51	(0.08	3.40)	0.49	(0.06	3.71)	-0.04	(-0.17	0.09)	
Other fibrotic patterns	4	0	0.0	9	2	22.2	0.305							0.22	(-0.05	0.49)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	2	11.8	37	4	10.8	0.917	0.92	(0.19	4.54)	0.91	(0.15	5.52)	-0.01	(-0.19	0.17)	
Underlying ILD Diagnosis in Groups																	0.069
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	2	16.7	34	2	5.9	0.254	0.35	(0.06	2.24)	0.31	(0.04	2.51)	-0.11	(-0.33	0.12)	
Other ILDs	5	0	0.0	6	2	33.3	0.154							0.33	(-0.04	0.71)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Hepatobiliary disorders
Dictionary-Derived Term: Cholecystitis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01 | 0.09)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02 | 0.16)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02 | 0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Hepatobiliary disorders
Dictionary-Derived Term: Cholestasis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02	0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03	0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03	0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Hepatobiliary disorders
Dictionary-Derived Term: Hepatic function abnormal

	Placebo			Nintedanib				Nintedanib vs Placebo [2]									
							p-value	Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	12	22.2	0.096	3.00	(0.72	12.46)	3.57	(0.74	17.28)	0.15	(-0.00	0.30)	
Age group																	0.194
<65 years	9	0	0.0	25	7	28.0	0.075							0.28	(0.10	0.46)	
>=65 years	18	2	11.1	29	5	17.2	0.566	1.55	(0.34	7.17)	1.67	(0.29	9.66)	0.06	(-0.14	0.26)	
Gender																	0.075
Male	11	2	18.2	26	5	19.2	0.941	1.06	(0.24	4.65)	1.07	(0.17	6.59)	0.01	(-0.26	0.28)	
Female	16	0	0.0	28	7	25.0	0.029							0.25	(0.09	0.41)	
HRCT pattern																	0.547
UIP-like pattern only	23	2	8.7	45	10	22.2	0.166	2.56	(0.61	10.71)	3.00	(0.60	15.03)	0.14	(-0.03	0.30)	
Other fibrotic patterns	4	0	0.0	9	2	22.2	0.305							0.22	(-0.05	0.49)	
Baseline FVC % predicted																	0.112
<=70%	10	0	0.0	17	6	35.3	0.033							0.35	(0.13	0.58)	
>70%	17	2	11.8	37	6	16.2	0.669	1.38	(0.31	6.14)	1.45	(0.26	8.07)	0.04	(-0.15	0.24)	
Underlying ILD Diagnosis in Groups																	0.059
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	2	18.2	0.829	1.27	(0.14	11.55)	1.33	(0.10	18.19)	0.04	(-0.31	0.38)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	10	29.4	0.034							0.29	(0.14	0.45)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Hepatobiliary disorders
Dictionary-Derived Term: Hepatic lesion

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02	0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03	0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03	0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Hepatobiliary disorders
Dictionary-Derived Term: Hepatic steatosis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Hepatobiliary disorders
Dictionary-Derived Term: Liver injury

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	3	5.6	0.212							0.06	(-0.01	0.12)	
Age group																	
<65 years	9	0	0.0	25	2	8.0	0.382							0.08	(-0.03	0.19)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03	0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	0	0.0	28	3	10.7	0.175							0.11	(-0.01	0.22)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02	0.10)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05	0.17)	
>70%	17	0	0.0	37	2	5.4	0.329							0.05	(-0.02	0.13)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	3	8.8	0.287							0.09	(-0.01	0.18)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Immune system disorders
Dictionary-Derived Term: Anti-neutrophil cytoplasmic antibody positive vasculitis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Immune system disorders
Dictionary-Derived Term: Hypersensitivity

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Bronchopulmonary aspergillosis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: COVID-19

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	7	25.9	54	15	27.8	0.860	1.07	(0.50	2.31)	1.10	(0.39	3.13)	0.02	(-0.19	0.22)	
Age group																	0.779
<65 years	9	2	22.2	25	7	28.0	0.736	1.26	(0.32	4.98)	1.36	(0.23	8.22)	0.06	(-0.27	0.38)	
>=65 years	18	5	27.8	29	8	27.6	0.989	0.99	(0.38	2.57)	0.99	(0.27	3.69)	-0.00	(-0.27	0.26)	
Gender																	0.217
Male	11	2	18.2	26	9	34.6	0.317	1.90	(0.49	7.42)	2.38	(0.42	13.47)	0.16	(-0.13	0.46)	
Female	16	5	31.3	28	6	21.4	0.469	0.69	(0.25	1.89)	0.60	(0.15	2.41)	-0.10	(-0.37	0.18)	
HRCT pattern																	0.478
UIP-like pattern only	23	5	21.7	45	12	26.7	0.657	1.23	(0.49	3.06)	1.31	(0.40	4.31)	0.05	(-0.16	0.26)	
Other fibrotic patterns	4	2	50.0	9	3	33.3	0.569	0.67	(0.17	2.56)	0.50	(0.05	5.51)	-0.17	(-0.75	0.41)	
Baseline FVC % predicted																	0.193
<=70%	10	4	40.0	17	4	23.5	0.365	0.59	(0.19	1.85)	0.46	(0.09	2.50)	-0.16	(-0.53	0.20)	
>70%	17	3	17.6	37	11	29.7	0.347	1.68	(0.54	5.27)	1.97	(0.47	8.27)	0.12	(-0.11	0.35)	
Underlying ILD Diagnosis in Groups																	0.689
Hypersensitivity pneumonitis	0	0	0.0	1	1	100.0											
Idiopathic nonspecific interstitial pneumonia	7	2	28.6	11	2	18.2	0.605	0.64	(0.11	3.54)	0.56	(0.06	5.24)	-0.10	(-0.51	0.30)	
Unclassifiable idiopathic interstitial pneumonia	3	2	66.7	2	2	100.0	0.361	1.50	(0.67	3.34)				0.33	(-0.20	0.87)	
Autoimmune ILDs	12	2	16.7	34	9	26.5	0.494	1.59	(0.40	6.34)	1.80	(0.33	9.84)	0.10	(-0.16	0.36)	
Other ILDs	5	1	20.0	6	1	16.7	0.887	0.83	(0.07	10.20)	0.80	(0.04	17.20)	-0.03	(-0.49	0.43)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: COVID-19 pneumonia

	Placebo			Nintedanib				Nintedanib vs Placebo [2]									
							p-value	Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	2	3.7	1.000	1.00	(0.09	10.54)	1.00	(0.09	11.54)	0.00	(-0.09	0.09)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	1	5.6	29	2	6.9	0.855	1.24	(0.12	12.72)	1.26	(0.11	14.98)	0.01	(-0.13	0.15)	
Gender																	0.322
Male	11	1	9.1	26	1	3.8	0.519	0.42	(0.03	6.17)	0.40	(0.02	7.03)	-0.05	(-0.24	0.13)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03	0.10)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	2	4.4	0.985	1.02	(0.10	10.69)	1.02	(0.09	11.92)	0.00	(-0.10	0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.332
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05	0.17)	
>70%	17	1	5.9	37	1	2.7	0.566	0.46	(0.03	6.92)	0.44	(0.03	7.56)	-0.03	(-0.16	0.09)	
Underlying ILD Diagnosis in Groups																	0.299
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Complicated appendicitis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Conjunctivitis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	1	1.9	0.613	0.50	(0.03	7.69)	0.49	(0.03	8.16)	-0.02	(-0.10	0.06)	
Age group																	0.098
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32	0.09)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03	0.10)	
Gender																	
Male	11	1	9.1	26	1	3.8	0.519	0.42	(0.03	6.17)	0.40	(0.02	7.03)	-0.05	(-0.24	0.13)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00	0.00)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	1	2.2	0.624	0.51	(0.03	7.80)	0.50	(0.03	8.38)	-0.02	(-0.12	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.175
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29	0.09)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	1	2.9	0.431	0.35	(0.02	5.21)	0.33	(0.02	5.79)	-0.05	(-0.22	0.11)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Epstein-Barr virus infection

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Febrile infection

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: H1N1 influenza

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32 | 0.09)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26 | 0.08)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29 | 0.09)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24 | 0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Hepatitis A

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Herpes zoster

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	2	3.7	1.000	1.00	(0.09	10.54)	1.00	(0.09	11.54)	0.00	(-0.09	0.09)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	1	5.6	29	2	6.9	0.855	1.24	(0.12	12.72)	1.26	(0.11	14.98)	0.01	(-0.13	0.15)	
Gender																	0.105
Male	11	0	0.0	26	2	7.7	0.344							0.08	(-0.03	0.18)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18	0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	2	4.4	0.985	1.02	(0.10	10.69)	1.02	(0.09	11.92)	0.00	(-0.10	0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.059
<=70%	10	0	0.0	17	2	11.8	0.260							0.12	(-0.04	0.27)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17	0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	2	5.9	0.768	0.71	(0.07	7.10)	0.69	(0.06	8.34)	-0.02	(-0.20	0.15)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Infected skin ulcer

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02	0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00	0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04	0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00	0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05	0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00	0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Influenza

	Placebo			Nintedanib				Nintedanib vs Placebo [2]									
							p-value	Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	3	5.6	0.717	1.50	(0.16	13.75)	1.53	(0.15	15.44)	0.02	(-0.08	0.11)	
Age group																	0.396
<65 years	9	1	11.1	25	2	8.0	0.778	0.72	(0.07	7.01)	0.70	(0.06	8.75)	-0.03	(-0.26	0.20)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03	0.10)	
Gender																	0.556
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04	0.11)	
Female	16	1	6.3	28	2	7.1	0.910	1.14	(0.11	11.64)	1.15	(0.10	13.82)	0.01	(-0.14	0.16)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	3	6.7	0.701	1.53	(0.17	13.93)	1.57	(0.15	16.01)	0.02	(-0.09	0.13)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.058
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29	0.09)	
>70%	17	0	0.0	37	3	8.1	0.227							0.08	(-0.01	0.17)	
Underlying ILD Diagnosis in Groups																	0.163
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	0	0.0	0.197	0.00			0.00			-0.14	(-0.40	0.12)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	2	5.9	0.390							0.06	(-0.02	0.14)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13	0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Laryngitis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26 | 0.08)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	1	25.0	9	0	0.0	0.118	0.00			0.00			-0.25	(-0.67 | 0.17)	
Baseline FVC % predicted																	
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29 | 0.09)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Nasopharyngitis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	1	1.9	0.613	0.50	(0.03	7.69)	0.49	(0.03	8.16)	-0.02	(-0.10	0.06)	
Age group																	0.211
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16	0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	1	6.3	28	1	3.6	0.682	0.57	(0.04	8.53)	0.56	(0.03	9.54)	-0.03	(-0.16	0.11)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	1	2.2	0.624	0.51	(0.03	7.80)	0.50	(0.03	8.38)	-0.02	(-0.12	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	1	5.9	37	1	2.7	0.566	0.46	(0.03	6.92)	0.44	(0.03	7.56)	-0.03	(-0.16	0.09)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	1	9.1	0.732	0.64	(0.05	8.61)	0.60	(0.03	11.47)	-0.05	(-0.36	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00	0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Pneumonia

	Placebo			Nintedanib				Nintedanib vs Placebo [2]									
							p-value	Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	6	22.2	54	6	11.1	0.185	0.50	(0.18	1.40)	0.44	(0.13	1.52)	-0.11	(-0.29	0.07)	
Age group																	0.267
<65 years	9	2	22.2	25	1	4.0	0.098	0.18	(0.02	1.75)	0.15	(0.01	1.86)	-0.18	(-0.46	0.10)	
>=65 years	18	4	22.2	29	5	17.2	0.673	0.78	(0.24	2.51)	0.73	(0.17	3.17)	-0.05	(-0.29	0.19)	
Gender																	0.076
Male	11	3	27.3	26	6	23.1	0.786	0.85	(0.26	2.79)	0.80	(0.16	4.00)	-0.04	(-0.35	0.27)	
Female	16	3	18.8	28	0	0.0	0.018	0.00			0.00			-0.19	(-0.38	0.00)	
HRCT pattern																	0.285
UIP-like pattern only	23	6	26.1	45	5	11.1	0.113	0.43	(0.15	1.25)	0.35	(0.10	1.32)	-0.15	(-0.35	0.05)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	0.648
<=70%	10	3	30.0	17	2	11.8	0.239	0.39	(0.08	1.96)	0.31	(0.04	2.30)	-0.18	(-0.51	0.14)	
>70%	17	3	17.6	37	4	10.8	0.487	0.61	(0.15	2.44)	0.57	(0.11	2.86)	-0.07	(-0.28	0.14)	
Underlying ILD Diagnosis in Groups																	0.799
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	2	28.6	11	1	9.1	0.280	0.32	(0.04	2.89)	0.25	(0.02	3.47)	-0.19	(-0.57	0.18)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	2	16.7	34	4	11.8	0.665	0.71	(0.15	3.37)	0.67	(0.11	4.21)	-0.05	(-0.29	0.19)	
Other ILDs	5	2	40.0	6	1	16.7	0.387	0.42	(0.05	3.36)	0.30	(0.02	4.91)	-0.23	(-0.76	0.29)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Pneumonia bacterial

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09 | 0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13 | 0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Pneumonia fungal

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24 | 0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Respiratory syncytial virus infection

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Respiratory tract infection

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	1	1.9	0.212	0.25	(0.02	2.64)	0.24	(0.02	2.73)	-0.06	(-0.16	0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	2	11.1	29	1	3.4	0.296	0.31	(0.03	3.18)	0.29	(0.02	3.40)	-0.08	(-0.24	0.08)	
Gender																	0.441
Male	11	1	9.1	26	1	3.8	0.519	0.42	(0.03	6.17)	0.40	(0.02	7.03)	-0.05	(-0.24	0.13)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18	0.06)	
HRCT pattern																	
UIP-like pattern only	23	2	8.7	45	1	2.2	0.219	0.26	(0.02	2.67)	0.24	(0.02	2.78)	-0.06	(-0.19	0.06)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.064
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05	0.17)	
>70%	17	2	11.8	37	0	0.0	0.033	0.00			0.00			-0.12	(-0.27	0.04)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	2	16.7	34	1	2.9	0.098	0.18	(0.02	1.78)	0.15	(0.01	1.85)	-0.14	(-0.36	0.08)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Tinea pedis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09 | 0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13 | 0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Upper respiratory tract infection

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	4	14.8	54	7	13.0	0.819	0.88	(0.28	2.73)	0.86	(0.23	3.22)	-0.02	(-0.18	0.14)	
Age group																	0.812
<65 years	9	2	22.2	25	4	16.0	0.675	0.72	(0.16	3.28)	0.67	(0.10	4.46)	-0.06	(-0.37	0.25)	
>=65 years	18	2	11.1	29	3	10.3	0.934	0.93	(0.17	5.04)	0.92	(0.14	6.14)	-0.01	(-0.19	0.17)	
Gender																	0.309
Male	11	2	18.2	26	2	7.7	0.348	0.42	(0.07	2.63)	0.38	(0.05	3.08)	-0.10	(-0.35	0.14)	
Female	16	2	12.5	28	5	17.9	0.640	1.43	(0.31	6.53)	1.52	(0.26	8.93)	0.05	(-0.16	0.27)	
HRCT pattern																	0.226
UIP-like pattern only	23	4	17.4	45	5	11.1	0.470	0.64	(0.19	2.15)	0.59	(0.14	2.47)	-0.06	(-0.24	0.12)	
Other fibrotic patterns	4	0	0.0	9	2	22.2	0.305							0.22	(-0.05	0.49)	
Baseline FVC % predicted																	0.775
<=70%	10	1	10.0	17	1	5.9	0.693	0.59	(0.04	8.41)	0.56	(0.03	10.12)	-0.04	(-0.26	0.18)	
>70%	17	3	17.6	37	6	16.2	0.896	0.92	(0.26	3.24)	0.90	(0.20	4.14)	-0.01	(-0.23	0.20)	
Underlying ILD Diagnosis in Groups																	0.386
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	3	25.0	34	6	17.6	0.581	0.71	(0.21	2.39)	0.64	(0.13	3.11)	-0.07	(-0.35	0.20)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Urinary tract infection

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	3	5.6	0.744	0.75	(0.13	4.22)	0.74	(0.12	4.69)	-0.02	(-0.13	0.10)	
Age group																	0.045
<65 years	9	0	0.0	25	3	12.0	0.276							0.12	(-0.01	0.25)	
>=65 years	18	2	11.1	29	0	0.0	0.067	0.00			0.00			-0.11	(-0.26	0.03)	
Gender																	0.118
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26	0.08)	
Female	16	1	6.3	28	3	10.7	0.620	1.71	(0.19	15.14)	1.80	(0.17	18.91)	0.04	(-0.12	0.21)	
HRCT pattern																	0.371
UIP-like pattern only	23	2	8.7	45	2	4.4	0.481	0.51	(0.08	3.40)	0.49	(0.06	3.71)	-0.04	(-0.17	0.09)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	0.093
<=70%	10	0	0.0	17	2	11.8	0.260							0.12	(-0.04	0.27)	
>70%	17	2	11.8	37	1	2.7	0.177	0.23	(0.02	2.36)	0.21	(0.02	2.48)	-0.09	(-0.25	0.07)	
Underlying ILD Diagnosis in Groups																	0.354
Hypersensitivity pneumonitis	0	0	0.0	1	1	100.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	1	2.9	0.431	0.35	(0.02	5.21)	0.33	(0.02	5.79)	-0.05	(-0.22	0.11)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Injury, poisoning and procedural complications
Dictionary-Derived Term: Compression fracture

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26 | 0.08)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	1	25.0	9	0	0.0	0.118	0.00			0.00			-0.25	(-0.67 | 0.17)	
Baseline FVC % predicted																	
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29 | 0.09)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Injury, poisoning and procedural complications
Dictionary-Derived Term: Contusion

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Injury, poisoning and procedural complications
Dictionary-Derived Term: Thoracic vertebral fracture

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Injury, poisoning and procedural complications
Dictionary-Derived Term: Urinary tract injury

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26 | 0.08)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Activated partial thromboplastin time prolonged

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Alanine aminotransferase increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	10	18.5	0.067	5.00	(0.67	37.06)	5.91	(0.71	48.84)	0.15	(0.02	0.27)	
Age group																	0.338
<65 years	9	0	0.0	25	6	24.0	0.105							0.24	(0.07	0.41)	
>=65 years	18	1	5.6	29	4	13.8	0.373	2.48	(0.30	20.50)	2.72	(0.28	26.49)	0.08	(-0.08	0.25)	
Gender																	0.187
Male	11	1	9.1	26	4	15.4	0.609	1.69	(0.21	13.48)	1.82	(0.18	18.41)	0.06	(-0.16	0.28)	
Female	16	0	0.0	28	6	21.4	0.046							0.21	(0.06	0.37)	
HRCT pattern																	0.259
UIP-like pattern only	23	0	0.0	45	6	13.3	0.067							0.13	(0.03	0.23)	
Other fibrotic patterns	4	1	25.0	9	4	44.4	0.506	1.78	(0.28	11.28)	2.40	(0.18	32.88)	0.19	(-0.34	0.73)	
Baseline FVC % predicted																	0.203
<=70%	10	1	10.0	17	3	17.6	0.589	1.76	(0.21	14.76)	1.93	(0.17	21.54)	0.08	(-0.18	0.34)	
>70%	17	0	0.0	37	7	18.9	0.055							0.19	(0.06	0.32)	
Underlying ILD Diagnosis in Groups																	0.585
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	1	50.0	0.171							0.50	(-0.19	1.19)	
Autoimmune ILDs	12	0	0.0	34	6	17.6	0.119							0.18	(0.05	0.30)	
Other ILDs	5	1	20.0	6	2	33.3	0.621	1.67	(0.21	13.43)	2.00	(0.13	31.98)	0.13	(-0.38	0.65)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Aspartate aminotransferase increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	8	14.8	0.339	2.00	(0.46	8.78)	2.17	(0.43	11.03)	0.07	(-0.06	0.21)	
Age group																	0.409
<65 years	9	0	0.0	25	3	12.0	0.276							0.12	(-0.01	0.25)	
>=65 years	18	2	11.1	29	5	17.2	0.566	1.55	(0.34	7.17)	1.67	(0.29	9.66)	0.06	(-0.14	0.26)	
Gender																	0.335
Male	11	1	9.1	26	2	7.7	0.887	0.85	(0.09	8.39)	0.83	(0.07	10.27)	-0.01	(-0.21	0.18)	
Female	16	1	6.3	28	6	21.4	0.185	3.43	(0.45	26.00)	4.09	(0.45	37.53)	0.15	(-0.04	0.34)	
HRCT pattern																	0.087
UIP-like pattern only	23	0	0.0	45	5	11.1	0.097							0.11	(0.02	0.20)	
Other fibrotic patterns	4	2	50.0	9	3	33.3	0.569	0.67	(0.17	2.56)	0.50	(0.05	5.51)	-0.17	(-0.75	0.41)	
Baseline FVC % predicted																	0.021
<=70%	10	2	20.0	17	1	5.9	0.260	0.29	(0.03	2.85)	0.25	(0.02	3.19)	-0.14	(-0.41	0.13)	
>70%	17	0	0.0	37	7	18.9	0.055							0.19	(0.06	0.32)	
Underlying ILD Diagnosis in Groups																	0.191
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	1	50.0	0.171							0.50	(-0.19	1.19)	
Autoimmune ILDs	12	0	0.0	34	5	14.7	0.159							0.15	(0.03	0.27)	
Other ILDs	5	2	40.0	6	1	16.7	0.387	0.42	(0.05	3.36)	0.30	(0.02	4.91)	-0.23	(-0.76	0.29)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Blood alkaline phosphatase increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	5	9.3	0.103							0.09	(0.02 | 0.17)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	4	13.8	0.099							0.14	(0.01 | 0.26)	
Gender																	
Male	11	0	0.0	26	2	7.7	0.344							0.08	(-0.03 | 0.18)	
Female	16	0	0.0	28	3	10.7	0.175							0.11	(-0.01 | 0.22)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	4	8.9	0.141							0.09	(0.01 | 0.17)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09 | 0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	4	10.8	0.159							0.11	(0.01 | 0.21)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	4	11.8	0.214							0.12	(0.01 | 0.23)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Blood bilirubin increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Blood creatine phosphokinase increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	1	1.9	0.212	0.25	(0.02	2.64)	0.24	(0.02	2.73)	-0.06	(-0.16	0.05)	
Age group																	0.120
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	2	11.1	29	0	0.0	0.067	0.00			0.00			-0.11	(-0.26	0.03)	
Gender																	0.330
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26	0.08)	
Female	16	1	6.3	28	1	3.6	0.682	0.57	(0.04	8.53)	0.56	(0.03	9.54)	-0.03	(-0.16	0.11)	
HRCT pattern																	
UIP-like pattern only	23	2	8.7	45	1	2.2	0.219	0.26	(0.02	2.67)	0.24	(0.02	2.78)	-0.06	(-0.19	0.06)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.064
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05	0.17)	
>70%	17	2	11.8	37	0	0.0	0.033	0.00			0.00			-0.12	(-0.27	0.04)	
Underlying ILD Diagnosis in Groups																	0.511
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	1	2.9	0.431	0.35	(0.02	5.21)	0.33	(0.02	5.79)	-0.05	(-0.22	0.11)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Blood creatinine increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26 | 0.08)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Blood glucose increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09 | 0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13 | 0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Blood lactate dehydrogenase increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	5	9.3	0.103							0.09	(0.02	0.17)	
Age group																	
<65 years	9	0	0.0	25	2	8.0	0.382							0.08	(-0.03	0.19)	
>=65 years	18	0	0.0	29	3	10.3	0.158							0.10	(-0.01	0.21)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04	0.11)	
Female	16	0	0.0	28	4	14.3	0.113							0.14	(0.01	0.27)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	4	8.9	0.141							0.09	(0.01	0.17)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	2	11.8	0.260							0.12	(-0.04	0.27)	
>70%	17	0	0.0	37	3	8.1	0.227							0.08	(-0.01	0.17)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	4	11.8	0.214							0.12	(0.01	0.23)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Blood pressure increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02	0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00	0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03	0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Blood thyroid stimulating hormone increased

	Placebo			Nintedanib				Nintedanib vs Placebo [2]									
							p-value	Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	2	3.7	1.000	1.00	(0.09	10.54)	1.00	(0.09	11.54)	0.00	(-0.09	0.09)	
Age group																	0.129
<65 years	9	0	0.0	25	2	8.0	0.382							0.08	(-0.03	0.19)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16	0.05)	
Gender																	0.322
Male	11	1	9.1	26	1	3.8	0.519	0.42	(0.03	6.17)	0.40	(0.02	7.03)	-0.05	(-0.24	0.13)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03	0.10)	
HRCT pattern																	0.063
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02	0.10)	
Other fibrotic patterns	4	1	25.0	9	0	0.0	0.118	0.00			0.00			-0.25	(-0.67	0.17)	
Baseline FVC % predicted																	0.424
<=70%	10	1	10.0	17	1	5.9	0.693	0.59	(0.04	8.41)	0.56	(0.03	10.12)	-0.04	(-0.26	0.18)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	0.535
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	1	20.0	6	1	16.7	0.887	0.83	(0.07	10.20)	0.80	(0.04	17.20)	-0.03	(-0.49	0.43)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Blood uric acid increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Brain natriuretic peptide increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Creatinine renal clearance decreased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01 | 0.09)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02 | 0.16)	
Gender																	
Male	11	0	0.0	26	2	7.7	0.344							0.08	(-0.03 | 0.18)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02 | 0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Electrocardiogram Q wave abnormal

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Electrocardiogram QT prolonged

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	1	25.0	9	0	0.0	0.118	0.00			0.00			-0.25	(-0.67 | 0.17)	
Baseline FVC % predicted																	
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29 | 0.09)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Electrocardiogram T wave abnormal

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Electrocardiogram T wave amplitude decreased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Eosinophil percentage increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Forced vital capacity decreased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29 | 0.09)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	0	0.0	0.197	0.00			0.00			-0.14	(-0.40 | 0.12)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Gamma-glutamyltransferase increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	10	18.5	0.067	5.00	(0.67	37.06)	5.91	(0.71	48.84)	0.15	(0.02	0.27)	
Age group																	0.081
<65 years	9	1	11.1	25	3	12.0	0.943	1.08	(0.13	9.10)	1.09	(0.10	12.07)	0.01	(-0.23	0.25)	
>=65 years	18	0	0.0	29	7	24.1	0.024							0.24	(0.09	0.40)	
Gender																	0.391
Male	11	0	0.0	26	5	19.2	0.118							0.19	(0.04	0.34)	
Female	16	1	6.3	28	5	17.9	0.280	2.86	(0.37	22.36)	3.26	(0.35	30.73)	0.12	(-0.07	0.30)	
HRCT pattern																	0.763
UIP-like pattern only	23	1	4.3	45	9	20.0	0.085	4.60	(0.62	34.12)	5.50	(0.65	46.42)	0.16	(0.01	0.30)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	0.590
<=70%	10	0	0.0	17	2	11.8	0.260							0.12	(-0.04	0.27)	
>70%	17	1	5.9	37	8	21.6	0.149	3.68	(0.50	27.10)	4.41	(0.51	38.53)	0.16	(-0.02	0.33)	
Underlying ILD Diagnosis in Groups																	0.772
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	1	50.0	0.171							0.50	(-0.19	1.19)	
Autoimmune ILDs	12	1	8.3	34	7	20.6	0.336	2.47	(0.34	18.06)	2.85	(0.31	25.98)	0.12	(-0.08	0.33)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13	0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Hepatic enzyme increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Lymphocyte count decreased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Lymphocyte percentage decreased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	3	5.6	0.212							0.06	(-0.01	0.12)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02	0.16)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04	0.11)	
Female	16	0	0.0	28	2	7.1	0.274							0.07	(-0.02	0.17)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02	0.10)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	3	8.1	0.227							0.08	(-0.01	0.17)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	3	8.8	0.287							0.09	(-0.01	0.18)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Monocyte count increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02	0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03	0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03	0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Monocyte percentage increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Myocardial necrosis marker increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: N-terminal prohormone brain natriuretic peptide increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Neutrophil count decreased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Neutrophil count increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	2	3.7	1.000	1.00	(0.09	10.54)	1.00	(0.09	11.54)	0.00	(-0.09	0.09)	
Age group																	0.479
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	1	5.6	29	1	3.4	0.728	0.62	(0.04	9.32)	0.61	(0.04	10.36)	-0.02	(-0.15	0.10)	
Gender																	0.435
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04	0.11)	
Female	16	1	6.3	28	1	3.6	0.682	0.57	(0.04	8.53)	0.56	(0.03	9.54)	-0.03	(-0.16	0.11)	
HRCT pattern																	0.085
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13	0.04)	
Other fibrotic patterns	4	0	0.0	9	2	22.2	0.305							0.22	(-0.05	0.49)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	1	5.9	37	2	5.4	0.943	0.92	(0.09	9.45)	0.91	(0.08	10.83)	-0.00	(-0.14	0.13)	
Underlying ILD Diagnosis in Groups																	0.217
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	1	2.9	0.431	0.35	(0.02	5.21)	0.33	(0.02	5.79)	-0.05	(-0.22	0.11)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13	0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Neutrophil percentage decreased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Neutrophil percentage increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	4	7.4	0.147							0.07	(0.00	0.14)	
Age group																	
<65 years	9	0	0.0	25	2	8.0	0.382							0.08	(-0.03	0.19)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02	0.16)	
Gender																	
Male	11	0	0.0	26	2	7.7	0.344							0.08	(-0.03	0.18)	
Female	16	0	0.0	28	2	7.1	0.274							0.07	(-0.02	0.17)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	3	6.7	0.205							0.07	(-0.01	0.14)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05	0.17)	
>70%	17	0	0.0	37	3	8.1	0.227							0.08	(-0.01	0.17)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	3	8.8	0.287							0.09	(-0.01	0.18)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Platelet count decreased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09 | 0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Protein total increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02	0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03	0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04	0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00	0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Protein urine present

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09 | 0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13 | 0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Red blood cell count decreased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: SARS-CoV-2 test positive

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Urinary occult blood positive

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Weight decreased

	Placebo			Nintedanib				Nintedanib vs Placebo [2]									
							p-value	Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	3	11.1	54	7	13.0	0.811	1.17	(0.33	4.16)	1.19	(0.28	5.02)	0.02	(-0.13	0.17)	
Age group																	0.917
<65 years	9	1	11.1	25	3	12.0	0.943	1.08	(0.13	9.10)	1.09	(0.10	12.07)	0.01	(-0.23	0.25)	
>=65 years	18	2	11.1	29	4	13.8	0.789	1.24	(0.25	6.10)	1.28	(0.21	7.82)	0.03	(-0.17	0.22)	
Gender																	0.611
Male	11	1	9.1	26	4	15.4	0.609	1.69	(0.21	13.48)	1.82	(0.18	18.41)	0.06	(-0.16	0.28)	
Female	16	2	12.5	28	3	10.7	0.858	0.86	(0.16	4.60)	0.84	(0.13	5.64)	-0.02	(-0.22	0.18)	
HRCT pattern																	0.797
UIP-like pattern only	23	2	8.7	45	5	11.1	0.756	1.28	(0.27	6.09)	1.31	(0.23	7.35)	0.02	(-0.12	0.17)	
Other fibrotic patterns	4	1	25.0	9	2	22.2	0.913	0.89	(0.11	7.20)	0.86	(0.05	13.48)	-0.03	(-0.53	0.48)	
Baseline FVC % predicted																	0.623
<=70%	10	1	10.0	17	3	17.6	0.589	1.76	(0.21	14.76)	1.93	(0.17	21.54)	0.08	(-0.18	0.34)	
>70%	17	2	11.8	37	4	10.8	0.917	0.92	(0.19	4.54)	0.91	(0.15	5.52)	-0.01	(-0.19	0.17)	
Underlying ILD Diagnosis in Groups																	0.944
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	2	18.2	0.829	1.27	(0.14	11.55)	1.33	(0.10	18.19)	0.04	(-0.31	0.38)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	3	8.8	0.959	1.06	(0.12	9.23)	1.06	(0.10	11.34)	0.00	(-0.18	0.19)	
Other ILDs	5	1	20.0	6	2	33.3	0.621	1.67	(0.21	13.43)	2.00	(0.13	31.98)	0.13	(-0.38	0.65)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: White blood cell count increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02	0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00	0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03	0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00	0.00)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Metabolism and nutrition disorders
Dictionary-Derived Term: Decreased appetite

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	5	9.3	0.103							0.09	(0.02 | 0.17)	
Age group																	
<65 years	9	0	0.0	25	2	8.0	0.382							0.08	(-0.03 | 0.19)	
>=65 years	18	0	0.0	29	3	10.3	0.158							0.10	(-0.01 | 0.21)	
Gender																	
Male	11	0	0.0	26	4	15.4	0.168							0.15	(0.02 | 0.29)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	5	11.1	0.097							0.11	(0.02 | 0.20)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	4	23.5	0.097							0.24	(0.03 | 0.44)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	2	18.2	0.231							0.18	(-0.05 | 0.41)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	2	5.9	0.390							0.06	(-0.02 | 0.14)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13 | 0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Metabolism and nutrition disorders
Dictionary-Derived Term: Electrolyte imbalance

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	2	7.4	54	0	0.0	0.043	0.00			0.00			-0.07	(-0.17 | 0.02)	
Age group																	
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32 | 0.09)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26 | 0.08)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	2	8.7	45	0	0.0	0.045	0.00			0.00			-0.09	(-0.20 | 0.03)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	2	11.8	37	0	0.0	0.033	0.00			0.00			-0.12	(-0.27 | 0.04)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24 | 0.07)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Metabolism and nutrition disorders
Dictionary-Derived Term: Hypercholesterolaemia

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32 | 0.09)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24 | 0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Metabolism and nutrition disorders
Dictionary-Derived Term: Hyperglycaemia

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	1	1.9	0.212	0.25	(0.02	2.64)	0.24	(0.02	2.73)	-0.06	(-0.16	0.05)	
Age group																	0.285
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32	0.09)	
>=65 years	18	1	5.6	29	1	3.4	0.728	0.62	(0.04	9.32)	0.61	(0.04	10.36)	-0.02	(-0.15	0.10)	
Gender																	0.441
Male	11	1	9.1	26	1	3.8	0.519	0.42	(0.03	6.17)	0.40	(0.02	7.03)	-0.05	(-0.24	0.13)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18	0.06)	
HRCT pattern																	
UIP-like pattern only	23	2	8.7	45	1	2.2	0.219	0.26	(0.02	2.67)	0.24	(0.02	2.78)	-0.06	(-0.19	0.06)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	2	11.8	37	1	2.7	0.177	0.23	(0.02	2.36)	0.21	(0.02	2.48)	-0.09	(-0.25	0.07)	
Underlying ILD Diagnosis in Groups																	0.511
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	1	2.9	0.431	0.35	(0.02	5.21)	0.33	(0.02	5.79)	-0.05	(-0.22	0.11)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Metabolism and nutrition disorders
Dictionary-Derived Term: Hyperkalaemia

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Metabolism and nutrition disorders
Dictionary-Derived Term: Hyperlipidaemia

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01 | 0.09)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02 | 0.16)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02 | 0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	2	5.9	0.390							0.06	(-0.02 | 0.14)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Metabolism and nutrition disorders
Dictionary-Derived Term: Hyperuricaemia

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01 | 0.09)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02 | 0.16)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02 | 0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	2	5.9	0.390							0.06	(-0.02 | 0.14)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Metabolism and nutrition disorders
Dictionary-Derived Term: Hypokalaemia

	Placebo			Nintedanib				Nintedanib vs Placebo [2]									
							p-value	Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	6	11.1	0.598	1.50	(0.32	6.94)	1.56	(0.29	8.31)	0.04	(-0.09	0.17)	
Age group																	0.169
<65 years	9	1	11.1	25	1	4.0	0.437	0.36	(0.03	5.17)	0.33	(0.02	5.97)	-0.07	(-0.29	0.15)	
>=65 years	18	1	5.6	29	5	17.2	0.243	3.10	(0.39	24.47)	3.54	(0.38	33.11)	0.12	(-0.06	0.29)	
Gender																	0.046
Male	11	0	0.0	26	5	19.2	0.118							0.19	(0.04	0.34)	
Female	16	2	12.5	28	1	3.6	0.258	0.29	(0.03	2.91)	0.26	(0.02	3.11)	-0.09	(-0.27	0.09)	
HRCT pattern																	0.552
UIP-like pattern only	23	2	8.7	45	5	11.1	0.756	1.28	(0.27	6.09)	1.31	(0.23	7.35)	0.02	(-0.12	0.17)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	0.856
<=70%	10	1	10.0	17	3	17.6	0.589	1.76	(0.21	14.76)	1.93	(0.17	21.54)	0.08	(-0.18	0.34)	
>70%	17	1	5.9	37	3	8.1	0.772	1.38	(0.15	12.31)	1.41	(0.14	14.65)	0.02	(-0.12	0.16)	
Underlying ILD Diagnosis in Groups																	0.340
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	2	16.7	34	5	14.7	0.871	0.88	(0.20	3.96)	0.86	(0.14	5.17)	-0.02	(-0.26	0.22)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13	0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Metabolism and nutrition disorders
Dictionary-Derived Term: Hypoproteinaemia

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	3	5.6	0.717	1.50	(0.16	13.75)	1.53	(0.15	15.44)	0.02	(-0.08	0.11)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	1	5.6	29	3	10.3	0.567	1.86	(0.21	16.56)	1.96	(0.19	20.45)	0.05	(-0.11	0.20)	
Gender																	0.444
Male	11	1	9.1	26	2	7.7	0.887	0.85	(0.09	8.39)	0.83	(0.07	10.27)	-0.01	(-0.21	0.18)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03	0.10)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	3	6.7	0.701	1.53	(0.17	13.93)	1.57	(0.15	16.01)	0.02	(-0.09	0.13)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	1	5.9	37	3	8.1	0.772	1.38	(0.15	12.31)	1.41	(0.14	14.65)	0.02	(-0.12	0.16)	
Underlying ILD Diagnosis in Groups																	0.105
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	3	8.8	0.287							0.09	(-0.01	0.18)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Musculoskeletal and connective tissue disorders
Dictionary-Derived Term: Arthralgia

	Placebo			Nintedanib				Nintedanib vs Placebo [2]									
							p-value	Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	1	1.9	0.613	0.50	(0.03	7.69)	0.49	(0.03	8.16)	-0.02	(-0.10	0.06)	
Age group																	
<65 years	9	1	11.1	25	1	4.0	0.437	0.36	(0.03	5.17)	0.33	(0.02	5.97)	-0.07	(-0.29	0.15)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00	0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	1	6.3	28	1	3.6	0.682	0.57	(0.04	8.53)	0.56	(0.03	9.54)	-0.03	(-0.16	0.11)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	1	2.2	0.624	0.51	(0.03	7.80)	0.50	(0.03	8.38)	-0.02	(-0.12	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.175
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29	0.09)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	1	2.9	0.431	0.35	(0.02	5.21)	0.33	(0.02	5.79)	-0.05	(-0.22	0.11)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Musculoskeletal and connective tissue disorders
Dictionary-Derived Term: Back pain

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	1	1.9	0.613	0.50	(0.03	7.69)	0.49	(0.03	8.16)	-0.02	(-0.10	0.06)	
Age group																	0.211
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16	0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	1	6.3	28	1	3.6	0.682	0.57	(0.04	8.53)	0.56	(0.03	9.54)	-0.03	(-0.16	0.11)	
HRCT pattern																	0.166
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13	0.04)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	1	5.9	37	1	2.7	0.566	0.46	(0.03	6.92)	0.44	(0.03	7.56)	-0.03	(-0.16	0.09)	
Underlying ILD Diagnosis in Groups																	0.168
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00	0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Musculoskeletal and connective tissue disorders
Dictionary-Derived Term: Bone pain

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Musculoskeletal and connective tissue disorders
Dictionary-Derived Term: Intervertebral disc protrusion

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01 | 0.09)	
Age group																	
<65 years	9	0	0.0	25	2	8.0	0.382							0.08	(-0.03 | 0.19)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02 | 0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	2	5.4	0.329							0.05	(-0.02 | 0.13)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Musculoskeletal and connective tissue disorders
Dictionary-Derived Term: Musculoskeletal stiffness

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Musculoskeletal and connective tissue disorders
Dictionary-Derived Term: Osteoporosis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Musculoskeletal and connective tissue disorders
Dictionary-Derived Term: Pain in extremity

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Musculoskeletal and connective tissue disorders
Dictionary-Derived Term: Rheumatoid arthritis

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32 | 0.09)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29 | 0.09)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24 | 0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Dictionary-Derived Term: Lung neoplasm malignant

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
							p-value	Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	0	0.0	0.197	0.00			0.00			-0.14	(-0.40 | 0.12)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Nervous system disorders
Dictionary-Derived Term: Carotid arteriosclerosis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Nervous system disorders
Dictionary-Derived Term: Cerebral infarction

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Nervous system disorders
Dictionary-Derived Term: Dizziness

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	2	3.7	1.000	1.00	(0.09	10.54)	1.00	(0.09	11.54)	0.00	(-0.09	0.09)	
Age group																	0.129
<65 years	9	0	0.0	25	2	8.0	0.382							0.08	(-0.03	0.19)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16	0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	1	6.3	28	2	7.1	0.910	1.14	(0.11	11.64)	1.15	(0.10	13.82)	0.01	(-0.14	0.16)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	2	4.4	0.985	1.02	(0.10	10.69)	1.02	(0.09	11.92)	0.00	(-0.10	0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.332
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05	0.17)	
>70%	17	1	5.9	37	1	2.7	0.566	0.46	(0.03	6.92)	0.44	(0.03	7.56)	-0.03	(-0.16	0.09)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	1	100.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	1	2.9	0.431	0.35	(0.02	5.21)	0.33	(0.02	5.79)	-0.05	(-0.22	0.11)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Nervous system disorders
Dictionary-Derived Term: Headache

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01 | 0.09)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02 | 0.16)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	2	7.1	0.274							0.07	(-0.02 | 0.17)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02 | 0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	2	5.4	0.329							0.05	(-0.02 | 0.13)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	2	5.9	0.390							0.06	(-0.02 | 0.14)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Nervous system disorders
Dictionary-Derived Term: Hypoaesthesia

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Nervous system disorders
Dictionary-Derived Term: Migraine

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Nervous system disorders
Dictionary-Derived Term: Sciatica

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Nervous system disorders
Dictionary-Derived Term: Tremor

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Psychiatric disorders
Dictionary-Derived Term: Agitation

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02	0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00	0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03	0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00	0.00)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00	0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Psychiatric disorders
Dictionary-Derived Term: Insomnia

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24 | 0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Renal and urinary disorders
Dictionary-Derived Term: Albuminuria

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	2	3.7	1.000	1.00	(0.09	10.54)	1.00	(0.09	11.54)	0.00	(-0.09	0.09)	
Age group																	0.040
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32	0.09)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02	0.16)	
Gender																	0.105
Male	11	0	0.0	26	2	7.7	0.344							0.08	(-0.03	0.18)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18	0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	2	4.4	0.985	1.02	(0.10	10.69)	1.02	(0.09	11.92)	0.00	(-0.10	0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.332
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05	0.17)	
>70%	17	1	5.9	37	1	2.7	0.566	0.46	(0.03	6.92)	0.44	(0.03	7.56)	-0.03	(-0.16	0.09)	
Underlying ILD Diagnosis in Groups																	0.267
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	1	2.9	0.431	0.35	(0.02	5.21)	0.33	(0.02	5.79)	-0.05	(-0.22	0.11)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Renal and urinary disorders
Dictionary-Derived Term: Glomerulonephritis chronic

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13 | 0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Renal and urinary disorders
Dictionary-Derived Term: Haematuria

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13 | 0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Renal and urinary disorders
Dictionary-Derived Term: Nephrolithiasis

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
							p-value	Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24 | 0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Renal and urinary disorders
Dictionary-Derived Term: Proteinuria

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	4	7.4	0.514	2.00	(0.23	17.03)	2.08	(0.22	19.58)	0.04	(-0.06	0.14)	
Age group																	0.666
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	1	5.6	29	3	10.3	0.567	1.86	(0.21	16.56)	1.96	(0.19	20.45)	0.05	(-0.11	0.20)	
Gender																	0.412
Male	11	0	0.0	26	2	7.7	0.344							0.08	(-0.03	0.18)	
Female	16	1	6.3	28	2	7.1	0.910	1.14	(0.11	11.64)	1.15	(0.10	13.82)	0.01	(-0.14	0.16)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	4	8.9	0.497	2.04	(0.24	17.25)	2.15	(0.23	20.40)	0.05	(-0.07	0.16)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	1	5.9	37	4	10.8	0.562	1.84	(0.22	15.23)	1.94	(0.20	18.79)	0.05	(-0.10	0.20)	
Underlying ILD Diagnosis in Groups																	0.397
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	3	8.8	0.959	1.06	(0.12	9.23)	1.06	(0.10	11.34)	0.00	(-0.18	0.19)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13	0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Asthma

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24 | 0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Bronchitis chronic

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Chronic obstructive pulmonary disease

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Cough

	Placebo			Nintedanib				Nintedanib vs Placebo [2]									
							p-value	Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	5	18.5	54	6	11.1	0.359	0.60	(0.20	1.79)	0.55	(0.15	2.00)	-0.07	(-0.24	0.09)	
Age group																	0.748
<65 years	9	3	33.3	25	4	16.0	0.270	0.48	(0.13	1.74)	0.38	(0.07	2.19)	-0.17	(-0.51	0.17)	
>=65 years	18	2	11.1	29	2	6.9	0.615	0.62	(0.10	4.03)	0.59	(0.08	4.63)	-0.04	(-0.21	0.13)	
Gender																	0.629
Male	11	2	18.2	26	2	7.7	0.348	0.42	(0.07	2.63)	0.38	(0.05	3.08)	-0.10	(-0.35	0.14)	
Female	16	3	18.8	28	4	14.3	0.697	0.76	(0.19	2.98)	0.72	(0.14	3.73)	-0.04	(-0.28	0.19)	
HRCT pattern																	0.141
UIP-like pattern only	23	5	21.7	45	4	8.9	0.139	0.41	(0.12	1.38)	0.35	(0.08	1.46)	-0.13	(-0.32	0.06)	
Other fibrotic patterns	4	0	0.0	9	2	22.2	0.305							0.22	(-0.05	0.49)	
Baseline FVC % predicted																	0.951
<=70%	10	1	10.0	17	1	5.9	0.693	0.59	(0.04	8.41)	0.56	(0.03	10.12)	-0.04	(-0.26	0.18)	
>70%	17	4	23.5	37	5	13.5	0.359	0.57	(0.18	1.87)	0.51	(0.12	2.20)	-0.10	(-0.33	0.13)	
Underlying ILD Diagnosis in Groups																	0.643
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	2	28.6	11	1	9.1	0.280	0.32	(0.04	2.89)	0.25	(0.02	3.47)	-0.19	(-0.57	0.18)	
Unclassifiable idiopathic interstitial pneumonia	3	1	33.3	2	1	50.0	0.709	1.50	(0.18	12.46)	2.00	(0.05	78.25)	0.17	(-0.71	1.04)	
Autoimmune ILDs	12	2	16.7	34	4	11.8	0.665	0.71	(0.15	3.37)	0.67	(0.11	4.21)	-0.05	(-0.29	0.19)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Epistaxis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13 | 0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Haemoptysis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01 | 0.09)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02 | 0.16)	
Gender																	
Male	11	0	0.0	26	2	7.7	0.344							0.08	(-0.03 | 0.18)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02 | 0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	2	5.4	0.329							0.05	(-0.02 | 0.13)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Hypoxia

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24 | 0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Interstitial lung disease

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	7	25.9	54	5	9.3	0.047	0.36	(0.12	1.02)	0.29	(0.08	1.03)	-0.17	(-0.35	0.02)	
Age group																	0.557
<65 years	9	4	44.4	25	3	12.0	0.039	0.27	(0.07	0.98)	0.17	(0.03	1.02)	-0.32	(-0.67	0.02)	
>=65 years	18	3	16.7	29	2	6.9	0.291	0.41	(0.08	2.24)	0.37	(0.06	2.47)	-0.10	(-0.29	0.10)	
Gender																	0.333
Male	11	1	9.1	26	2	7.7	0.887	0.85	(0.09	8.39)	0.83	(0.07	10.27)	-0.01	(-0.21	0.18)	
Female	16	6	37.5	28	3	10.7	0.034	0.29	(0.08	0.99)	0.20	(0.04	0.96)	-0.27	(-0.53	-0.00)	
HRCT pattern																	0.116
UIP-like pattern only	23	6	26.1	45	2	4.4	0.009	0.17	(0.04	0.78)	0.13	(0.02	0.72)	-0.22	(-0.41	-0.03)	
Other fibrotic patterns	4	1	25.0	9	3	33.3	0.764	1.33	(0.19	9.21)	1.50	(0.11	21.31)	0.08	(-0.44	0.61)	
Baseline FVC % predicted																	0.584
<=70%	10	4	40.0	17	2	11.8	0.088	0.29	(0.07	1.33)	0.20	(0.03	1.40)	-0.28	(-0.62	0.06)	
>70%	17	3	17.6	37	3	8.1	0.300	0.46	(0.10	2.05)	0.41	(0.07	2.29)	-0.10	(-0.30	0.11)	
Underlying ILD Diagnosis in Groups																	0.823
Hypersensitivity pneumonitis	0	0	0.0	1	1	100.0											
Idiopathic nonspecific interstitial pneumonia	7	2	28.6	11	1	9.1	0.280	0.32	(0.04	2.89)	0.25	(0.02	3.47)	-0.19	(-0.57	0.18)	
Unclassifiable idiopathic interstitial pneumonia	3	1	33.3	2	0	0.0	0.361	0.00			0.00			-0.33	(-0.87	0.20)	
Autoimmune ILDs	12	3	25.0	34	2	5.9	0.067	0.24	(0.04	1.24)	0.19	(0.03	1.30)	-0.19	(-0.45	0.07)	
Other ILDs	5	1	20.0	6	1	16.7	0.887	0.83	(0.07	10.20)	0.80	(0.04	17.20)	-0.03	(-0.49	0.43)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Lung disorder

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	0	0.0	0.197	0.00			0.00			-0.14	(-0.40 | 0.12)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Oropharyngeal pain

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Pleural effusion

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29 | 0.09)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	1	33.3	2	0	0.0	0.361	0.00			0.00			-0.33	(-0.87 | 0.20)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Pneumothorax

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26 | 0.08)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	1	25.0	9	0	0.0	0.118	0.00			0.00			-0.25	(-0.67 | 0.17)	
Baseline FVC % predicted																	
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29 | 0.09)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Productive cough

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01 | 0.09)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02 | 0.16)	
Gender																	
Male	11	0	0.0	26	2	7.7	0.344							0.08	(-0.03 | 0.18)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02 | 0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	2	5.4	0.329							0.05	(-0.02 | 0.13)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Pulmonary alveolar haemorrhage

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Respiratory failure

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	2	3.7	0.468	0.50	(0.07	3.36)	0.48	(0.06	3.61)	-0.04	(-0.15	0.07)	
Age group																	0.150
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32	0.09)	
>=65 years	18	1	5.6	29	2	6.9	0.855	1.24	(0.12	12.72)	1.26	(0.11	14.98)	0.01	(-0.13	0.15)	
Gender																	0.302
Male	11	1	9.1	26	2	7.7	0.887	0.85	(0.09	8.39)	0.83	(0.07	10.27)	-0.01	(-0.21	0.18)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18	0.06)	
HRCT pattern																	0.258
UIP-like pattern only	23	2	8.7	45	1	2.2	0.219	0.26	(0.02	2.67)	0.24	(0.02	2.78)	-0.06	(-0.19	0.06)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09	0.32)	
Baseline FVC % predicted																	0.285
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29	0.09)	
>70%	17	1	5.9	37	2	5.4	0.943	0.92	(0.09	9.45)	0.91	(0.08	10.83)	-0.00	(-0.14	0.13)	
Underlying ILD Diagnosis in Groups																	0.436
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	0	0.0	0.197	0.00			0.00			-0.14	(-0.40	0.12)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	1	20.0	6	1	16.7	0.887	0.83	(0.07	10.20)	0.80	(0.04	17.20)	-0.03	(-0.49	0.43)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Skin and subcutaneous tissue disorders
Dictionary-Derived Term: Alopecia

	Placebo			Nintedanib				Nintedanib vs Placebo [2]							
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01	0.09)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02	0.16)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	0	0.0	28	2	7.1	0.274							0.07	(-0.02	0.17)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02	0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05	0.17)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	2	5.9	0.390							0.06	(-0.02	0.14)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Skin and subcutaneous tissue disorders
Dictionary-Derived Term: Dermatitis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Skin and subcutaneous tissue disorders
Dictionary-Derived Term: Eczema

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24 | 0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Skin and subcutaneous tissue disorders
Dictionary-Derived Term: Pruritus

	Placebo			Nintedanib				Nintedanib vs Placebo [2]							
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01	0.09)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	0	0.0	29	2	6.9	0.255							0.07	(-0.02	0.16)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04	0.11)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03	0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02	0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	2	5.4	0.329							0.05	(-0.02	0.13)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	2	5.9	0.390							0.06	(-0.02	0.14)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Skin and subcutaneous tissue disorders
Dictionary-Derived Term: Rash

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32 | 0.09)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26 | 0.08)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29 | 0.09)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24 | 0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Skin and subcutaneous tissue disorders
Dictionary-Derived Term: Urticaria

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11 | 0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16 | 0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13 | 0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17 | 0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24 | 0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Vascular disorders
Dictionary-Derived Term: Circulatory collapse

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Vascular disorders
Dictionary-Derived Term: Deep vein thrombosis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	1	1.9	0.613	0.50	(0.03	7.69)	0.49	(0.03	8.16)	-0.02	(-0.10	0.06)	
Age group																	0.098
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32	0.09)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03	0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	1	6.3	28	1	3.6	0.682	0.57	(0.04	8.53)	0.56	(0.03	9.54)	-0.03	(-0.16	0.11)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	1	2.2	0.624	0.51	(0.03	7.80)	0.50	(0.03	8.38)	-0.02	(-0.12	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.175
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29	0.09)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	1	9.1	0.732	0.64	(0.05	8.61)	0.60	(0.03	11.47)	-0.05	(-0.36	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00	0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Vascular disorders
Dictionary-Derived Term: Hypertension

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	2	3.7	0.311							0.04	(-0.01	0.09)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03	0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	0	0.0	28	2	7.1	0.274							0.07	(-0.02	0.17)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	2	4.4	0.305							0.04	(-0.02	0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	2	5.4	0.329							0.05	(-0.02	0.13)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.8.1 Proportion of patients with adverse events on PT level over the whole trial by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Vascular disorders
Dictionary-Derived Term: Peripheral arterial occlusive disease

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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1.3.9 Serious adverse events on SOC and PT level

Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Cardiac disorders
Dictionary-Derived Term: Angina unstable

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Cardiac disorders
Dictionary-Derived Term: Atrial fibrillation

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Cardiac disorders
Dictionary-Derived Term: Cardiac failure

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	1	1.9	0.613	0.50	(0.03	7.69)	0.49	(0.03	8.16)	-0.02	(-0.10	0.06)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	1	5.6	29	1	3.4	0.728	0.62	(0.04	9.32)	0.61	(0.04	10.36)	-0.02	(-0.15	0.10)	
Gender																	
Male	11	1	9.1	26	1	3.8	0.519	0.42	(0.03	6.17)	0.40	(0.02	7.03)	-0.05	(-0.24	0.13)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00	0.00)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	1	2.2	0.624	0.51	(0.03	7.80)	0.50	(0.03	8.38)	-0.02	(-0.12	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	1	5.9	37	1	2.7	0.566	0.46	(0.03	6.92)	0.44	(0.03	7.56)	-0.03	(-0.16	0.09)	
Underlying ILD Diagnosis in Groups																	0.234
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Cardiac disorders
Dictionary-Derived Term: Coronary artery disease

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Ear and labyrinth disorders
Dictionary-Derived Term: Vertigo

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Gastrointestinal disorders
Dictionary-Derived Term: Large intestine polyp

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: General disorders and administration site conditions
Dictionary-Derived Term: Chest pain

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]							p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11	0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16	0.05)	
Gender																	
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26	0.08)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00	0.00)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13	0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17	0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00	0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Immune system disorders
Dictionary-Derived Term: Anti-neutrophil cytoplasmic antibody positive vasculitis

	Placebo			Nintedanib			Nintedanib vs Placebo									
							p-value	[2] Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Bronchopulmonary aspergillosis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: COVID-19

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]							p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02	0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03	0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04	0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00	0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: COVID-19 pneumonia

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	2	3.7	1.000	1.00	(0.09	10.54)	1.00	(0.09	11.54)	0.00	(-0.09	0.09)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	1	5.6	29	2	6.9	0.855	1.24	(0.12	12.72)	1.26	(0.11	14.98)	0.01	(-0.13	0.15)	
Gender																	0.322
Male	11	1	9.1	26	1	3.8	0.519	0.42	(0.03	6.17)	0.40	(0.02	7.03)	-0.05	(-0.24	0.13)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	2	4.4	0.985	1.02	(0.10	10.69)	1.02	(0.09	11.92)	0.00	(-0.10	0.10)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	0.332
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	1	5.9	37	1	2.7	0.566	0.46	(0.03	6.92)	0.44	(0.03	7.56)	-0.03	(-0.16	0.09)	
Underlying ILD Diagnosis in Groups																	0.299
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55 | 0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Complicated appendicitis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Infected skin ulcer

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Pneumonia

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	4	14.8	54	5	9.3	0.453	0.63	(0.18	2.14)	0.59	(0.14	2.39)	-0.06	(-0.21	0.10)	
Age group																	0.600
<65 years	9	1	11.1	25	1	4.0	0.437	0.36	(0.03	5.17)	0.33	(0.02	5.97)	-0.07	(-0.29	0.15)	
>=65 years	18	3	16.7	29	4	13.8	0.788	0.83	(0.21	3.28)	0.80	(0.16	4.08)	-0.03	(-0.24	0.18)	
Gender																	0.320
Male	11	3	27.3	26	5	19.2	0.587	0.71	(0.20	2.45)	0.63	(0.12	3.30)	-0.08	(-0.38	0.22)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18	0.06)	
HRCT pattern																	
UIP-like pattern only	23	4	17.4	45	5	11.1	0.470	0.64	(0.19	2.15)	0.59	(0.14	2.47)	-0.06	(-0.24	0.12)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.489
<=70%	10	1	10.0	17	2	11.8	0.888	1.18	(0.12	11.39)	1.20	(0.09	15.20)	0.02	(-0.22	0.26)	
>70%	17	3	17.6	37	3	8.1	0.300	0.46	(0.10	2.05)	0.41	(0.07	2.29)	-0.10	(-0.30	0.11)	
Underlying ILD Diagnosis in Groups																	0.219
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	2	16.7	34	4	11.8	0.665	0.71	(0.15	3.37)	0.67	(0.11	4.21)	-0.05	(-0.29	0.19)	
Other ILDs	5	2	40.0	6	0	0.0	0.087	0.00			0.00			-0.40	(-0.83	0.03)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Pneumonia bacterial

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09 | 0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	1	16.7	0.338							0.17	(-0.13 | 0.46)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Respiratory syncytial virus infection

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Upper respiratory tract infection

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]							p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	2	7.4	54	0	0.0	0.043	0.00			0.00			-0.07	(-0.17	0.02)	
Age group																	
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32	0.09)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16	0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	2	12.5	28	0	0.0	0.056	0.00			0.00			-0.13	(-0.29	0.04)	
HRCT pattern																	
UIP-like pattern only	23	2	8.7	45	0	0.0	0.045	0.00			0.00			-0.09	(-0.20	0.03)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	2	11.8	37	0	0.0	0.033	0.00			0.00			-0.12	(-0.27	0.04)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24	0.07)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Infections and infestations
Dictionary-Derived Term: Urinary tract infection

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04 | 0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00 | 0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00 | 0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03 | 0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00 | 0.00)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09 | 0.32)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Injury, poisoning and procedural complications
Dictionary-Derived Term: Thoracic vertebral fracture

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]							p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02	0.05)	
Age group																	
<65 years	9	0	0.0	25	1	4.0	0.543							0.04	(-0.04	0.12)	
>=65 years	18	0	0.0	29	0	0.0								0.00	(0.00	0.00)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	0	0.0	28	1	3.6	0.444							0.04	(-0.03	0.10)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03	0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Investigations
Dictionary-Derived Term: Myocardial necrosis marker increased

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	1	5.9	0.434							0.06	(-0.05 | 0.17)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00 | 0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Dictionary-Derived Term: Lung neoplasm malignant

	Placebo			Nintedanib				Nintedanib vs Placebo [2]							
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11	0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16	0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18	0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13	0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17	0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	0	0.0	0.197	0.00			0.00			-0.14	(-0.40	0.12)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00	0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Nervous system disorders
Dictionary-Derived Term: Cerebral infarction

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Asthma

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]							p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11	0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16	0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18	0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13	0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17	0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24	0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Bronchitis chronic

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Chronic obstructive pulmonary disease

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Interstitial lung disease

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]							p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	3	11.1	54	0	0.0	0.013	0.00			0.00			-0.11	(-0.23	0.01)	
Age group																	
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32	0.09)	
>=65 years	18	2	11.1	29	0	0.0	0.067	0.00			0.00			-0.11	(-0.26	0.03)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	3	18.8	28	0	0.0	0.018	0.00			0.00			-0.19	(-0.38	0.00)	
HRCT pattern																	
UIP-like pattern only	23	3	13.0	45	0	0.0	0.013	0.00			0.00			-0.13	(-0.27	0.01)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	2	20.0	17	0	0.0	0.055	0.00			0.00			-0.20	(-0.45	0.05)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17	0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	0	0.0	0.197	0.00			0.00			-0.14	(-0.40	0.12)	
Unclassifiable idiopathic interstitial pneumonia	3	1	33.3	2	0	0.0	0.361	0.00			0.00			-0.33	(-0.87	0.20)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24	0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Lung disorder

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]							p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11	0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16	0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18	0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13	0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17	0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	0	0.0	0.197	0.00			0.00			-0.14	(-0.40	0.12)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00	0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Pleural effusion

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]							p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11	0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16	0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18	0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13	0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29	0.09)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00	0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	1	33.3	2	0	0.0	0.361	0.00			0.00			-0.33	(-0.87	0.20)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00	0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Pneumothorax

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]							p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11	0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16	0.05)	
Gender																	
Male	11	1	9.1	26	0	0.0	0.119	0.00			0.00			-0.09	(-0.26	0.08)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00	0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	0	0.0								0.00	(0.00	0.00)	
Other fibrotic patterns	4	1	25.0	9	0	0.0	0.118	0.00			0.00			-0.25	(-0.67	0.17)	
Baseline FVC % predicted																	
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29	0.09)	
>70%	17	0	0.0	37	0	0.0								0.00	(0.00	0.00)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00	0.00)	
Other ILDs	5	1	20.0	6	0	0.0	0.251	0.00			0.00			-0.20	(-0.55	0.15)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Productive cough

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Pulmonary alveolar haemorrhage

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	1	9.1	0.412							0.09	(-0.08 | 0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00 | 0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Respiratory, thoracic and mediastinal disorders
Dictionary-Derived Term: Respiratory failure

	Placebo			Nintedanib				Nintedanib vs Placebo [2]								
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	p-value [1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	p-value [3]
Overall summary																	
All patients	27	2	7.4	54	2	3.7	0.468	0.50	(0.07	3.36)	0.48	(0.06	3.61)	-0.04	(-0.15	0.07)	
Age group																	0.150
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32 | 0.09)	
>=65 years	18	1	5.6	29	2	6.9	0.855	1.24	(0.12	12.72)	1.26	(0.11	14.98)	0.01	(-0.13	0.15)	
Gender																	0.302
Male	11	1	9.1	26	2	7.7	0.887	0.85	(0.09	8.39)	0.83	(0.07	10.27)	-0.01	(-0.21	0.18)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18 | 0.06)	
HRCT pattern																	0.258
UIP-like pattern only	23	2	8.7	45	1	2.2	0.219	0.26	(0.02	2.67)	0.24	(0.02	2.78)	-0.06	(-0.19	0.06)	
Other fibrotic patterns	4	0	0.0	9	1	11.1	0.488							0.11	(-0.09 | 0.32)	
Baseline FVC % predicted																	0.285
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29 | 0.09)	
>70%	17	1	5.9	37	2	5.4	0.943	0.92	(0.09	9.45)	0.91	(0.08	10.83)	-0.00	(-0.14	0.13)	
Underlying ILD Diagnosis in Groups																	0.436
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	0	0.0	0.197	0.00			0.00			-0.14	(-0.40 | 0.12)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	1	20.0	6	1	16.7	0.887	0.83	(0.07	10.20)	0.80	(0.04	17.20)	-0.03	(-0.49	0.43)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Skin and subcutaneous tissue disorders
Dictionary-Derived Term: Eczema

	Placebo			Nintedanib			Nintedanib vs Placebo [2]								
							p-value	Risk ratio			Odds ratio			Risk difference			p-value
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	0	0.0	0.155	0.00			0.00			-0.04	(-0.11	0.03)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00	0.00)	
>=65 years	18	1	5.6	29	0	0.0	0.199	0.00			0.00			-0.06	(-0.16	0.05)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	1	6.3	28	0	0.0	0.181	0.00			0.00			-0.06	(-0.18	0.06)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	0	0.0	0.159	0.00			0.00			-0.04	(-0.13	0.04)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00	0.00)	
>70%	17	1	5.9	37	0	0.0	0.136	0.00			0.00			-0.06	(-0.17	0.05)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00	0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	1	8.3	34	0	0.0	0.089	0.00			0.00			-0.08	(-0.24	0.07)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Vascular disorders
Dictionary-Derived Term: Circulatory collapse

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]								p-value
								Risk ratio			Odds ratio			Risk difference		
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	0	0.0	54	1	1.9	0.477							0.02	(-0.02 | 0.05)	
Age group																	
<65 years	9	0	0.0	25	0	0.0								0.00	(0.00 | 0.00)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03 | 0.10)	
Gender																	
Male	11	0	0.0	26	1	3.8	0.510							0.04	(-0.04 | 0.11)	
Female	16	0	0.0	28	0	0.0								0.00	(0.00 | 0.00)	
HRCT pattern																	
UIP-like pattern only	23	0	0.0	45	1	2.2	0.471							0.02	(-0.02 | 0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00 | 0.00)	
Baseline FVC % predicted																	
<=70%	10	0	0.0	17	0	0.0								0.00	(0.00 | 0.00)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03 | 0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	0	0.0	11	0	0.0								0.00	(0.00 | 0.00)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00 | 0.00)	
Autoimmune ILDs	12	0	0.0	34	1	2.9	0.548							0.03	(-0.03 | 0.09)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00 | 0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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Table 3.9.1 Proportion of patients with serious adverse events on PT level over the whole trial by subgroup, by treatment, primary SOC and preferred term and by subgroup - Treated Set

Body System or Organ Class: Vascular disorders
Dictionary-Derived Term: Deep vein thrombosis

	Placebo			Nintedanib			p-value	Nintedanib vs Placebo [2]									p-value
								Risk ratio			Odds ratio			Risk difference			
	N	n	%	N	n	%	[1]	RR	Lower	Upper	OR	Lower	Upper	RD	Lower	Upper	[3]
Overall summary																	
All patients	27	1	3.7	54	1	1.9	0.613	0.50	(0.03	7.69)	0.49	(0.03	8.16)	-0.02	(-0.10	0.06)	
Age group																	0.098
<65 years	9	1	11.1	25	0	0.0	0.091	0.00			0.00			-0.11	(-0.32	0.09)	
>=65 years	18	0	0.0	29	1	3.4	0.426							0.03	(-0.03	0.10)	
Gender																	
Male	11	0	0.0	26	0	0.0								0.00	(0.00	0.00)	
Female	16	1	6.3	28	1	3.6	0.682	0.57	(0.04	8.53)	0.56	(0.03	9.54)	-0.03	(-0.16	0.11)	
HRCT pattern																	
UIP-like pattern only	23	1	4.3	45	1	2.2	0.624	0.51	(0.03	7.80)	0.50	(0.03	8.38)	-0.02	(-0.12	0.07)	
Other fibrotic patterns	4	0	0.0	9	0	0.0								0.00	(0.00	0.00)	
Baseline FVC % predicted																	0.175
<=70%	10	1	10.0	17	0	0.0	0.184	0.00			0.00			-0.10	(-0.29	0.09)	
>70%	17	0	0.0	37	1	2.7	0.494							0.03	(-0.03	0.08)	
Underlying ILD Diagnosis in Groups																	
Hypersensitivity pneumonitis	0	0	0.0	1	0	0.0											
Idiopathic nonspecific interstitial pneumonia	7	1	14.3	11	1	9.1	0.732	0.64	(0.05	8.61)	0.60	(0.03	11.47)	-0.05	(-0.36	0.26)	
Unclassifiable idiopathic interstitial pneumonia	3	0	0.0	2	0	0.0								0.00	(0.00	0.00)	
Autoimmune ILDs	12	0	0.0	34	0	0.0								0.00	(0.00	0.00)	
Other ILDs	5	0	0.0	6	0	0.0								0.00	(0.00	0.00)	

[1] p-value based on Chi-Square test.
[2] Risk ratios and odds ratios with confidence intervals (CIs) are estimated by Cochran-Mantel-Haenszel method.
Risk differences with CIs are estimated by the method described in Greenland and Robins (1985).
A ratio less than one or risk difference less than zero indicates less risk for Nint 150bid.
[3] Treatment by subgroup interaction p-value for homogeneity of the odds ratio, based on the Breslow-Day test.
Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
MedDRA version used for reporting: 27.0

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1.3.10 Adverse events leading to treatment discontinuation on SOC and PT level

Table 3.10.1 Frequency of patients with adverse events leading to treatment discontinuation by treatment, primary SOC and preferred term over the whole trial - Treated Set

System organ class/ Preferred term	Placebo N	Placebo %	Nintedanib N	Nintedanib %
Number of patients	27	100.0	54	100.0
Number of patients with at least one adverse event leading to premature treatment discontinuation	1	3.7	10	18.5
Cardiac disorders	0	0.0	1	1.9
Angina unstable	0	0.0	1	1.9
Arteriosclerosis coronary artery	0	0.0	1	1.9
Gastrointestinal disorders	0	0.0	2	3.7
Abdominal pain upper	0	0.0	1	1.9
Diarrhoea	0	0.0	1	1.9
Nausea	0	0.0	1	1.9
Vomiting	0	0.0	1	1.9
Hepatobiliary disorders	0	0.0	3	5.6
Liver injury	0	0.0	3	5.6
Infections and infestations	1	3.7	2	3.7
COVID-19	0	0.0	1	1.9
Pneumonia	1	3.7	1	1.9
Investigations	0	0.0	1	1.9
Hepatic enzyme increased	0	0.0	1	1.9
Skin and subcutaneous tissue disorders	0	0.0	1	1.9
Alopecia	0	0.0	1	1.9

[1] Only treatment emergent AEs are displayed: AEs with an onset date between first trial drug intake and last drug intake +7 days.
[2] Treatment discontinuations are premature and permanent.
[3] Percentages are calculated using total number of patients per treatment as the denominator.
MedDRA version used for reporting: 27.0

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2.4 Metaanalyse der Nintedanib-Studien

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M.2 Meta analysis for trials 1199.247 and 1199.434

M.2.1 Efficacy Analysis

M.2.1.1 Time to event analyses

M.2.1.1.1 Analyses of composite endpoints

M.2.1.1.1.1 Time to first confirmed acute ILD exacerbation or death

Table M.2.1.1.1.1: 1 Meta-analysis comparing Nintedanib versus Placebo for time to first confirmed acute ILD exacerbation or death over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Hazard ratio (95% CI)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Hazard ratio (95% CI)	Wt	Fixed effects Nin 150bid vs Placebo Hazard ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	0.67 (0.46, 0.98)	86.7	0.71 (0.27, 1.85)	13.3	0.68 (0.48, 0.96)	0.0299	0.0	0.9300
Age								
<65 years	0.53 (0.25, 1.14)	78.1	0.62 (0.15, 2.61)	21.9	0.55 (0.28, 1.08)	0.0836	0.0	0.8541
>=65 years	0.77 (0.50, 1.18)	90.2	0.74 (0.20, 2.76)	9.8	0.76 (0.50, 1.15)	0.1996	0.0	0.9563
Sex								
Male	0.80 (0.51, 1.26)	95.6	2.61 (0.31,21.75)	4.4	0.84 (0.54, 1.32)	0.4536	12.7	0.2844
Female	0.47 (0.23, 0.94)	76.8	0.36 (0.10, 1.27)	23.2	0.44 (0.24, 0.81)	0.0083	0.0	0.7152
Baseline FVC percent predicted								
<=70%	0.69 (0.44, 1.09)	88.9	0.60 (0.17, 2.20)	11.1	0.68 (0.44, 1.05)	0.0806	0.0	0.8486
>70%	0.60 (0.31, 1.18)	87.5	0.37 (0.06, 2.19)	12.5	0.56 (0.30, 1.06)	0.0767	0.0	0.6102
Baseline HRCT pattern								
UIP-like	0.62 (0.39, 0.97)	84.2	0.49 (0.17, 1.40)	15.8	0.59 (0.39, 0.90)	0.0142	0.0	0.6997
Other fibrotic patterns								
Underlying ILD diagnosis								
iNSIP	0.64 (0.23, 1.81)	74.9	0.83 (0.14, 5.00)	25.1	0.68 (0.28, 1.68)	0.4075	0.0	0.8020
Unclassifiable IIP								
HP								
Autoimmune ILD	0.58 (0.27, 1.27)	77.6	0.64 (0.15, 2.72)	22.4	0.60 (0.30, 1.18)	0.1378	0.0	0.9071
Other ILD	0.89 (0.30, 2.68)	86.5	0.87 (0.05,13.95)	13.5	0.89 (0.32, 2.47)	0.8234	0.0	0.9834
Region								
Europe								
Asia	0.20 (0.07, 0.58)	44.5	0.71 (0.27, 1.85)	55.5	0.40 (0.19, 0.82)	0.0124	66.5	0.0840
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the inverse-variance method. Heterogeneity p-value was based on Cochran's Q test.
Estimates for the comparison of Nintedanib versus Placebo are only presented if estimates from both studies are available, enabling a meta-analysis to be performed. NC = not calculable, Wt = study weight in the meta-analysis.
The estimates from trial 1199-0247 and 1199-0434 are based on a Cox regression model estimated in overall with categorical treatment and stratified by baseline HRCT pattern (UIP-like/Other fibrotic patterns).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.

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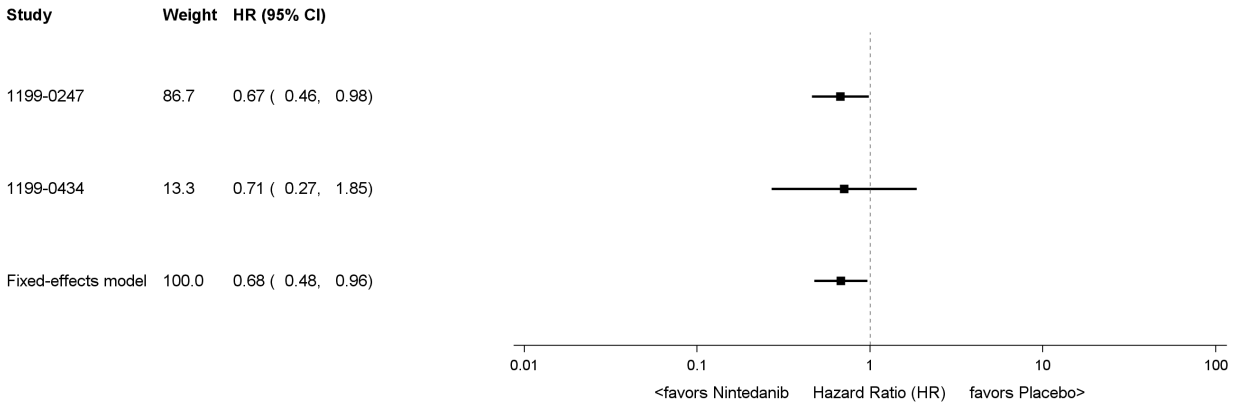

Figure M.2.1.1.1.1: 1 Forest Plot comparing Nintedanib versus Placebo for time to first confirmed acute ILD exacerbation or death over the whole trial

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Figure M.2.1.1.1.1: 1

M.2.1.1.2 Analyses of single endpoints

M.2.1.1.2.1 Time to death

Table M.2.1.1.2.1: 1 Meta-analysis comparing Nintedanib versus Placebo for time to death over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Hazard ratio (95% CI)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Hazard ratio (95% CI)	Wt	Fixed effects Nin 150bid vs Placebo Hazard ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	0.78 (0.50, 1.21)	90.9	1.05 (0.26, 4.20)	9.1	0.80 (0.53, 1.21)	0.2930	0.0	0.6855
Age								
<65 years								
>=65 years	0.83 (0.50, 1.36)	90.2	0.79 (0.18, 3.52)	9.8	0.82 (0.52, 1.32)	0.4171	0.0	0.9515
Sex								
Male	0.93 (0.55, 1.56)	94.8	1.85 (0.21,16.57)	5.2	0.96 (0.58, 1.59)	0.8843	0.0	0.5484
Female	0.50 (0.21, 1.19)	83.8	0.59 (0.08, 4.22)	16.2	0.52 (0.23, 1.14)	0.1003	0.0	0.8788
Baseline FVC percent predicted								
<=70%	0.87 (0.51, 1.47)	91.1	0.87 (0.16, 4.77)	8.9	0.87 (0.52, 1.44)	0.5783	0.0	0.9936
>70%	0.58 (0.26, 1.29)	90.0	1.13 (0.10,12.41)	10.0	0.62 (0.29, 1.32)	0.2151	0.0	0.6069
Baseline HRCT pattern								
UIP-like	0.66 (0.40, 1.10)	88.1	1.05 (0.26, 4.20)	11.9	0.70 (0.43, 1.13)	0.1404	0.0	0.5377
Other fibrotic patterns								
Underlying ILD diagnosis								
iNSIP	0.63 (0.21, 1.95)	82.2	1.19 (0.11,13.16)	17.8	0.71 (0.26, 1.96)	0.5087	0.0	0.6431
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia	0.24 (0.07, 0.87)	54.5	1.05 (0.26, 4.20)	45.5	0.47 (0.19, 1.21)	0.1174	56.9	0.1278
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the inverse-variance method. Heterogeneity p-value was based on Cochran's Q test.
Estimates for the comparison of Nintedanib versus Placebo are only presented if estimates from both studies are available, enabling a meta-analysis to be performed. NC = not calculable, Wt = study weight in the meta-analysis.
The estimates from trial 1199-0247 and 1199-0434 are based on a Cox regression model estimated in overall with categorical treatment and stratified by baseline HRCT pattern (UIP-like/Other fibrotic patterns).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.

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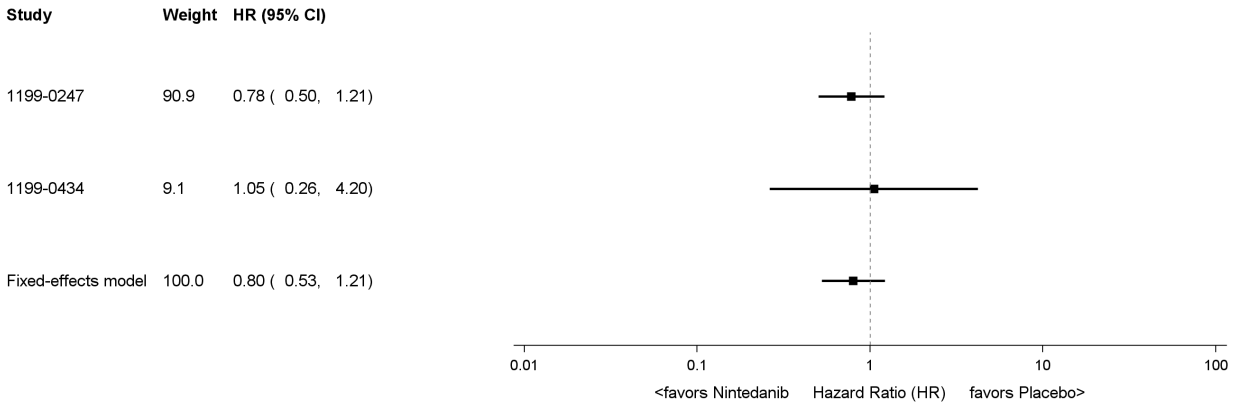

Figure M.2.1.1.2.1: 1 Forest Plot comparing Nintedanib versus Placebo for time to death over the whole trial

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M.2.1.1.2.2 Time to first confirmed acute ILD exacerbation

Table M.2.1.1.2.2: 1 Meta-analysis comparing Nintedanib versus Placebo for time to first confirmed acute ILD exacerbation over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Hazard ratio (95% CI)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Hazard ratio (95% CI)	Wt	Fixed effects Nin 150bid vs Placebo Hazard ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	0.63 (0.37, 1.07)	81.1	0.42 (0.14, 1.26)	18.9	0.59 (0.37, 0.94)	0.0279	0.0	0.5149
Age								
<65 years								
>=65 years								
Sex								
Male								
Female								
Baseline FVC percent predicted								
<=70%								
>70%								
Baseline HRCT pattern								
UIP-like								
Other fibrotic patterns								
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia								
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the inverse-variance method. Heterogeneity p-value was based on Cochran's Q test.
Estimates for the comparison of Nintedanib versus Placebo are only presented if estimates from both studies are available, enabling a meta-analysis to be performed. NC = not calculable, Wt = study weight in the meta-analysis.
The estimates from trial 1199-0247 and 1199-0434 are based on a Cox regression model estimated in overall with categorical treatment and stratified by baseline HRCT pattern (UIP-like/Other fibrotic patterns).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.

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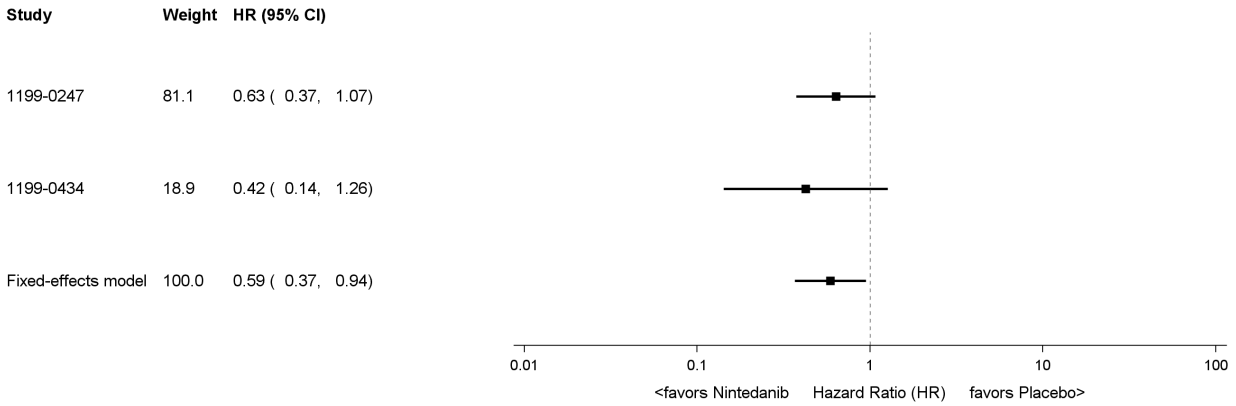

Figure M.2.1.1.2.2: 1 Forest Plot comparing Nintedanib versus Placebo for time to first confirmed acute ILD exacerbation over the whole trial

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M.2.2 Safety analysis

M.2.2.1 Safety analysis over the whole trial

M.2.2.1.1 Adverse events overall over the whole trial

Table M.2.2.1.1: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with any adverse events over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	308/331 (93.1)	326/332 (98.2)	90.1	25/ 27 (92.6)	54/ 54 (100.0)	9.9	1.06 (1.02, 1.09)	0.0006	0.0	0.7198
Age										
<65 years	110/121 (90.9)	135/139 (97.1)	90.6	8/ 9 (88.9)	25/ 25 (100.0)	9.4	1.07 (1.01, 1.14)	0.0259	0.0	0.7212
>=65 years	198/210 (94.3)	191/193 (99.0)	89.8	17/ 18 (94.4)	29/ 29 (100.0)	10.2	1.05 (1.01, 1.09)	0.0066	0.0	0.9176
Sex										
Male	164/177 (92.7)	176/179 (98.3)	91.9	10/ 11 (90.9)	26/ 26 (100.0)	8.1	1.06 (1.02, 1.11)	0.0074	0.0	0.7646
Female	144/154 (93.5)	150/153 (98.0)	88.0	15/ 16 (93.8)	28/ 28 (100.0)	12.0	1.05 (1.00, 1.10)	0.0338	0.0	0.8471
Baseline FVC percent predicted										
<=70%	185/193 (95.9)	193/196 (98.5)	94.0	9/ 10 (90.0)	17/ 17 (100.0)	6.0	1.03 (1.00, 1.07)	0.0811	0.0	0.5544
>70%	123/138 (89.1)	133/136 (97.8)	84.5	16/ 17 (94.1)	37/ 37 (100.0)	15.5	1.09 (1.03, 1.16)	0.0030	0.0	0.6699
Baseline HRCT pattern										
UIP-like	190/206 (92.2)	203/206 (98.5)	86.5	22/ 23 (95.7)	45/ 45 (100.0)	13.5	1.07 (1.02, 1.11)	0.0018	0.0	0.6978
Other fibrotic patterns	118/125 (94.4)	123/126 (97.6)	96.3	3/ 4 (75.0)	9/ 9 (100.0)	3.7	1.04 (0.99, 1.10)	0.1208	0.0	0.4500
Underlying ILD diagnosis										
iNSIP	52/ 61 (85.2)	60/ 64 (93.8)	87.2	6/ 7 (85.7)	11/ 11 (100.0)	12.8	1.11 (0.99, 1.24)	0.0849	0.0	0.7912
Unclassifiable IIP	48/ 50 (96.0)	64/ 64 (100.0)	95.0	3/ 3 (100.0)	2/ 2 (100.0)	5.0	1.04 (0.97, 1.11)	0.2779	0.0	0.8984
HP	86/ 89 (96.6)	84/ 84 (100.0)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	82/ 88 (93.2)	80/ 82 (97.6)	82.6	11/ 12 (91.7)	34/ 34 (100.0)	17.4	1.05 (0.99, 1.12)	0.1059	0.0	0.7048
Other ILD	40/ 43 (93.0)	38/ 38 (100.0)	86.5	5/ 5 (100.0)	6/ 6 (100.0)	13.5	1.06 (0.97, 1.17)	0.1833	0.0	0.6704
Region										
Europe										
Asia	74/ 76 (97.4)	79/ 79 (100.0)	69.2	25/ 27 (92.6)	54/ 54 (100.0)	30.8	1.04 (0.99, 1.09)	0.0840	0.0	0.4375
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.1: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with any adverse events over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	308/331 (93.1)	326/332 (98.2)	90.0	25/ 27 (92.6)	54/ 54 (100.0)	10.0	5.35 (2.37, 8.33)	0.0	0.7145
Age									
<65 years	110/121 (90.9)	135/139 (97.1)	90.2	8/ 9 (88.9)	25/ 25 (100.0)	9.8	6.63 (0.93, 12.33)	0.0	0.7174
>=65 years	198/210 (94.3)	191/193 (99.0)	89.7	17/ 18 (94.4)	29/ 29 (100.0)	10.3	4.75 (1.38, 8.11)	0.0	0.9236
Sex									
Male	164/177 (92.7)	176/179 (98.3)	91.6	10/ 11 (90.9)	26/ 26 (100.0)	8.4	5.92 (1.68, 10.15)	0.0	0.7671
Female	144/154 (93.5)	150/153 (98.0)	87.8	15/ 16 (93.8)	28/ 28 (100.0)	12.2	4.71 (0.42, 8.99)	0.0	0.8485
Baseline FVC percent predicted									
<=70%	185/193 (95.9)	193/196 (98.5)	93.5	9/ 10 (90.0)	17/ 17 (100.0)	6.5	3.05 (-0.34, 6.44)	0.0	0.5488
>70%	123/138 (89.1)	133/136 (97.8)	85.0	16/ 17 (94.1)	37/ 37 (100.0)	15.0	8.22 (2.96, 13.48)	0.0	0.6792
Baseline HRCT pattern									
UIP-like	190/206 (92.2)	203/206 (98.5)	86.8	22/ 23 (95.7)	45/ 45 (100.0)	13.2	6.04 (2.32, 9.75)	0.0	0.7019
Other fibrotic patterns	118/125 (94.4)	123/126 (97.6)	95.2	3/ 4 (75.0)	9/ 9 (100.0)	4.8	4.11 (-0.95, 9.18)	0.0	0.4121
Underlying ILD diagnosis									
iNSIP	52/ 61 (85.2)	60/ 64 (93.8)	86.8	6/ 7 (85.7)	11/ 11 (100.0)	13.2	9.08 (-0.99, 19.15)	0.0	0.7861
Unclassifiable IIP	48/ 50 (96.0)	64/ 64 (100.0)	94.4	3/ 3 (100.0)	2/ 2 (100.0)	5.6	3.71 (-2.91, 10.34)	0.0	0.8850
HP	86/ 89 (96.6)	84/ 84 (100.0)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	82/ 88 (93.2)	80/ 82 (97.6)	82.1	11/ 12 (91.7)	34/ 34 (100.0)	17.9	5.02 (-0.96, 11.01)	0.0	0.7009
Other ILD	40/ 43 (93.0)	38/ 38 (100.0)	86.5	5/ 5 (100.0)	6/ 6 (100.0)	13.5	5.89 (-2.61, 14.39)	0.0	0.6604
Region									
Europe									
Asia	74/ 76 (97.4)	79/ 79 (100.0)	68.0	25/ 27 (92.6)	54/ 54 (100.0)	32.0	4.08 (-0.44, 8.60)	0.0	0.4332
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.1: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with any adverse events over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	308/331 (93.1)	326/332 (98.2)	93.2	25/ 27 (92.6)	54/ 54 (100.0)	6.8	4.30 (1.81,10.22)	0.0	0.6755
Age									
<65 years	110/121 (90.9)	135/139 (97.1)	90.9	8/ 9 (88.9)	25/ 25 (100.0)	9.1	3.55 (1.19,10.63)	0.0	0.7774
>=65 years	198/210 (94.3)	191/193 (99.0)	81.8	17/ 18 (94.4)	29/ 29 (100.0)	18.2	5.43 (1.40,21.01)	0.0	0.8112
Sex									
Male	164/177 (92.7)	176/179 (98.3)	88.2	10/ 11 (90.9)	26/ 26 (100.0)	11.8	4.67 (1.44,15.14)	0.0	0.9860
Female	144/154 (93.5)	150/153 (98.0)	86.9	15/ 16 (93.8)	28/ 28 (100.0)	13.1	3.54 (1.06,11.82)	0.0	0.9339
Baseline FVC percent predicted									
<=70%	185/193 (95.9)	193/196 (98.5)	87.5	9/ 10 (90.0)	17/ 17 (100.0)	12.5	2.95 (0.86,10.11)	0.0	0.8219
>70%	123/138 (89.1)	133/136 (97.8)	87.1	16/ 17 (94.1)	37/ 37 (100.0)	12.9	5.28 (1.65,16.94)	0.0	0.9042
Baseline HRCT pattern									
UIP-like	190/206 (92.2)	203/206 (98.5)	86.8	22/ 23 (95.7)	45/ 45 (100.0)	13.2	5.49 (1.73,17.40)	0.0	0.8460
Other fibrotic patterns	118/125 (94.4)	123/126 (97.6)	90.2	3/ 4 (75.0)	9/ 9 (100.0)	9.8	2.74 (0.77, 9.69)	0.0	0.6409
Underlying ILD diagnosis									
iNSIP	52/ 61 (85.2)	60/ 64 (93.8)	89.5	6/ 7 (85.7)	11/ 11 (100.0)	10.5	2.76 (0.87, 8.71)	0.0	0.7885
Unclassifiable IIP	48/ 50 (96.0)	64/ 64 (100.0)	53.3	3/ 3 (100.0)	2/ 2 (100.0)	46.7	3.55 (0.35,36.16)	0.0	0.5095
HP	86/ 89 (96.6)	84/ 84 (100.0)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	82/ 88 (93.2)	80/ 82 (97.6)	84.8	11/ 12 (91.7)	34/ 34 (100.0)	15.2	3.28 (0.78,13.86)	0.0	0.7329
Other ILD	40/ 43 (93.0)	38/ 38 (100.0)	50.0	5/ 5 (100.0)	6/ 6 (100.0)	50.0	4.07 (0.42,39.16)	0.0	0.4520
Region									
Europe									
Asia	74/ 76 (97.4)	79/ 79 (100.0)	54.3	25/ 27 (92.6)	54/ 54 (100.0)	45.7	6.28 (0.80,49.23)	0.0	0.8595
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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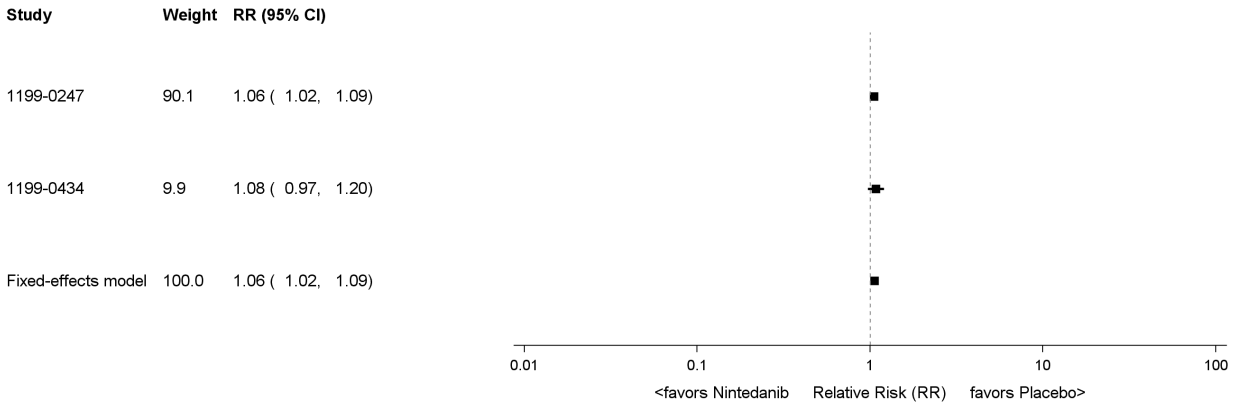

Figure M.2.2.1.1: 1 Forest Plot comparing Nintedanib versus Placebo for patients with any adverse events over the whole trial

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Table M.2.2.1.1: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with any adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	308/331 (93.1)	326/332 (98.2)	90.1	25/ 27 (92.6)	54/ 54 (100.0)	9.9	1.06 (1.02, 1.09)	0.0006	0.0	0.7198
Age										
<65 years										
>=65 years										
Sex										
Male										
Female										
Baseline FVC percent predicted										
<=70%										
>70%										
Baseline HRCT pattern										
UIP-like										
Other fibrotic patterns										
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Disease-related events were defined as confirmed acute ILD exacerbations.

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Table M.2.2.1.1: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with any adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	308/331 (93.1)	326/332 (98.2)	90.0	25/ 27 (92.6)	54/ 54 (100.0)	10.0	5.35 (2.37, 8.33)	0.0	0.7145
Age									
<65 years									
>=65 years									
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Disease-related events were defined as confirmed acute ILD exacerbations.

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Table M.2.2.1.1: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with any adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	308/331 (93.1)	326/332 (98.2)	93.2	25/ 27 (92.6)	54/ 54 (100.0)	6.8	4.30 (1.81,10.22)	0.0	0.6755
Age									
<65 years									
>=65 years									
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Disease-related events were defined as confirmed acute ILD exacerbations.

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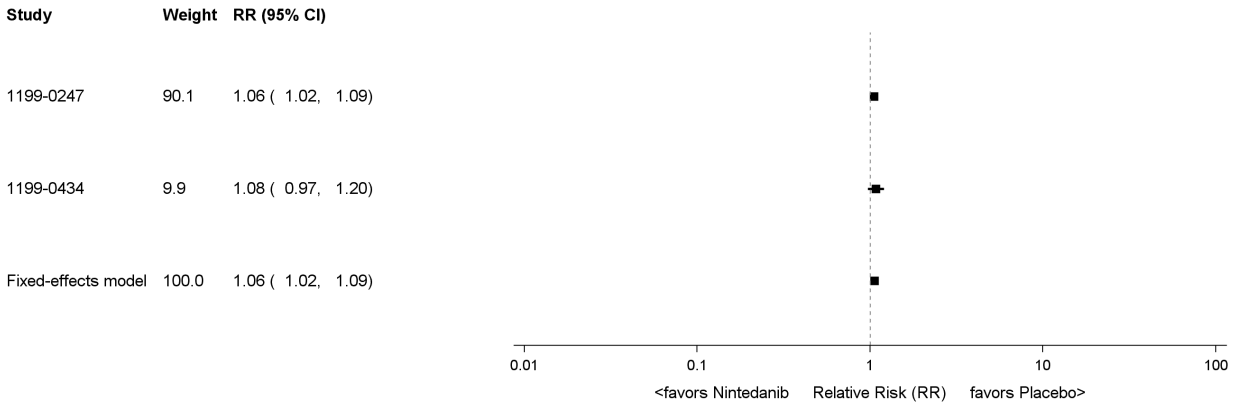

Figure M.2.2.1.1: 2 Forest Plot comparing Nintedanib versus Placebo for patients with any adverse events (excluding disease-related events) over the whole trial

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Table M.2.2.1.1: 3 Meta-analysis comparing Nintedanib versus Placebo for patients with serious adverse events over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	164/331 (49.5)	147/332 (44.3)	91.1	12/ 27 (44.4)	20/ 54 (37.0)	8.9	0.89 (0.76, 1.04)	0.1359	0.0	0.8102
Age										
<65 years	51/121 (42.1)	50/139 (36.0)	92.5	3/ 9 (33.3)	6/ 25 (24.0)	7.5	0.84 (0.63, 1.13)	0.2572	0.0	0.7807
>=65 years	113/210 (53.8)	97/193 (50.3)	90.7	9/ 18 (50.0)	14/ 29 (48.3)	9.3	0.94 (0.78, 1.12)	0.4769	0.0	0.9172
Sex										
Male	97/177 (54.8)	88/179 (49.2)	93.3	5/ 11 (45.5)	14/ 26 (53.8)	6.7	0.92 (0.76, 1.11)	0.3759	0.0	0.4765
Female	67/154 (43.5)	59/153 (38.6)	88.2	7/ 16 (43.8)	6/ 28 (21.4)	11.8	0.84 (0.65, 1.09)	0.1826	34.6	0.2163
Baseline FVC percent predicted										
<=70%	111/193 (57.5)	97/196 (49.5)	95.7	4/ 10 (40.0)	6/ 17 (35.3)	4.3	0.86 (0.72, 1.03)	0.1109	0.0	0.9613
>70%	53/138 (38.4)	50/136 (36.8)	82.8	8/ 17 (47.1)	14/ 37 (37.8)	17.2	0.93 (0.71, 1.23)	0.6118	0.0	0.6348
Baseline HRCT pattern										
UIP-like	108/206 (52.4)	93/206 (45.1)	88.1	11/ 23 (47.8)	18/ 45 (40.0)	11.9	0.86 (0.71, 1.04)	0.1096	0.0	0.9230
Other fibrotic patterns	56/125 (44.8)	54/126 (42.9)	97.6	1/ 4 (25.0)	2/ 9 (22.2)	2.4	0.96 (0.72, 1.26)	0.7455	0.0	0.9456
Underlying ILD diagnosis										
iNSIP	24/ 61 (39.3)	19/ 64 (29.7)	91.0	2/ 7 (28.6)	5/ 11 (45.5)	9.0	0.83 (0.53, 1.31)	0.4239	5.0	0.3049
Unclassifiable IIP	30/ 50 (60.0)	31/ 64 (48.4)	96.3	1/ 3 (33.3)	0/ 2 (0.0)	3.7	0.79 (0.56, 1.11)	0.1768	0.0	0.6318
HP	45/ 89 (50.6)	41/ 84 (48.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	43/ 88 (48.9)	40/ 82 (48.8)	84.9	5/ 12 (41.7)	14/ 34 (41.2)	15.1	1.00 (0.75, 1.33)	0.9824	0.0	0.9811
Other ILD	22/ 43 (51.2)	16/ 38 (42.1)	82.5	4/ 5 (80.0)	1/ 6 (16.7)	17.5	0.72 (0.45, 1.13)	0.1484	50.1	0.1569
Region										
Europe										
Asia	43/ 76 (56.6)	39/ 79 (49.4)	73.3	12/ 27 (44.4)	20/ 54 (37.0)	26.7	0.86 (0.66, 1.12)	0.2674	0.0	0.8849
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.1: 3 Meta-analysis comparing Nintedanib versus Placebo for patients with serious adverse events over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	164/331 (49.5)	147/332 (44.3)	90.2	12/ 27 (44.4)	20/ 54 (37.0)	9.8	-5.48 (-12.68, 1.72)	0.0	0.8613
Age									
<65 years	51/121 (42.1)	50/139 (36.0)	90.7	3/ 9 (33.3)	6/ 25 (24.0)	9.3	-6.47 (-17.73, 4.78)	0.0	0.8673
>=65 years	113/210 (53.8)	97/193 (50.3)	90.1	9/ 18 (50.0)	14/ 29 (48.3)	9.9	-3.37 (-12.63, 5.89)	0.0	0.9080
Sex									
Male	97/177 (54.8)	88/179 (49.2)	92.0	5/ 11 (45.5)	14/ 26 (53.8)	8.0	-4.52 (-14.46, 5.42)	0.0	0.4525
Female	67/154 (43.5)	59/153 (38.6)	88.3	7/ 16 (43.8)	6/ 28 (21.4)	11.7	-6.98 (-17.25, 3.29)	18.7	0.2673
Baseline FVC percent predicted									
<=70%	111/193 (57.5)	97/196 (49.5)	93.9	4/ 10 (40.0)	6/ 17 (35.3)	6.1	-7.82 (-17.38, 1.74)	0.0	0.8682
>70%	53/138 (38.4)	50/136 (36.8)	85.5	8/ 17 (47.1)	14/ 37 (37.8)	14.5	-2.74 (-13.38, 7.89)	0.0	0.6277
Baseline HRCT pattern									
UIP-like	108/206 (52.4)	93/206 (45.1)	87.1	11/ 23 (47.8)	18/ 45 (40.0)	12.9	-7.35 (-16.33, 1.63)	0.0	0.9681
Other fibrotic patterns	56/125 (44.8)	54/126 (42.9)	95.8	1/ 4 (25.0)	2/ 9 (22.2)	4.2	-1.98 (-13.93, 9.97)	0.0	0.9748
Underlying ILD diagnosis									
iNSIP	24/ 61 (39.3)	19/ 64 (29.7)	88.0	2/ 7 (28.6)	5/ 11 (45.5)	12.0	-6.46 (-22.02, 9.10)	16.4	0.2740
Unclassifiable IIP	30/ 50 (60.0)	31/ 64 (48.4)	94.4	1/ 3 (33.3)	0/ 2 (0.0)	5.6	-12.25 (-29.86, 5.35)	0.0	0.7101
HP	45/ 89 (50.6)	41/ 84 (48.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	43/ 88 (48.9)	40/ 82 (48.8)	82.7	5/ 12 (41.7)	14/ 34 (41.2)	17.3	-0.15 (-13.80, 13.49)	0.0	0.9822
Other ILD	22/ 43 (51.2)	16/ 38 (42.1)	88.1	4/ 5 (80.0)	1/ 6 (16.7)	11.9	-15.52 (-35.38, 4.34)	77.1	0.0365
Region									
Europe									
Asia	43/ 76 (56.6)	39/ 79 (49.4)	68.3	12/ 27 (44.4)	20/ 54 (37.0)	31.7	-7.27 (-20.18, 5.63)	0.0	0.9889
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.1: 3 Meta-analysis comparing Nintedanib versus Placebo for patients with serious adverse events over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	164/331 (49.5)	147/332 (44.3)	90.1	12/ 27 (44.4)	20/ 54 (37.0)	9.9	0.80 (0.60, 1.07)	0.0	0.8493
Age									
<65 years	51/121 (42.1)	50/139 (36.0)	91.2	3/ 9 (33.3)	6/ 25 (24.0)	8.8	0.76 (0.47, 1.23)	0.0	0.8217
>=65 years	113/210 (53.8)	97/193 (50.3)	90.4	9/ 18 (50.0)	14/ 29 (48.3)	9.6	0.87 (0.60, 1.27)	0.0	0.9077
Sex									
Male	97/177 (54.8)	88/179 (49.2)	93.9	5/ 11 (45.5)	14/ 26 (53.8)	6.1	0.83 (0.56, 1.24)	0.0	0.4547
Female	67/154 (43.5)	59/153 (38.6)	85.4	7/ 16 (43.8)	6/ 28 (21.4)	14.6	0.75 (0.49, 1.15)	26.9	0.2422
Baseline FVC percent predicted									
<=70%	111/193 (57.5)	97/196 (49.5)	94.5	4/ 10 (40.0)	6/ 17 (35.3)	5.5	0.73 (0.49, 1.07)	0.0	0.8848
>70%	53/138 (38.4)	50/136 (36.8)	83.0	8/ 17 (47.1)	14/ 37 (37.8)	17.0	0.89 (0.57, 1.40)	0.0	0.6311
Baseline HRCT pattern									
UIP-like	108/206 (52.4)	93/206 (45.1)	87.1	11/ 23 (47.8)	18/ 45 (40.0)	12.9	0.74 (0.52, 1.07)	0.0	0.9618
Other fibrotic patterns	56/125 (44.8)	54/126 (42.9)	96.8	1/ 4 (25.0)	2/ 9 (22.2)	3.2	0.92 (0.56, 1.51)	0.0	0.9580
Underlying ILD diagnosis									
iNSIP	24/ 61 (39.3)	19/ 64 (29.7)	92.8	2/ 7 (28.6)	5/ 11 (45.5)	7.2	0.75 (0.38, 1.50)	10.6	0.2903
Unclassifiable IIP	30/ 50 (60.0)	31/ 64 (48.4)	94.1	1/ 3 (33.3)	0/ 2 (0.0)	5.9	0.61 (0.29, 1.26)	0.0	0.6778
HP	45/ 89 (50.6)	41/ 84 (48.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	43/ 88 (48.9)	40/ 82 (48.8)	83.0	5/ 12 (41.7)	14/ 34 (41.2)	17.0	0.99 (0.57, 1.72)	0.0	0.9820
Other ILD	22/ 43 (51.2)	16/ 38 (42.1)	76.7	4/ 5 (80.0)	1/ 6 (16.7)	23.3	0.54 (0.24, 1.23)	61.7	0.1061
Region									
Europe									
Asia	43/ 76 (56.6)	39/ 79 (49.4)	68.8	12/ 27 (44.4)	20/ 54 (37.0)	31.2	0.74 (0.44, 1.26)	0.0	0.9759
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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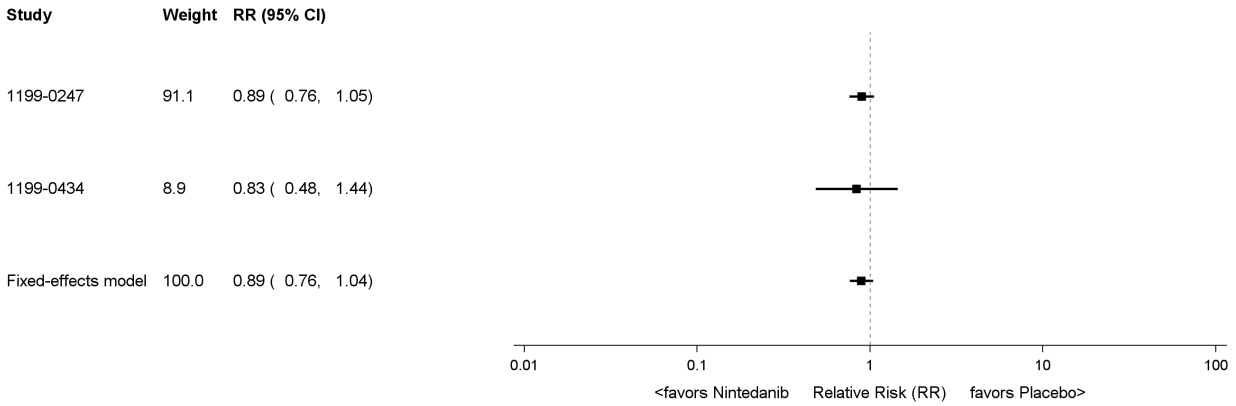

Figure M.2.2.1.1: 3 Forest Plot comparing Nintedanib versus Placebo for patients with serious adverse events over the whole trial

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Table M.2.2.1.1: 4 Meta-analysis comparing Nintedanib versus Placebo for patients with serious adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	151/331 (45.6)	140/332 (42.2)	90.4	12/ 27 (44.4)	20/ 54 (37.0)	9.6	0.92 (0.78, 1.08)	0.2933	0.0	0.7230
Age										
<65 years										
>=65 years										
Sex										
Male										
Female										
Baseline FVC percent predicted										
<=70%										
>70%										
Baseline HRCT pattern										
UIP-like										
Other fibrotic patterns										
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Disease-related events were defined as confirmed acute ILD exacerbations.

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Table M.2.2.1.1: 4 Meta-analysis comparing Nintedanib versus Placebo for patients with serious adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	151/331 (45.6)	140/332 (42.2)	90.2	12/ 27 (44.4)	20/ 54 (37.0)	9.8	-3.84 (-11.00, 3.33)	0.0	0.7462
Age									
<65 years									
>=65 years									
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Disease-related events were defined as confirmed acute ILD exacerbations.

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Table M.2.2.1.1: 4 Meta-analysis comparing Nintedanib versus Placebo for patients with serious adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	151/331 (45.6)	140/332 (42.2)	89.7	12/ 27 (44.4)	20/ 54 (37.0)	10.3	0.86 (0.64, 1.15)	0.0	0.7399
Age									
<65 years									
>=65 years									
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Disease-related events were defined as confirmed acute ILD exacerbations.

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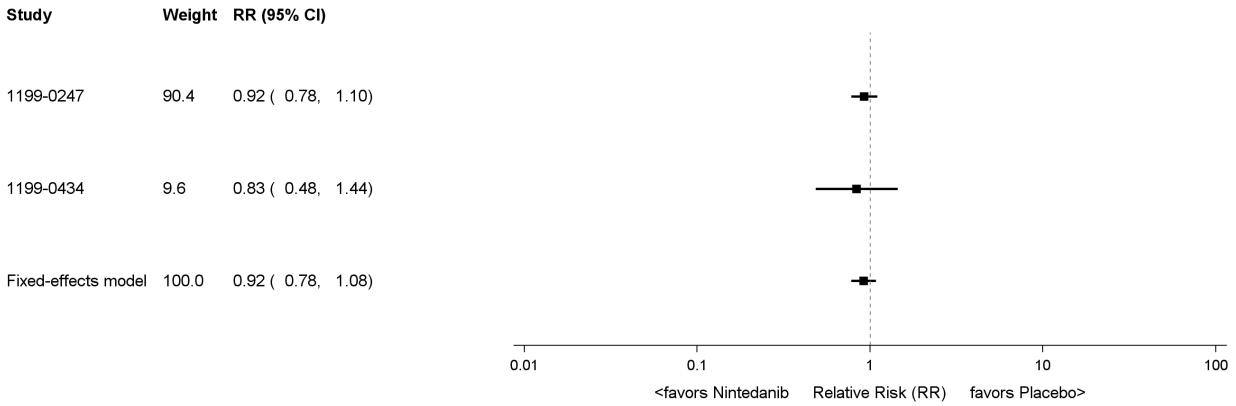

Figure M.2.2.1.1: 4 Forest Plot comparing Nintedanib versus Placebo for patients with serious adverse events (excluding disease-related events) over the whole trial

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M.2.2.1.2 Adverse events leading to treatment discontinuation over the whole trial

Table M.2.2.1.2: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with any adverse events leading to treatment discontinuation over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid					
Overall	48/331 (14.5)	73/332 (22.0)	97.3	1/ 27 (3.7)	10/ 54 (18.5)	2.7	1.61 (1.16, 2.23)	0.0043	24.6	0.2494
Age										
<65 years	13/121 (10.7)	19/139 (13.7)	97.3	0/ 9 (0.0)	2/ 25 (8.0)	2.7	1.34 (0.70, 2.57)	0.3806	0.0	0.5969
>=65 years	35/210 (16.7)	54/193 (28.0)	96.4	1/ 18 (5.6)	8/ 29 (27.6)	3.6	1.80 (1.24, 2.60)	0.0020	8.8	0.2949
Sex										
Male	26/177 (14.7)	41/179 (22.9)	94.9	1/ 11 (9.1)	2/ 26 (7.7)	5.1	1.52 (0.98, 2.36)	0.0589	0.0	0.6082
Female	22/154 (14.3)	32/153 (20.9)	97.9	0/ 16 (0.0)	8/ 28 (28.6)	2.1	1.71 (1.05, 2.79)	0.0298	42.8	0.1860
Baseline FVC percent predicted										
<=70%	32/193 (16.6)	43/196 (21.9)	98.6	0/ 10 (0.0)	4/ 17 (23.5)	1.4	1.41 (0.94, 2.12)	0.0992	4.4	0.3065
>70%	16/138 (11.6)	30/136 (22.1)	92.1	1/ 17 (5.9)	6/ 37 (16.2)	7.9	1.97 (1.15, 3.38)	0.0139	0.0	0.7308
Baseline HRCT pattern										
UIP-like	30/206 (14.6)	50/206 (24.3)	95.8	1/ 23 (4.3)	9/ 45 (20.0)	4.2	1.79 (1.20, 2.68)	0.0045	0.0	0.3306
Other fibrotic patterns	18/125 (14.4)	23/126 (18.3)	97.7	0/ 4 (0.0)	1/ 9 (11.1)	2.3	1.29 (0.74, 2.26)	0.3646	0.0	0.7297
Underlying ILD diagnosis										
iNSIP	7/ 61 (11.5)	14/ 64 (21.9)	93.8	0/ 7 (0.0)	2/ 11 (18.2)	6.2	2.05 (0.91, 4.62)	0.0818	0.0	0.6371
Unclassifiable IIP	11/ 50 (22.0)	15/ 64 (23.4)	96.3	0/ 3 (0.0)	0/ 2 (0.0)	3.7	1.06 (0.54, 2.08)	0.8590	0.0	0.9737
HP	12/ 89 (13.5)	18/ 84 (21.4)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	12/ 88 (13.6)	17/ 82 (20.7)	88.7	1/ 12 (8.3)	8/ 34 (23.5)	11.3	1.67 (0.88, 3.17)	0.1178	0.0	0.5605
Other ILD	6/ 43 (14.0)	9/ 38 (23.7)	91.9	0/ 5 (0.0)	0/ 6 (0.0)	8.1	1.64 (0.66, 4.07)	0.2846	0.0	0.7901
Region										
Europe										
Asia	14/ 76 (18.4)	19/ 79 (24.1)	91.5	1/ 27 (3.7)	10/ 54 (18.5)	8.5	1.62 (0.90, 2.92)	0.1066	36.6	0.2091
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.2: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with any adverse events leading to treatment discontinuation over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	48/331 (14.5)	73/332 (22.0)	90.2	1/ 27 (3.7)	10/ 54 (18.5)	9.8	8.20 (2.78, 13.62)	6.8	0.3003
Age									
<65 years	13/121 (10.7)	19/139 (13.7)	90.2	0/ 9 (0.0)	2/ 25 (8.0)	9.8	3.38 (-3.95, 10.70)	0.0	0.6041
>=65 years	35/210 (16.7)	54/193 (28.0)	90.1	1/ 18 (5.6)	8/ 29 (27.6)	9.9	12.38 (4.84, 19.92)	0.0	0.3178
Sex									
Male	26/177 (14.7)	41/179 (22.9)	92.0	1/ 11 (9.1)	2/ 26 (7.7)	8.0	7.45 (-0.14, 15.04)	0.0	0.3789
Female	22/154 (14.3)	32/153 (20.9)	87.8	0/ 16 (0.0)	8/ 28 (28.6)	12.2	9.15 (1.38, 16.92)	76.1	0.0409
Baseline FVC percent predicted									
<=70%	32/193 (16.6)	43/196 (21.9)	93.5	0/ 10 (0.0)	4/ 17 (23.5)	6.5	6.43 (-1.02, 13.89)	45.0	0.1774
>70%	16/138 (11.6)	30/136 (22.1)	85.5	1/ 17 (5.9)	6/ 37 (16.2)	14.5	10.45 (2.58, 18.32)	0.0	0.9890
Baseline HRCT pattern									
UIP-like	30/206 (14.6)	50/206 (24.3)	87.1	1/ 23 (4.3)	9/ 45 (20.0)	12.9	10.47 (3.61, 17.33)	0.0	0.4730
Other fibrotic patterns	18/125 (14.4)	23/126 (18.3)	95.2	0/ 4 (0.0)	1/ 9 (11.1)	4.8	4.13 (-4.69, 12.96)	0.0	0.7335
Underlying ILD diagnosis									
iNSIP	7/ 61 (11.5)	14/ 64 (21.9)	86.8	0/ 7 (0.0)	2/ 11 (18.2)	13.2	11.19 (-0.59, 22.97)	0.0	0.7014
Unclassifiable IIP	11/ 50 (22.0)	15/ 64 (23.4)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	1.36 (-13.55, 16.26)	0.0	0.9592
HP	12/ 89 (13.5)	18/ 84 (21.4)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	12/ 88 (13.6)	17/ 82 (20.7)	82.7	1/ 12 (8.3)	8/ 34 (23.5)	17.3	8.50 (-1.57, 18.56)	0.0	0.5083
Other ILD	6/ 43 (14.0)	9/ 38 (23.7)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	8.39 (-6.83, 23.61)	0.0	0.5715
Region									
Europe									
Asia	14/ 76 (18.4)	19/ 79 (24.1)	68.3	1/ 27 (3.7)	10/ 54 (18.5)	31.7	8.54 (-1.09, 18.17)	0.4	0.3164
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.2: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with any adverse events leading to treatment discontinuation over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	48/331 (14.5)	73/332 (22.0)	97.2	1/ 27 (3.7)	10/ 54 (18.5)	2.8	1.78 (1.21, 2.63)	25.2	0.2474
Age									
<65 years	13/121 (10.7)	19/139 (13.7)	97.2	0/ 9 (0.0)	2/ 25 (8.0)	2.8	1.39 (0.67, 2.90)	0.0	0.5949
>=65 years	35/210 (16.7)	54/193 (28.0)	96.4	1/ 18 (5.6)	8/ 29 (27.6)	3.6	2.10 (1.32, 3.35)	10.9	0.2893
Sex									
Male	26/177 (14.7)	41/179 (22.9)	94.0	1/ 11 (9.1)	2/ 26 (7.7)	6.0	1.67 (0.98, 2.84)	0.0	0.5787
Female	22/154 (14.3)	32/153 (20.9)	98.2	0/ 16 (0.0)	8/ 28 (28.6)	1.8	1.91 (1.08, 3.37)	49.9	0.1578
Baseline FVC percent predicted									
<=70%	32/193 (16.6)	43/196 (21.9)	98.6	0/ 10 (0.0)	4/ 17 (23.5)	1.4	1.52 (0.93, 2.51)	13.2	0.2831
>70%	16/138 (11.6)	30/136 (22.1)	91.5	1/ 17 (5.9)	6/ 37 (16.2)	8.5	2.24 (1.19, 4.21)	0.0	0.7581
Baseline HRCT pattern									
UIP-like	30/206 (14.6)	50/206 (24.3)	95.5	1/ 23 (4.3)	9/ 45 (20.0)	4.5	2.04 (1.26, 3.31)	0.0	0.3370
Other fibrotic patterns	18/125 (14.4)	23/126 (18.3)	97.6	0/ 4 (0.0)	1/ 9 (11.1)	2.4	1.36 (0.70, 2.64)	0.0	0.7288
Underlying ILD diagnosis									
iNSIP	7/ 61 (11.5)	14/ 64 (21.9)	93.7	0/ 7 (0.0)	2/ 11 (18.2)	6.3	2.35 (0.92, 6.02)	0.0	0.6389
Unclassifiable IIP	11/ 50 (22.0)	15/ 64 (23.4)	95.8	0/ 3 (0.0)	0/ 2 (0.0)	4.2	1.08 (0.45, 2.57)	0.0	0.9710
HP	12/ 89 (13.5)	18/ 84 (21.4)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	12/ 88 (13.6)	17/ 82 (20.7)	89.0	1/ 12 (8.3)	8/ 34 (23.5)	11.0	1.85 (0.87, 3.92)	0.0	0.5494
Other ILD	6/ 43 (14.0)	9/ 38 (23.7)	90.4	0/ 5 (0.0)	0/ 6 (0.0)	9.6	1.83 (0.61, 5.48)	0.0	0.7648
Region									
Europe									
Asia	14/ 76 (18.4)	19/ 79 (24.1)	90.9	1/ 27 (3.7)	10/ 54 (18.5)	9.1	1.81 (0.90, 3.67)	36.3	0.2103
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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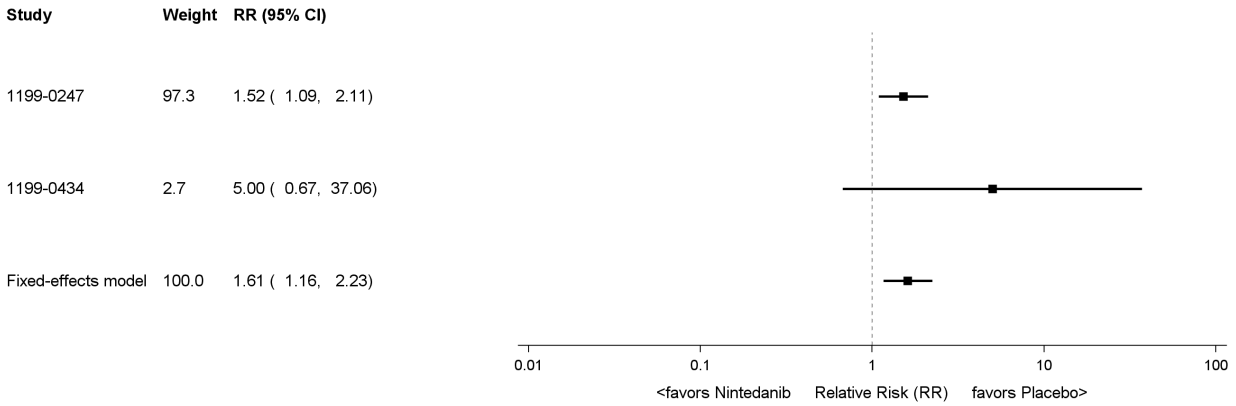

Cochran's Q pvalue: 0.2494
I^2: 24.6

Figure M.2.2.1.2: 1 Forest Plot comparing Nintedanib versus Placebo for patients with any adverse events leading to treatment discontinuation over the whole trial

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Table M.2.2.1.2: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with any adverse events leading to treatment discontinuation (excluding disease-related events) over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	41/331 (12.4)	71/332 (21.4)	96.9	1/ 27 (3.7)	10/ 54 (18.5)	3.1	1.83 (1.29, 2.59)	0.0007	4.8	0.3055
Age										
<65 years	11/121 (9.1)	19/139 (13.7)	96.8	0/ 9 (0.0)	2/ 25 (8.0)	3.2	1.57 (0.79, 3.14)	0.1978	0.0	0.6557
>=65 years	30/210 (14.3)	52/193 (26.9)	95.9	1/ 18 (5.6)	8/ 29 (27.6)	4.1	2.01 (1.35, 2.99)	0.0006	0.0	0.3511
Sex										
Male	23/177 (13.0)	40/179 (22.3)	94.3	1/ 11 (9.1)	2/ 26 (7.7)	5.7	1.67 (1.06, 2.64)	0.0284	0.0	0.5528
Female	18/154 (11.7)	31/153 (20.3)	97.5	0/ 16 (0.0)	8/ 28 (28.6)	2.5	2.03 (1.20, 3.44)	0.0084	32.8	0.2226
Baseline FVC percent predicted										
<=70%	28/193 (14.5)	42/196 (21.4)	98.4	0/ 10 (0.0)	4/ 17 (23.5)	1.6	1.57 (1.02, 2.42)	0.0392	0.0	0.3389
>70%	13/138 (9.4)	29/136 (21.3)	90.4	1/ 17 (5.9)	6/ 37 (16.2)	9.6	2.31 (1.29, 4.15)	0.0051	0.0	0.8559
Baseline HRCT pattern										
UIP-like	26/206 (12.6)	49/206 (23.8)	95.2	1/ 23 (4.3)	9/ 45 (20.0)	4.8	2.02 (1.32, 3.09)	0.0012	0.0	0.3937
Other fibrotic patterns	15/125 (12.0)	22/126 (17.5)	97.2	0/ 4 (0.0)	1/ 9 (11.1)	2.8	1.48 (0.81, 2.70)	0.1985	0.0	0.7852
Underlying ILD diagnosis										
iNSIP	5/ 61 (8.2)	14/ 64 (21.9)	91.5	0/ 7 (0.0)	2/ 11 (18.2)	8.5	2.81 (1.12, 7.05)	0.0282	0.0	0.7853
Unclassifiable IIP	10/ 50 (20.0)	15/ 64 (23.4)	95.9	0/ 3 (0.0)	0/ 2 (0.0)	4.1	1.16 (0.58, 2.34)	0.6678	0.0	0.9343
HP	11/ 89 (12.4)	17/ 84 (20.2)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	10/ 88 (11.4)	17/ 82 (20.7)	86.7	1/ 12 (8.3)	8/ 34 (23.5)	13.3	1.96 (0.99, 3.87)	0.0532	0.0	0.6835
Other ILD	5/ 43 (11.6)	8/ 38 (21.1)	90.4	0/ 5 (0.0)	0/ 6 (0.0)	9.6	1.73 (0.64, 4.66)	0.2762	0.0	0.7666
Region										
Europe										
Asia	12/ 76 (15.8)	19/ 79 (24.1)	90.2	1/ 27 (3.7)	10/ 54 (18.5)	9.8	1.86 (1.00, 3.47)	0.0490	18.3	0.2686
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Disease-related events were defined as confirmed acute ILD exacerbations.

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Table M.2.2.1.2: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with any adverse events leading to treatment discontinuation (excluding disease-related events) over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid				
Overall	41/331 (12.4)	71/332 (21.4)	90.2	1/ 27 (3.7)	10/ 54 (18.5)	9.8	9.57 (4.32, 14.82)	0.0	0.4084
Age									
<65 years	11/121 (9.1)	19/139 (13.7)	90.2	0/ 9 (0.0)	2/ 25 (8.0)	9.8	4.87 (-2.22, 11.96)	0.0	0.7371
>=65 years	30/210 (14.3)	52/193 (26.9)	90.1	1/ 18 (5.6)	8/ 29 (27.6)	9.9	13.59 (6.26, 20.92)	0.0	0.3801
Sex									
Male	23/177 (13.0)	40/179 (22.3)	92.0	1/ 11 (9.1)	2/ 26 (7.7)	8.0	8.49 (1.09, 15.90)	0.0	0.3234
Female	18/154 (11.7)	31/153 (20.3)	87.8	0/ 16 (0.0)	8/ 28 (28.6)	12.2	10.86 (3.38, 18.34)	71.3	0.0620
Baseline FVC percent predicted									
<=70%	28/193 (14.5)	42/196 (21.4)	93.5	0/ 10 (0.0)	4/ 17 (23.5)	6.5	7.90 (0.64, 15.15)	33.4	0.2206
>70%	13/138 (9.4)	29/136 (21.3)	85.5	1/ 17 (5.9)	6/ 37 (16.2)	14.5	11.68 (4.09, 19.26)	0.0	0.8670
Baseline HRCT pattern									
UIP-like	26/206 (12.6)	49/206 (23.8)	87.1	1/ 23 (4.3)	9/ 45 (20.0)	12.9	11.74 (5.06, 18.43)	0.0	0.5858
Other fibrotic patterns	15/125 (12.0)	22/126 (17.5)	95.2	0/ 4 (0.0)	1/ 9 (11.1)	4.8	5.66 (-2.80, 14.12)	0.0	0.8053
Underlying ILD diagnosis									
iNSIP	5/ 61 (8.2)	14/ 64 (21.9)	86.8	0/ 7 (0.0)	2/ 11 (18.2)	13.2	14.03 (2.80, 25.27)	0.0	0.8617
Unclassifiable IIP	10/ 50 (20.0)	15/ 64 (23.4)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	3.24 (-11.39, 17.88)	0.0	0.9026
HP	11/ 89 (12.4)	17/ 84 (20.2)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	10/ 88 (11.4)	17/ 82 (20.7)	82.7	1/ 12 (8.3)	8/ 34 (23.5)	17.3	10.38 (0.57, 20.18)	0.0	0.6320
Other ILD	5/ 43 (11.6)	8/ 38 (21.1)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	8.13 (-6.34, 22.59)	0.0	0.5786
Region									
Europe									
Asia	12/ 76 (15.8)	19/ 79 (24.1)	68.3	1/ 27 (3.7)	10/ 54 (18.5)	31.7	10.34 (0.93, 19.76)	0.0	0.4686
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Disease-related events were defined as confirmed acute ILD exacerbations.

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Table M.2.2.1.2: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with any adverse events leading to treatment discontinuation (excluding disease-related events) over the whole trial

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	41/331 (12.4)	71/332 (21.4)	96.7	1/ 27 (3.7)	10/ 54 (18.5)	3.3	2.05 (1.37, 3.09)	4.1	0.3071
Age									
<65 years	11/121 (9.1)	19/139 (13.7)	96.7	0/ 9 (0.0)	2/ 25 (8.0)	3.3	1.66 (0.77, 3.59)	0.0	0.6577
>=65 years	30/210 (14.3)	52/193 (26.9)	95.9	1/ 18 (5.6)	8/ 29 (27.6)	4.1	2.39 (1.47, 3.87)	0.0	0.3456
Sex									
Male	23/177 (13.0)	40/179 (22.3)	93.3	1/ 11 (9.1)	2/ 26 (7.7)	6.7	1.85 (1.07, 3.21)	0.0	0.5232
Female	18/154 (11.7)	31/153 (20.3)	97.8	0/ 16 (0.0)	8/ 28 (28.6)	2.2	2.30 (1.26, 4.20)	40.9	0.1931
Baseline FVC percent predicted									
<=70%	28/193 (14.5)	42/196 (21.4)	98.5	0/ 10 (0.0)	4/ 17 (23.5)	1.5	1.73 (1.03, 2.89)	0.1	0.3171
>70%	13/138 (9.4)	29/136 (21.3)	89.8	1/ 17 (5.9)	6/ 37 (16.2)	10.2	2.66 (1.36, 5.19)	0.0	0.8837
Baseline HRCT pattern									
UIP-like	26/206 (12.6)	49/206 (23.8)	94.9	1/ 23 (4.3)	9/ 45 (20.0)	5.1	2.33 (1.41, 3.85)	0.0	0.4043
Other fibrotic patterns	15/125 (12.0)	22/126 (17.5)	97.2	0/ 4 (0.0)	1/ 9 (11.1)	2.8	1.58 (0.79, 3.18)	0.0	0.7862
Underlying ILD diagnosis									
iNSIP	5/ 61 (8.2)	14/ 64 (21.9)	91.5	0/ 7 (0.0)	2/ 11 (18.2)	8.5	3.31 (1.17, 9.35)	0.0	0.7900
Unclassifiable IIP	10/ 50 (20.0)	15/ 64 (23.4)	95.4	0/ 3 (0.0)	0/ 2 (0.0)	4.6	1.21 (0.50, 2.94)	0.0	0.9284
HP	11/ 89 (12.4)	17/ 84 (20.2)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	10/ 88 (11.4)	17/ 82 (20.7)	87.1	1/ 12 (8.3)	8/ 34 (23.5)	12.9	2.21 (1.01, 4.86)	0.0	0.6732
Other ILD	5/ 43 (11.6)	8/ 38 (21.1)	89.0	0/ 5 (0.0)	0/ 6 (0.0)	11.0	1.91 (0.60, 6.13)	0.0	0.7460
Region									
Europe									
Asia	12/ 76 (15.8)	19/ 79 (24.1)	89.5	1/ 27 (3.7)	10/ 54 (18.5)	10.5	2.13 (1.02, 4.43)	15.2	0.2774
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Disease-related events were defined as confirmed acute ILD exacerbations.

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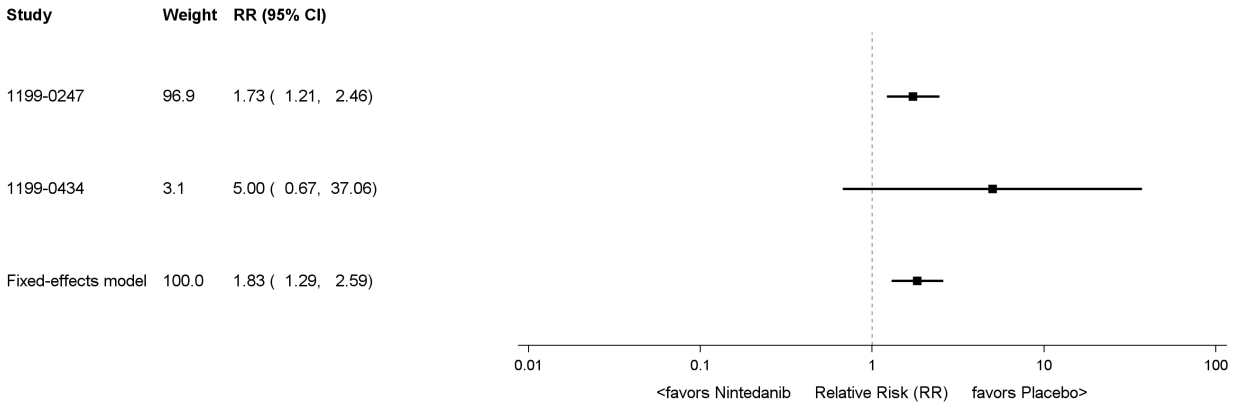

Figure M.2.2.1.2: 2 Forest Plot comparing Nintedanib versus Placebo for patients with any adverse events leading to treatment discontinuation (excluding disease-related events) over the whole trial

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M.2.2.1.3 Adverse events on SOC level over the whole trial

Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Blood and lymphatic system disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	16/331 (4.8)	17/332 (5.1)	75.0	4/ 27 (14.8)	3/ 54 (5.6)	25.0	0.89 (0.49, 1.61)	0.6953	40.4	0.1953
Age										
<65 years	6/121 (5.0)	9/139 (6.5)	94.3	0/ 9 (0.0)	0/ 25 (0.0)	5.7	1.29 (0.48, 3.43)	0.6117	0.0	0.9074
>=65 years	10/210 (4.8)	8/193 (4.1)	66.0	4/ 18 (22.2)	3/ 29 (10.3)	34.0	0.73 (0.35, 1.56)	0.4181	0.0	0.4571
Sex										
Male	8/177 (4.5)	11/179 (6.1)	74.1	2/ 11 (18.2)	3/ 26 (11.5)	25.9	1.17 (0.54, 2.54)	0.6879	0.0	0.4241
Female	8/154 (5.2)	6/153 (3.9)	72.6	2/ 16 (12.5)	0/ 28 (0.0)	27.4	0.59 (0.23, 1.50)	0.2664	13.9	0.2813
Baseline FVC percent predicted										
<=70%	12/193 (6.2)	11/196 (5.6)	96.3	0/ 10 (0.0)	1/ 17 (5.9)	3.7	0.97 (0.45, 2.08)	0.9281	0.0	0.5637
>70%	4/138 (2.9)	6/136 (4.4)	42.0	4/ 17 (23.5)	2/ 37 (5.4)	58.0	0.77 (0.32, 1.88)	0.5700	70.2	0.0671
Baseline HRCT pattern										
UIP-like	9/206 (4.4)	10/206 (4.9)	63.0	4/ 23 (17.4)	2/ 45 (4.4)	37.0	0.79 (0.38, 1.66)	0.5408	59.0	0.1184
Other fibrotic patterns	7/125 (5.6)	7/126 (5.6)	94.3	0/ 4 (0.0)	1/ 9 (11.1)	5.7	1.08 (0.41, 2.85)	0.8843	0.0	0.6435
Underlying ILD diagnosis										
iNSIP	2/ 61 (3.3)	2/ 64 (3.1)	54.7	1/ 7 (14.3)	0/ 11 (0.0)	45.3	0.65 (0.14, 3.02)	0.5805	0.0	0.4876
Unclassifiable IIP	2/ 50 (4.0)	5/ 64 (7.8)	82.4	0/ 3 (0.0)	0/ 2 (0.0)	17.6	1.79 (0.41, 7.69)	0.4368	0.0	0.7450
HP	5/ 89 (5.6)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	7/ 88 (8.0)	4/ 82 (4.9)	82.0	1/ 12 (8.3)	2/ 34 (5.9)	18.0	0.63 (0.22, 1.82)	0.3924	0.0	0.9155
Other ILD	0/ 43 (0.0)	1/ 38 (2.6)	18.6	2/ 5 (40.0)	1/ 6 (16.7)	81.4	0.92 (0.19, 4.39)	0.9180	10.3	0.2910
Region										
Europe										
Asia	2/ 76 (2.6)	6/ 79 (7.6)	27.7	4/ 27 (14.8)	3/ 54 (5.6)	72.3	1.07 (0.42, 2.73)	0.8885	71.9	0.0591
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Blood and lymphatic system disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	16/331 (4.8)	17/332 (5.1)	90.2	4/ 27 (14.8)	3/ 54 (5.6)	9.8	-0.65 (-3.96, 2.67)	34.9	0.2152
Age									
<65 years	6/121 (5.0)	9/139 (6.5)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	1.37 (-3.85, 6.59)	0.0	0.8246
>=65 years	10/210 (4.8)	8/193 (4.1)	90.1	4/ 18 (22.2)	3/ 29 (10.3)	9.9	-1.74 (-5.98, 2.51)	0.0	0.3274
Sex									
Male	8/177 (4.5)	11/179 (6.1)	92.0	2/ 11 (18.2)	3/ 26 (11.5)	8.0	0.96 (-3.80, 5.73)	0.0	0.5379
Female	8/154 (5.2)	6/153 (3.9)	87.8	2/ 16 (12.5)	0/ 28 (0.0)	12.2	-2.57 (-7.19, 2.04)	25.1	0.2478
Baseline FVC percent predicted									
<=70%	12/193 (6.2)	11/196 (5.6)	93.5	0/ 10 (0.0)	1/ 17 (5.9)	6.5	-0.21 (-4.73, 4.31)	0.0	0.4998
>70%	4/138 (2.9)	6/136 (4.4)	85.5	4/ 17 (23.5)	2/ 37 (5.4)	14.5	-1.34 (-6.25, 3.57)	67.6	0.0788
Baseline HRCT pattern									
UIP-like	9/206 (4.4)	10/206 (4.9)	87.1	4/ 23 (17.4)	2/ 45 (4.4)	12.9	-1.24 (-5.37, 2.88)	57.8	0.1238
Other fibrotic patterns	7/125 (5.6)	7/126 (5.6)	95.2	0/ 4 (0.0)	1/ 9 (11.1)	4.8	0.42 (-5.20, 6.05)	0.0	0.5593
Underlying ILD diagnosis									
iNSIP	2/ 61 (3.3)	2/ 64 (3.1)	86.8	1/ 7 (14.3)	0/ 11 (0.0)	13.2	-1.83 (-8.46, 4.80)	0.0	0.4097
Unclassifiable IIP	2/ 50 (4.0)	5/ 64 (7.8)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	3.60 (-4.99, 12.18)	0.0	0.8891
HP	5/ 89 (5.6)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	7/ 88 (8.0)	4/ 82 (4.9)	82.7	1/ 12 (8.3)	2/ 34 (5.9)	17.3	-2.97 (-9.74, 3.81)	0.0	0.9485
Other ILD	0/ 43 (0.0)	1/ 38 (2.6)	88.3	2/ 5 (40.0)	1/ 6 (16.7)	11.7	-0.45 (-9.01, 8.10)	0.0	0.3356
Region									
Europe									
Asia	2/ 76 (2.6)	6/ 79 (7.6)	68.3	4/ 27 (14.8)	3/ 54 (5.6)	31.7	0.45 (-6.17, 7.07)	66.0	0.0862
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Blood and lymphatic system disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	16/331 (4.8)	17/332 (5.1)	75.1	4/ 27 (14.8)	3/ 54 (5.6)	24.9	0.88 (0.47, 1.67)	40.9	0.1933
Age									
<65 years	6/121 (5.0)	9/139 (6.5)	94.1	0/ 9 (0.0)	0/ 25 (0.0)	5.9	1.31 (0.46, 3.68)	0.0	0.9047
>=65 years	10/210 (4.8)	8/193 (4.1)	67.5	4/ 18 (22.2)	3/ 29 (10.3)	32.5	0.71 (0.31, 1.62)	0.0	0.4294
Sex									
Male	8/177 (4.5)	11/179 (6.1)	75.2	2/ 11 (18.2)	3/ 26 (11.5)	24.8	1.19 (0.51, 2.75)	0.0	0.4369
Female	8/154 (5.2)	6/153 (3.9)	72.2	2/ 16 (12.5)	0/ 28 (0.0)	27.8	0.58 (0.21, 1.54)	17.5	0.2708
Baseline FVC percent predicted									
<=70%	12/193 (6.2)	11/196 (5.6)	96.4	0/ 10 (0.0)	1/ 17 (5.9)	3.6	0.96 (0.43, 2.17)	0.0	0.5586
>70%	4/138 (2.9)	6/136 (4.4)	42.3	4/ 17 (23.5)	2/ 37 (5.4)	57.7	0.76 (0.28, 2.04)	71.3	0.0618
Baseline HRCT pattern									
UIP-like	9/206 (4.4)	10/206 (4.9)	62.9	4/ 23 (17.4)	2/ 45 (4.4)	37.1	0.78 (0.35, 1.74)	60.1	0.1133
Other fibrotic patterns	7/125 (5.6)	7/126 (5.6)	94.9	0/ 4 (0.0)	1/ 9 (11.1)	5.1	1.08 (0.39, 3.02)	0.0	0.6333
Underlying ILD diagnosis									
iNSIP	2/ 61 (3.3)	2/ 64 (3.1)	55.2	1/ 7 (14.3)	0/ 11 (0.0)	44.8	0.63 (0.12, 3.26)	0.0	0.4726
Unclassifiable IIP	2/ 50 (4.0)	5/ 64 (7.8)	83.4	0/ 3 (0.0)	0/ 2 (0.0)	16.6	1.86 (0.39, 8.80)	0.0	0.7641
HP	5/ 89 (5.6)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	7/ 88 (8.0)	4/ 82 (4.9)	82.2	1/ 12 (8.3)	2/ 34 (5.9)	17.8	0.61 (0.20, 1.88)	0.0	0.9179
Other ILD	0/ 43 (0.0)	1/ 38 (2.6)	20.9	2/ 5 (40.0)	1/ 6 (16.7)	79.1	0.91 (0.14, 5.89)	17.4	0.2712
Region									
Europe									
Asia	2/ 76 (2.6)	6/ 79 (7.6)	27.2	4/ 27 (14.8)	3/ 54 (5.6)	72.8	1.07 (0.38, 3.03)	72.2	0.0578
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Cardiac disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	49/331 (14.8)	47/332 (14.2)	97.4	1/ 27 (3.7)	8/ 54 (14.8)	2.6	1.04 (0.72, 1.49)	0.8447	46.0	0.1734
Age										
<65 years	11/121 (9.1)	15/139 (10.8)	96.8	0/ 9 (0.0)	3/ 25 (12.0)	3.2	1.31 (0.64, 2.70)	0.4618	0.0	0.4698
>=65 years	38/210 (18.1)	32/193 (16.6)	96.7	1/ 18 (5.6)	5/ 29 (17.2)	3.3	0.99 (0.65, 1.50)	0.9547	22.2	0.2568
Sex										
Male	35/177 (19.8)	33/179 (18.4)	96.2	1/ 11 (9.1)	5/ 26 (19.2)	3.8	0.98 (0.64, 1.48)	0.9159	0.0	0.4385
Female	14/154 (9.1)	14/153 (9.2)	96.8	0/ 16 (0.0)	3/ 28 (10.7)	3.2	1.16 (0.59, 2.29)	0.6734	0.0	0.3209
Baseline FVC percent predicted										
<=70%	29/193 (15.0)	28/196 (14.3)	98.4	0/ 10 (0.0)	3/ 17 (17.6)	1.6	1.03 (0.64, 1.64)	0.9137	11.1	0.2889
>70%	20/138 (14.5)	19/136 (14.0)	93.5	1/ 17 (5.9)	5/ 37 (13.5)	6.5	1.05 (0.60, 1.83)	0.8636	0.0	0.4283
Baseline HRCT pattern										
UIP-like	35/206 (17.0)	28/206 (13.6)	96.4	1/ 23 (4.3)	8/ 45 (17.8)	3.6	0.92 (0.59, 1.43)	0.7095	58.1	0.1222
Other fibrotic patterns	14/125 (11.2)	19/126 (15.1)	97.1	0/ 4 (0.0)	0/ 9 (0.0)	2.9	1.34 (0.71, 2.53)	0.3722	0.0	0.8884
Underlying ILD diagnosis										
iNSIP	7/ 61 (11.5)	6/ 64 (9.4)	93.8	0/ 7 (0.0)	1/ 11 (9.1)	6.2	0.93 (0.35, 2.46)	0.8841	0.0	0.5164
Unclassifiable IIP	7/ 50 (14.0)	11/ 64 (17.2)	94.2	0/ 3 (0.0)	0/ 2 (0.0)	5.8	1.21 (0.52, 2.84)	0.6536	0.0	0.9159
HP	17/ 89 (19.1)	12/ 84 (14.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	9/ 88 (10.2)	12/ 82 (14.6)	95.7	0/ 12 (0.0)	7/ 34 (20.6)	4.3	1.82 (0.82, 4.01)	0.1405	0.0	0.3212
Other ILD	9/ 43 (20.9)	6/ 38 (15.8)	84.2	1/ 5 (20.0)	0/ 6 (0.0)	15.8	0.68 (0.28, 1.66)	0.4007	0.0	0.5725
Region										
Europe										
Asia	7/ 76 (9.2)	12/ 79 (15.2)	84.3	1/ 27 (3.7)	8/ 54 (14.8)	15.7	2.02 (0.90, 4.52)	0.0871	0.0	0.4317
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Cardiac disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	49/331 (14.8)	47/332 (14.2)	90.2	1/ 27 (3.7)	8/ 54 (14.8)	9.8	0.50 (-4.47, 5.47)	68.1	0.0765
Age									
<65 years	11/121 (9.1)	15/139 (10.8)	90.2	0/ 9 (0.0)	3/ 25 (12.0)	9.8	2.64 (-4.12, 9.40)	5.3	0.3042
>=65 years	38/210 (18.1)	32/193 (16.6)	90.1	1/ 18 (5.6)	5/ 29 (17.2)	9.9	-0.20 (-7.08, 6.67)	46.9	0.1701
Sex									
Male	35/177 (19.8)	33/179 (18.4)	92.0	1/ 11 (9.1)	5/ 26 (19.2)	8.0	-0.42 (-8.15, 7.31)	0.0	0.3522
Female	14/154 (9.1)	14/153 (9.2)	87.8	0/ 16 (0.0)	3/ 28 (10.7)	12.2	1.30 (-4.60, 7.20)	41.6	0.1909
Baseline FVC percent predicted									
<=70%	29/193 (15.0)	28/196 (14.3)	93.5	0/ 10 (0.0)	3/ 17 (17.6)	6.5	0.38 (-6.34, 7.09)	55.5	0.1337
>70%	20/138 (14.5)	19/136 (14.0)	85.5	1/ 17 (5.9)	5/ 37 (13.5)	14.5	0.66 (-6.77, 8.09)	0.0	0.3678
Baseline HRCT pattern									
UIP-like	35/206 (17.0)	28/206 (13.6)	87.1	1/ 23 (4.3)	8/ 45 (17.8)	12.9	-1.23 (-7.54, 5.08)	77.7	0.0342
Other fibrotic patterns	14/125 (11.2)	19/126 (15.1)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	3.69 (-4.36, 11.74)	0.0	0.7903
Underlying ILD diagnosis									
iNSIP	7/ 61 (11.5)	6/ 64 (9.4)	86.8	0/ 7 (0.0)	1/ 11 (9.1)	13.2	-0.74 (-10.59, 9.11)	0.0	0.4492
Unclassifiable IIP	7/ 50 (14.0)	11/ 64 (17.2)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	3.01 (-9.93, 15.94)	0.0	0.9089
HP	17/ 89 (19.1)	12/ 84 (14.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	9/ 88 (10.2)	12/ 82 (14.6)	82.1	0/ 12 (0.0)	7/ 34 (20.6)	17.9	7.15 (-1.47, 15.77)	61.7	0.1063
Other ILD	9/ 43 (20.9)	6/ 38 (15.8)	86.2	1/ 5 (20.0)	0/ 6 (0.0)	13.8	-6.76 (-22.26, 8.73)	0.0	0.5936
Region									
Europe									
Asia	7/ 76 (9.2)	12/ 79 (15.2)	68.3	1/ 27 (3.7)	8/ 54 (14.8)	31.7	7.61 (-0.33, 15.55)	0.0	0.5209
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Cardiac disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	49/331 (14.8)	47/332 (14.2)	97.4	1/ 27 (3.7)	8/ 54 (14.8)	2.6	1.04 (0.69, 1.58)	49.4	0.1599
Age									
<65 years	11/121 (9.1)	15/139 (10.8)	96.9	0/ 9 (0.0)	3/ 25 (12.0)	3.1	1.35 (0.61, 2.97)	0.0	0.4559
>=65 years	38/210 (18.1)	32/193 (16.6)	96.7	1/ 18 (5.6)	5/ 29 (17.2)	3.3	0.99 (0.60, 1.62)	27.0	0.2417
Sex									
Male	35/177 (19.8)	33/179 (18.4)	96.2	1/ 11 (9.1)	5/ 26 (19.2)	3.8	0.97 (0.58, 1.62)	0.0	0.4234
Female	14/154 (9.1)	14/153 (9.2)	96.9	0/ 16 (0.0)	3/ 28 (10.7)	3.1	1.17 (0.56, 2.45)	3.7	0.3081
Baseline FVC percent predicted									
<=70%	29/193 (15.0)	28/196 (14.3)	98.5	0/ 10 (0.0)	3/ 17 (17.6)	1.5	1.03 (0.60, 1.78)	19.2	0.2658
>70%	20/138 (14.5)	19/136 (14.0)	93.5	1/ 17 (5.9)	5/ 37 (13.5)	6.5	1.06 (0.56, 2.01)	0.0	0.4198
Baseline HRCT pattern									
UIP-like	35/206 (17.0)	28/206 (13.6)	96.5	1/ 23 (4.3)	8/ 45 (17.8)	3.5	0.91 (0.55, 1.51)	61.7	0.1062
Other fibrotic patterns	14/125 (11.2)	19/126 (15.1)	96.8	0/ 4 (0.0)	0/ 9 (0.0)	3.2	1.39 (0.67, 2.89)	0.0	0.8804
Underlying ILD diagnosis									
iNSIP	7/ 61 (11.5)	6/ 64 (9.4)	94.0	0/ 7 (0.0)	1/ 11 (9.1)	6.0	0.92 (0.31, 2.70)	0.0	0.5079
Unclassifiable IIP	7/ 50 (14.0)	11/ 64 (17.2)	94.1	0/ 3 (0.0)	0/ 2 (0.0)	5.9	1.26 (0.46, 3.42)	0.0	0.9147
HP	17/ 89 (19.1)	12/ 84 (14.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	9/ 88 (10.2)	12/ 82 (14.6)	96.1	0/ 12 (0.0)	7/ 34 (20.6)	3.9	1.96 (0.83, 4.64)	8.2	0.2966
Other ILD	9/ 43 (20.9)	6/ 38 (15.8)	82.9	1/ 5 (20.0)	0/ 6 (0.0)	17.1	0.63 (0.22, 1.84)	0.0	0.5704
Region									
Europe									
Asia	7/ 76 (9.2)	12/ 79 (15.2)	84.2	1/ 27 (3.7)	8/ 54 (14.8)	15.8	2.20 (0.91, 5.32)	0.0	0.4333
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Ear and labyrinth disorders

Subgroup / Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo: Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	12/331 (3.6)	9/332 (2.7)	96.4	0/ 27 (0.0)	2/ 54 (3.7)	3.6	0.86 (0.38, 1.94)	0.7233	0.0	0.3707
Age										
<65 years	5/121 (4.1)	4/139 (2.9)	93.2	0/ 9 (0.0)	2/ 25 (8.0)	6.8	0.90 (0.27, 2.96)	0.8644	0.0	0.4263
>=65 years	7/210 (3.3)	5/193 (2.6)	93.4	0/ 18 (0.0)	0/ 29 (0.0)	6.6	0.79 (0.27, 2.35)	0.6741	0.0	0.9052
Sex										
Male	5/177 (2.8)	3/179 (1.7)	92.3	0/ 11 (0.0)	2/ 26 (7.7)	7.7	0.84 (0.24, 2.96)	0.7896	0.0	0.3579
Female	7/154 (4.5)	6/153 (3.9)	93.8	0/ 16 (0.0)	0/ 28 (0.0)	6.2	0.87 (0.31, 2.44)	0.7935	0.0	0.9447
Baseline FVC percent predicted										
<=70%	7/193 (3.6)	7/196 (3.6)	93.8	0/ 10 (0.0)	0/ 17 (0.0)	6.2	0.99 (0.36, 2.67)	0.9773	0.0	0.9941
>70%	5/138 (3.6)	2/136 (1.5)	92.0	0/ 17 (0.0)	2/ 37 (5.4)	8.0	0.69 (0.18, 2.63)	0.5834	19.3	0.2658
Baseline HRCT pattern										
UIP-like	9/206 (4.4)	6/206 (2.9)	95.3	0/ 23 (0.0)	2/ 45 (4.4)	4.7	0.83 (0.32, 2.12)	0.6909	0.0	0.3392
Other fibrotic patterns	3/125 (2.4)	3/126 (2.4)	87.6	0/ 4 (0.0)	0/ 9 (0.0)	12.4	0.99 (0.23, 4.34)	0.9926	0.0	0.9972
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Ear and labyrinth disorders

Subgroup / Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo: Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	12/331 (3.6)	9/332 (2.7)	90.0	0/ 27 (0.0)	2/ 54 (3.7)	10.0	-0.46 (-2.96, 2.04)	29.6	0.2334
Age									
<65 years	5/121 (4.1)	4/139 (2.9)	90.2	0/ 9 (0.0)	2/ 25 (8.0)	9.8	-0.39 (-4.74, 3.95)	11.6	0.2876
>=65 years	7/210 (3.3)	5/193 (2.6)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	-0.67 (-3.75, 2.41)	0.0	0.8685
Sex									
Male	5/177 (2.8)	3/179 (1.7)	91.6	0/ 11 (0.0)	2/ 26 (7.7)	8.4	-0.44 (-3.51, 2.63)	20.9	0.2609
Female	7/154 (4.5)	6/153 (3.9)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	-0.55 (-4.64, 3.55)	0.0	0.9012
Baseline FVC percent predicted									
<=70%	7/193 (3.6)	7/196 (3.6)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-0.05 (-3.63, 3.52)	0.0	0.9939
>70%	5/138 (3.6)	2/136 (1.5)	85.0	0/ 17 (0.0)	2/ 37 (5.4)	15.0	-1.05 (-4.56, 2.46)	43.8	0.1824
Baseline HRCT pattern									
UIP-like	9/206 (4.4)	6/206 (2.9)	86.8	0/ 23 (0.0)	2/ 45 (4.4)	13.2	-0.69 (-4.01, 2.63)	36.9	0.2081
Other fibrotic patterns	3/125 (2.4)	3/126 (2.4)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-0.02 (-3.85, 3.81)	0.0	0.9989
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Ear and labyrinth disorders

Subgroup / Category	Trial 1199_0247: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247: Wt	Trial 1199_0434: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434: Wt	Fixed effects: Nin 150bid vs Placebo: Odds ratio (95% CI)	Heterogeneity: I^2	Heterogeneity: p-value
Overall	12/331 (3.6)	9/332 (2.7)	96.5	0/ 27 (0.0)	2/ 54 (3.7)	3.5	0.86 (0.38, 1.97)	0.0	0.3657
Age									
<65 years	5/121 (4.1)	4/139 (2.9)	93.7	0/ 9 (0.0)	2/ 25 (8.0)	6.3	0.90 (0.27, 3.00)	0.0	0.4173
>=65 years	7/210 (3.3)	5/193 (2.6)	93.4	0/ 18 (0.0)	0/ 29 (0.0)	6.6	0.79 (0.26, 2.41)	0.0	0.9044
Sex									
Male	5/177 (2.8)	3/179 (1.7)	92.9	0/ 11 (0.0)	2/ 26 (7.7)	7.1	0.84 (0.24, 2.94)	0.0	0.3508
Female	7/154 (4.5)	6/153 (3.9)	93.7	0/ 16 (0.0)	0/ 28 (0.0)	6.3	0.87 (0.30, 2.54)	0.0	0.9436
Baseline FVC percent predicted									
<=70%	7/193 (3.6)	7/196 (3.6)	93.8	0/ 10 (0.0)	0/ 17 (0.0)	6.2	0.99 (0.35, 2.77)	0.0	0.9941
>70%	5/138 (3.6)	2/136 (1.5)	92.4	0/ 17 (0.0)	2/ 37 (5.4)	7.6	0.68 (0.18, 2.57)	20.8	0.2610
Baseline HRCT pattern									
UIP-like	9/206 (4.4)	6/206 (2.9)	95.4	0/ 23 (0.0)	2/ 45 (4.4)	4.6	0.82 (0.31, 2.15)	0.0	0.3334
Other fibrotic patterns	3/125 (2.4)	3/126 (2.4)	88.1	0/ 4 (0.0)	0/ 9 (0.0)	11.9	0.99 (0.22, 4.54)	0.0	0.9973
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Eye disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	28/331 (8.5)	23/332 (6.9)	98.4	0/ 27 (0.0)	0/ 54 (0.0)	1.6	0.82 (0.49, 1.39)	0.4644	0.0	0.9251
Age										
<65 years	3/121 (2.5)	6/139 (4.3)	89.2	0/ 9 (0.0)	0/ 25 (0.0)	10.8	1.66 (0.45, 6.09)	0.4440	0.0	0.8128
>=65 years	25/210 (11.9)	17/193 (8.8)	98.1	0/ 18 (0.0)	0/ 29 (0.0)	1.9	0.74 (0.42, 1.33)	0.3181	0.0	0.8836
Sex										
Male	20/177 (11.3)	13/179 (7.3)	98.0	0/ 11 (0.0)	0/ 26 (0.0)	2.0	0.65 (0.34, 1.26)	0.1995	0.0	0.8398
Female	8/154 (5.2)	10/153 (6.5)	94.5	0/ 16 (0.0)	0/ 28 (0.0)	5.5	1.24 (0.52, 3.00)	0.6269	0.0	0.9132
Baseline FVC percent predicted										
<=70%	12/193 (6.2)	13/196 (6.6)	96.3	0/ 10 (0.0)	0/ 17 (0.0)	3.7	1.06 (0.50, 2.24)	0.8699	0.0	0.9751
>70%	16/138 (11.6)	10/136 (7.4)	97.4	0/ 17 (0.0)	0/ 37 (0.0)	2.6	0.64 (0.31, 1.35)	0.2444	0.0	0.8336
Baseline HRCT pattern										
UIP-like	20/206 (9.7)	18/206 (8.7)	97.8	0/ 23 (0.0)	0/ 45 (0.0)	2.2	0.90 (0.49, 1.64)	0.7368	0.0	0.9604
Other fibrotic patterns	8/125 (6.4)	5/126 (4.0)	95.0	0/ 4 (0.0)	0/ 9 (0.0)	5.0	0.64 (0.22, 1.83)	0.4041	0.0	0.8253
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	2/ 64 (3.1)	68.3	0/ 7 (0.0)	0/ 11 (0.0)	31.7	1.62 (0.22,12.11)	0.6389	0.0	0.7826
Unclassifiable IIP	7/ 50 (14.0)	7/ 64 (10.9)	94.2	0/ 3 (0.0)	0/ 2 (0.0)	5.8	0.79 (0.31, 2.05)	0.6328	0.0	0.8995
HP	11/ 89 (12.4)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	6/ 88 (6.8)	4/ 82 (4.9)	93.8	0/ 12 (0.0)	0/ 34 (0.0)	6.2	0.73 (0.22, 2.39)	0.6071	0.0	0.8862
Other ILD	3/ 43 (7.0)	3/ 38 (7.9)	85.0	0/ 5 (0.0)	0/ 6 (0.0)	15.0	1.11 (0.27, 4.63)	0.8841	0.0	0.9527
Region										
Europe										
Asia	11/ 76 (14.5)	7/ 79 (8.9)	96.2	0/ 27 (0.0)	0/ 54 (0.0)	3.8	0.63 (0.26, 1.50)	0.2943	0.0	0.8201
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Eye disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	28/331 (8.5)	23/332 (6.9)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	-1.38 (-5.06, 2.31)	0.0	0.6402
Age									
<65 years	3/121 (2.5)	6/139 (4.3)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	1.66 (-2.46, 5.78)	0.0	0.7806
>=65 years	25/210 (11.9)	17/193 (8.8)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	-2.78 (-8.16, 2.61)	0.0	0.5469
Sex									
Male	20/177 (11.3)	13/179 (7.3)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-3.70 (-9.29, 1.89)	0.0	0.5238
Female	8/154 (5.2)	10/153 (6.5)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	1.18 (-3.56, 5.92)	0.0	0.7969
Baseline FVC percent predicted									
<=70%	12/193 (6.2)	13/196 (6.6)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	0.39 (-4.25, 5.03)	0.0	0.9555
>70%	16/138 (11.6)	10/136 (7.4)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	-3.61 (-9.59, 2.38)	0.0	0.4140
Baseline HRCT pattern									
UIP-like	20/206 (9.7)	18/206 (8.7)	86.8	0/ 23 (0.0)	0/ 45 (0.0)	13.2	-0.84 (-5.75, 4.07)	0.0	0.8145
Other fibrotic patterns	8/125 (6.4)	5/126 (4.0)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-2.31 (-7.69, 3.07)	0.0	0.8643
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	2/ 64 (3.1)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	1.29 (-4.01, 6.58)	0.0	0.8860
Unclassifiable IIP	7/ 50 (14.0)	7/ 64 (10.9)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	-2.89 (-14.86, 9.08)	0.0	0.9120
HP	11/ 89 (12.4)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	6/ 88 (6.8)	4/ 82 (4.9)	82.1	0/ 12 (0.0)	0/ 34 (0.0)	17.9	-1.59 (-7.60, 4.41)	0.0	0.7427
Other ILD	3/ 43 (7.0)	3/ 38 (7.9)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	0.79 (-9.88, 11.46)	0.0	0.9541
Region									
Europe									
Asia	11/ 76 (14.5)	7/ 79 (8.9)	67.7	0/ 27 (0.0)	0/ 54 (0.0)	32.3	-3.80 (-10.82, 3.22)	0.0	0.3283
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Eye disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	28/331 (8.5)	23/332 (6.9)	98.3	0/ 27 (0.0)	0/ 54 (0.0)	1.7	0.81 (0.46, 1.43)	0.0	0.9200
Age									
<65 years	3/121 (2.5)	6/139 (4.3)	89.0	0/ 9 (0.0)	0/ 25 (0.0)	11.0	1.69 (0.44, 6.49)	0.0	0.8118
>=65 years	25/210 (11.9)	17/193 (8.8)	97.9	0/ 18 (0.0)	0/ 29 (0.0)	2.1	0.72 (0.38, 1.37)	0.0	0.8732
Sex									
Male	20/177 (11.3)	13/179 (7.3)	97.9	0/ 11 (0.0)	0/ 26 (0.0)	2.1	0.62 (0.30, 1.28)	0.0	0.8286
Female	8/154 (5.2)	10/153 (6.5)	94.3	0/ 16 (0.0)	0/ 28 (0.0)	5.7	1.26 (0.50, 3.21)	0.0	0.9100
Baseline FVC percent predicted									
<=70%	12/193 (6.2)	13/196 (6.6)	96.2	0/ 10 (0.0)	0/ 17 (0.0)	3.8	1.07 (0.48, 2.37)	0.0	0.9744
>70%	16/138 (11.6)	10/136 (7.4)	97.2	0/ 17 (0.0)	0/ 37 (0.0)	2.8	0.62 (0.27, 1.39)	0.0	0.8205
Baseline HRCT pattern									
UIP-like	20/206 (9.7)	18/206 (8.7)	97.6	0/ 23 (0.0)	0/ 45 (0.0)	2.4	0.89 (0.46, 1.73)	0.0	0.9571
Other fibrotic patterns	8/125 (6.4)	5/126 (4.0)	95.1	0/ 4 (0.0)	0/ 9 (0.0)	4.9	0.62 (0.21, 1.88)	0.0	0.8280
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	2/ 64 (3.1)	68.7	0/ 7 (0.0)	0/ 11 (0.0)	31.3	1.64 (0.20,13.19)	0.0	0.7868
Unclassifiable IIP	7/ 50 (14.0)	7/ 64 (10.9)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	0.77 (0.26, 2.27)	0.0	0.9015
HP	11/ 89 (12.4)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	6/ 88 (6.8)	4/ 82 (4.9)	93.6	0/ 12 (0.0)	0/ 34 (0.0)	6.4	0.72 (0.21, 2.50)	0.0	0.8820
Other ILD	3/ 43 (7.0)	3/ 38 (7.9)	85.0	0/ 5 (0.0)	0/ 6 (0.0)	15.0	1.12 (0.24, 5.24)	0.0	0.9528
Region									
Europe									
Asia	11/ 76 (14.5)	7/ 79 (8.9)	95.9	0/ 27 (0.0)	0/ 54 (0.0)	4.1	0.59 (0.22, 1.57)	0.0	0.8006
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	164/331 (49.5)	279/332 (84.0)	93.9	8/ 27 (29.6)	35/ 54 (64.8)	6.1	1.73 (1.53, 1.94)	<.0001	0.0	0.4249
Age										
<65 years	52/121 (43.0)	114/139 (82.0)	92.6	3/ 9 (33.3)	14/ 25 (56.0)	7.4	1.89 (1.53, 2.35)	<.0001	0.0	0.8048
>=65 years	112/210 (53.3)	165/193 (85.5)	94.6	5/ 18 (27.8)	21/ 29 (72.4)	5.4	1.66 (1.44, 1.91)	<.0001	31.2	0.2279
Sex										
Male	89/177 (50.3)	151/179 (84.4)	95.5	3/ 11 (27.3)	13/ 26 (50.0)	4.5	1.68 (1.44, 1.98)	<.0001	0.0	0.8686
Female	75/154 (48.7)	128/153 (83.7)	92.2	5/ 16 (31.3)	22/ 28 (78.6)	7.8	1.78 (1.50, 2.12)	<.0001	0.0	0.3338
Baseline FVC percent predicted										
<=70%	103/193 (53.4)	165/196 (84.2)	95.4	4/ 10 (40.0)	8/ 17 (47.1)	4.6	1.56 (1.35, 1.80)	<.0001	0.0	0.5333
>70%	61/138 (44.2)	114/136 (83.8)	91.7	4/ 17 (23.5)	27/ 37 (73.0)	8.3	2.00 (1.63, 2.44)	<.0001	12.5	0.2851
Baseline HRCT pattern										
UIP-like	107/206 (51.9)	175/206 (85.0)	93.1	6/ 23 (26.1)	29/ 45 (64.4)	6.9	1.69 (1.47, 1.96)	<.0001	17.2	0.2717
Other fibrotic patterns	57/125 (45.6)	104/126 (82.5)	95.4	2/ 4 (50.0)	6/ 9 (66.7)	4.6	1.79 (1.46, 2.19)	<.0001	0.0	0.5870
Underlying ILD diagnosis										
iNSIP	18/ 61 (29.5)	48/ 64 (75.0)	88.3	2/ 7 (28.6)	8/ 11 (72.7)	11.7	2.54 (1.72, 3.76)	<.0001	0.0	0.9982
Unclassifiable IIP	21/ 50 (42.0)	59/ 64 (92.2)	98.0	0/ 3 (0.0)	2/ 2 (100.0)	2.0	2.27 (1.63, 3.16)	<.0001	0.0	0.4142
HP	54/ 89 (60.7)	71/ 84 (84.5)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	48/ 88 (54.5)	69/ 82 (84.1)	94.0	2/ 12 (16.7)	20/ 34 (58.8)	6.0	1.66 (1.33, 2.08)	<.0001	34.4	0.2168
Other ILD	23/ 43 (53.5)	32/ 38 (84.2)	83.2	4/ 5 (80.0)	4/ 6 (66.7)	16.8	1.45 (1.09, 1.93)	0.0105	60.8	0.1100
Region										
Europe										
Asia	44/ 76 (57.9)	75/ 79 (94.9)	80.8	8/ 27 (29.6)	35/ 54 (64.8)	19.2	1.75 (1.42, 2.14)	<.0001	0.0	0.3811
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	164/331 (49.5)	279/332 (84.0)	90.2	8/ 27 (29.6)	35/ 54 (64.8)	9.8	34.56 (28.18, 40.93)	0.0	0.9515
Age									
<65 years	52/121 (43.0)	114/139 (82.0)	90.7	3/ 9 (33.3)	14/ 25 (56.0)	9.3	37.52 (27.08, 47.96)	0.0	0.3987
>=65 years	112/210 (53.3)	165/193 (85.5)	90.1	5/ 18 (27.8)	21/ 29 (72.4)	9.9	33.40 (25.41, 41.39)	0.0	0.3760
Sex									
Male	89/177 (50.3)	151/179 (84.4)	92.0	3/ 11 (27.3)	13/ 26 (50.0)	8.0	33.17 (24.41, 41.93)	0.0	0.5109
Female	75/154 (48.7)	128/153 (83.7)	88.3	5/ 16 (31.3)	22/ 28 (78.6)	11.7	36.41 (27.16, 45.66)	0.0	0.4041
Baseline FVC percent predicted									
<=70%	103/193 (53.4)	165/196 (84.2)	93.9	4/ 10 (40.0)	8/ 17 (47.1)	6.1	29.37 (20.87, 37.87)	28.0	0.2385
>70%	61/138 (44.2)	114/136 (83.8)	85.5	4/ 17 (23.5)	27/ 37 (73.0)	14.5	41.05 (31.51, 50.59)	0.0	0.4725
Baseline HRCT pattern									
UIP-like	107/206 (51.9)	175/206 (85.0)	87.1	6/ 23 (26.1)	29/ 45 (64.4)	12.9	33.70 (25.82, 41.57)	0.0	0.6656
Other fibrotic patterns	57/125 (45.6)	104/126 (82.5)	95.8	2/ 4 (50.0)	6/ 9 (66.7)	4.2	36.08 (25.30, 46.86)	0.0	0.4999
Underlying ILD diagnosis									
iNSIP	18/ 61 (29.5)	48/ 64 (75.0)	88.0	2/ 7 (28.6)	8/ 11 (72.7)	12.0	45.33 (30.68, 59.98)	0.0	0.9540
Unclassifiable IIP	21/ 50 (42.0)	59/ 64 (92.2)	94.4	0/ 3 (0.0)	2/ 2 (100.0)	5.6	51.39 (36.76, 66.02)	0.0	0.4495
HP	54/ 89 (60.7)	71/ 84 (84.5)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	48/ 88 (54.5)	69/ 82 (84.1)	82.7	2/ 12 (16.7)	20/ 34 (58.8)	17.3	31.77 (20.01, 43.53)	0.0	0.4092
Other ILD	23/ 43 (53.5)	32/ 38 (84.2)	88.1	4/ 5 (80.0)	4/ 6 (66.7)	11.9	25.48 (7.74, 43.21)	59.6	0.1154
Region									
Europe									
Asia	44/ 76 (57.9)	75/ 79 (94.9)	68.3	8/ 27 (29.6)	35/ 54 (64.8)	31.7	36.45 (25.75, 47.15)	0.0	0.8824
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	164/331 (49.5)	279/332 (84.0)	87.5	8/ 27 (29.6)	35/ 54 (64.8)	12.5	5.24 (3.72, 7.37)	0.0	0.7076
Age									
<65 years	52/121 (43.0)	114/139 (82.0)	83.7	3/ 9 (33.3)	14/ 25 (56.0)	16.3	5.48 (3.23, 9.31)	0.7	0.3157
>=65 years	112/210 (53.3)	165/193 (85.5)	90.1	5/ 18 (27.8)	21/ 29 (72.4)	9.9	5.32 (3.38, 8.38)	0.0	0.6947
Sex									
Male	89/177 (50.3)	151/179 (84.4)	86.9	3/ 11 (27.3)	13/ 26 (50.0)	13.1	4.98 (3.10, 8.01)	0.0	0.3997
Female	75/154 (48.7)	128/153 (83.7)	90.0	5/ 16 (31.3)	22/ 28 (78.6)	10.0	5.66 (3.44, 9.31)	0.0	0.5960
Baseline FVC percent predicted									
<=70%	103/193 (53.4)	165/196 (84.2)	86.0	4/ 10 (40.0)	8/ 17 (47.1)	14.0	4.19 (2.66, 6.59)	54.4	0.1387
>70%	61/138 (44.2)	114/136 (83.8)	86.9	4/ 17 (23.5)	27/ 37 (73.0)	13.1	6.83 (4.06,11.51)	0.0	0.6913
Baseline HRCT pattern									
UIP-like	107/206 (51.9)	175/206 (85.0)	85.1	6/ 23 (26.1)	29/ 45 (64.4)	14.9	5.21 (3.38, 8.03)	0.0	0.9781
Other fibrotic patterns	57/125 (45.6)	104/126 (82.5)	91.5	2/ 4 (50.0)	6/ 9 (66.7)	8.5	5.33 (3.04, 9.34)	0.0	0.4106
Underlying ILD diagnosis									
iNSIP	18/ 61 (29.5)	48/ 64 (75.0)	87.4	2/ 7 (28.6)	8/ 11 (72.7)	12.6	7.10 (3.39,14.88)	0.0	0.9498
Unclassifiable IIP	21/ 50 (42.0)	59/ 64 (92.2)	96.4	0/ 3 (0.0)	2/ 2 (100.0)	3.6	17.00 (6.01,48.10)	0.0	0.7271
HP	54/ 89 (60.7)	71/ 84 (84.5)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	48/ 88 (54.5)	69/ 82 (84.1)	85.8	2/ 12 (16.7)	20/ 34 (58.8)	14.2	4.81 (2.48, 9.34)	0.0	0.6050
Other ILD	23/ 43 (53.5)	32/ 38 (84.2)	70.1	4/ 5 (80.0)	4/ 6 (66.7)	29.9	3.40 (1.32, 8.78)	53.8	0.1412
Region									
Europe									
Asia	44/ 76 (57.9)	75/ 79 (94.9)	37.7	8/ 27 (29.6)	35/ 54 (64.8)	62.3	7.87 (3.83,16.17)	55.4	0.1342
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: General disorders and administration site conditions

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	112/331 (33.8)	96/332 (28.9)	94.4	5/ 27 (18.5)	12/ 54 (22.2)	5.6	0.87 (0.70, 1.09)	0.2296	0.0	0.4893
Age										
<65 years	34/121 (28.1)	40/139 (28.8)	96.1	1/ 9 (11.1)	6/ 25 (24.0)	3.9	1.07 (0.73, 1.56)	0.7334	0.0	0.4674
>=65 years	78/210 (37.1)	56/193 (29.0)	93.8	4/ 18 (22.2)	6/ 29 (20.7)	6.2	0.79 (0.60, 1.04)	0.0923	0.0	0.7659
Sex										
Male	65/177 (36.7)	54/179 (30.2)	95.9	2/ 11 (18.2)	8/ 26 (30.8)	4.1	0.86 (0.64, 1.14)	0.2954	0.8	0.3154
Female	47/154 (30.5)	42/153 (27.5)	92.5	3/ 16 (18.8)	4/ 28 (14.3)	7.5	0.89 (0.63, 1.25)	0.4980	0.0	0.8175
Baseline FVC percent predicted										
<=70%	76/193 (39.4)	59/196 (30.1)	98.4	1/ 10 (10.0)	5/ 17 (29.4)	1.6	0.80 (0.61, 1.05)	0.1079	41.6	0.1908
>70%	36/138 (26.1)	37/136 (27.2)	86.7	4/ 17 (23.5)	7/ 37 (18.9)	13.3	1.01 (0.70, 1.46)	0.9531	0.0	0.6589
Baseline HRCT pattern										
UIP-like	69/206 (33.5)	65/206 (31.6)	91.2	5/ 23 (21.7)	7/ 45 (15.6)	8.8	0.92 (0.70, 1.21)	0.5548	0.0	0.6141
Other fibrotic patterns	43/125 (34.4)	31/126 (24.6)	99.0	0/ 4 (0.0)	5/ 9 (55.6)	1.0	0.79 (0.54, 1.16)	0.2248	47.1	0.1690
Underlying ILD diagnosis										
iNSIP	14/ 61 (23.0)	13/ 64 (20.3)	96.8	0/ 7 (0.0)	4/ 11 (36.4)	3.2	1.10 (0.58, 2.08)	0.7723	41.3	0.1917
Unclassifiable IIP	20/ 50 (40.0)	29/ 64 (45.3)	97.9	0/ 3 (0.0)	0/ 2 (0.0)	2.1	1.13 (0.73, 1.74)	0.5782	0.0	0.9477
HP	35/ 89 (39.3)	27/ 84 (32.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	24/ 88 (27.3)	13/ 82 (15.9)	79.7	4/ 12 (33.3)	6/ 34 (17.6)	20.3	0.57 (0.34, 0.97)	0.0380	0.0	0.8823
Other ILD	19/ 43 (44.2)	14/ 38 (36.8)	94.2	1/ 5 (20.0)	2/ 6 (33.3)	5.8	0.88 (0.53, 1.48)	0.6337	0.0	0.5286
Region										
Europe										
Asia	18/ 76 (23.7)	19/ 79 (24.1)	73.3	5/ 27 (18.5)	12/ 54 (22.2)	26.7	1.06 (0.66, 1.72)	0.7990	0.0	0.7643
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: General disorders and administration site conditions

Subgroup / Category	Trial 1199_0247: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247: Wt	Trial 1199_0434: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434: Wt	Fixed effects: Nin 150bid vs Placebo: Risk difference (95% CI)	Heterogeneity: I^2	Heterogeneity: p-value
Overall	112/331 (33.8)	96/332 (28.9)	90.2	5/ 27 (18.5)	12/ 54 (22.2)	9.8	-4.08 (-10.69, 2.54)	0.0	0.3904
Age									
<65 years	34/121 (28.1)	40/139 (28.8)	90.7	1/ 9 (11.1)	6/ 25 (24.0)	9.3	1.81 (-8.46, 12.08)	0.0	0.4040
>=65 years	78/210 (37.1)	56/193 (29.0)	90.1	4/ 18 (22.2)	6/ 29 (20.7)	9.9	-7.47 (-16.06, 1.11)	0.0	0.6175
Sex									
Male	65/177 (36.7)	54/179 (30.2)	92.0	2/ 11 (18.2)	8/ 26 (30.8)	8.0	-5.03 (-14.32, 4.26)	33.9	0.2185
Female	47/154 (30.5)	42/153 (27.5)	88.3	3/ 16 (18.8)	4/ 28 (14.3)	11.7	-3.23 (-12.59, 6.12)	0.0	0.9137
Baseline FVC percent predicted									
<=70%	76/193 (39.4)	59/196 (30.1)	93.9	1/ 10 (10.0)	5/ 17 (29.4)	6.1	-7.53 (-16.55, 1.48)	71.4	0.0614
>70%	36/138 (26.1)	37/136 (27.2)	85.5	4/ 17 (23.5)	7/ 37 (18.9)	14.5	0.29 (-9.31, 9.88)	0.0	0.6657
Baseline HRCT pattern									
UIP-like	69/206 (33.5)	65/206 (31.6)	87.1	5/ 23 (21.7)	7/ 45 (15.6)	12.9	-2.49 (-10.77, 5.80)	0.0	0.7038
Other fibrotic patterns	43/125 (34.4)	31/126 (24.6)	95.2	0/ 4 (0.0)	5/ 9 (55.6)	4.8	-6.99 (-17.82, 3.84)	87.9	0.0040
Underlying ILD diagnosis									
iNSIP	14/ 61 (23.0)	13/ 64 (20.3)	86.8	0/ 7 (0.0)	4/ 11 (36.4)	13.2	2.03 (-11.16, 15.23)	75.4	0.0437
Unclassifiable IIP	20/ 50 (40.0)	29/ 64 (45.3)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	5.01 (-12.47, 22.49)	0.0	0.8524
HP	35/ 89 (39.3)	27/ 84 (32.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	24/ 88 (27.3)	13/ 82 (15.9)	82.7	4/ 12 (33.3)	6/ 34 (17.6)	17.3	-12.16 (-23.48, -0.84)	0.0	0.7939
Other ILD	19/ 43 (44.2)	14/ 38 (36.8)	88.1	1/ 5 (20.0)	2/ 6 (33.3)	11.9	-4.88 (-24.66, 14.90)	0.0	0.4672
Region									
Europe									
Asia	18/ 76 (23.7)	19/ 79 (24.1)	68.3	5/ 27 (18.5)	12/ 54 (22.2)	31.7	1.43 (-9.44, 12.29)	0.0	0.7738
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: General disorders and administration site conditions

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	112/331 (33.8)	96/332 (28.9)	93.9	5/ 27 (18.5)	12/ 54 (22.2)	6.1	0.82 (0.60, 1.13)	0.0	0.4582
Age									
<65 years	34/121 (28.1)	40/139 (28.8)	95.9	1/ 9 (11.1)	6/ 25 (24.0)	4.1	1.10 (0.65, 1.85)	0.0	0.4534
>=65 years	78/210 (37.1)	56/193 (29.0)	93.1	4/ 18 (22.2)	6/ 29 (20.7)	6.9	0.71 (0.47, 1.06)	0.0	0.7148
Sex									
Male	65/177 (36.7)	54/179 (30.2)	95.9	2/ 11 (18.2)	8/ 26 (30.8)	4.1	0.80 (0.52, 1.22)	13.8	0.2816
Female	47/154 (30.5)	42/153 (27.5)	91.2	3/ 16 (18.8)	4/ 28 (14.3)	8.8	0.85 (0.53, 1.36)	0.0	0.8403
Baseline FVC percent predicted									
<=70%	76/193 (39.4)	59/196 (30.1)	98.4	1/ 10 (10.0)	5/ 17 (29.4)	1.6	0.71 (0.47, 1.07)	52.0	0.1488
>70%	36/138 (26.1)	37/136 (27.2)	85.4	4/ 17 (23.5)	7/ 37 (18.9)	14.6	1.02 (0.62, 1.67)	0.0	0.6605
Baseline HRCT pattern									
UIP-like	69/206 (33.5)	65/206 (31.6)	89.4	5/ 23 (21.7)	7/ 45 (15.6)	10.6	0.89 (0.60, 1.32)	0.0	0.6380
Other fibrotic patterns	43/125 (34.4)	31/126 (24.6)	99.4	0/ 4 (0.0)	5/ 9 (55.6)	0.6	0.72 (0.42, 1.22)	63.9	0.0961
Underlying ILD diagnosis									
iNSIP	14/ 61 (23.0)	13/ 64 (20.3)	97.5	0/ 7 (0.0)	4/ 11 (36.4)	2.5	1.12 (0.51, 2.47)	52.0	0.1490
Unclassifiable IIP	20/ 50 (40.0)	29/ 64 (45.3)	96.8	0/ 3 (0.0)	0/ 2 (0.0)	3.2	1.23 (0.59, 2.58)	0.0	0.9226
HP	35/ 89 (39.3)	27/ 84 (32.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	24/ 88 (27.3)	13/ 82 (15.9)	80.0	4/ 12 (33.3)	6/ 34 (17.6)	20.0	0.49 (0.25, 0.96)	0.0	0.8520
Other ILD	19/ 43 (44.2)	14/ 38 (36.8)	93.9	1/ 5 (20.0)	2/ 6 (33.3)	6.1	0.81 (0.35, 1.89)	0.0	0.5015
Region									
Europe									
Asia	18/ 76 (23.7)	19/ 79 (24.1)	72.9	5/ 27 (18.5)	12/ 54 (22.2)	27.1	1.08 (0.58, 2.02)	0.0	0.7667
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Hepatobiliary disorders

Subgroup / Category	Trial 1199_0247: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247: Wt	Trial 1199_0434: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434: Wt	Fixed effects: Nin 150bid vs Placebo: Risk ratio (95% CI)	p-value	Heterogeneity: I^2	Heterogeneity p-value
Overall	11/331 (3.3)	41/332 (12.3)	80.5	2/ 27 (7.4)	18/ 54 (33.3)	19.5	3.87 (2.15, 6.97)	<.0001	0.0	0.8063
Age										
<65 years	2/121 (1.7)	17/139 (12.2)	84.6	0/ 9 (0.0)	9/ 25 (36.0)	15.4	8.30 (2.11,32.64)	0.0025	0.0	0.7785
>=65 years	9/210 (4.3)	24/193 (12.4)	77.7	2/ 18 (11.1)	9/ 29 (31.0)	22.3	2.88 (1.49, 5.55)	0.0016	0.0	0.9627
Sex										
Male	6/177 (3.4)	25/179 (14.0)	68.2	2/ 11 (18.2)	7/ 26 (26.9)	31.8	3.28 (1.59, 6.79)	0.0014	32.3	0.2242
Female	5/154 (3.2)	16/153 (10.5)	91.5	0/ 16 (0.0)	11/ 28 (39.3)	8.5	4.50 (1.76,11.52)	0.0017	0.8	0.3154
Baseline FVC percent predicted										
<=70%	8/193 (4.1)	27/196 (13.8)	94.5	0/ 10 (0.0)	7/ 17 (41.2)	5.5	3.80 (1.81, 8.00)	0.0004	0.0	0.4423
>70%	3/138 (2.2)	14/136 (10.3)	52.1	2/ 17 (11.8)	11/ 37 (29.7)	47.9	3.68 (1.48, 9.14)	0.0051	0.0	0.5069
Baseline HRCT pattern										
UIP-like	8/206 (3.9)	24/206 (11.7)	75.1	2/ 23 (8.7)	15/ 45 (33.3)	24.9	3.21 (1.63, 6.32)	0.0008	0.0	0.7625
Other fibrotic patterns	3/125 (2.4)	17/126 (13.5)	87.6	0/ 4 (0.0)	3/ 9 (33.3)	12.4	5.59 (1.79,17.45)	0.0031	0.0	0.9778
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	9/ 64 (14.1)	45.6	1/ 7 (14.3)	4/ 11 (36.4)	54.4	5.30 (1.31,21.41)	0.0193	0.0	0.4013
Unclassifiable IIP	1/ 50 (2.0)	16/ 64 (25.0)	70.1	0/ 3 (0.0)	0/ 2 (0.0)	29.9	9.06 (1.70,48.38)	0.0100	27.9	0.2389
HP	5/ 89 (5.6)	6/ 84 (7.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	3/ 88 (3.4)	7/ 82 (8.5)	88.2	0/ 12 (0.0)	14/ 34 (41.2)	11.8	4.55 (1.27,16.30)	0.0198	1.4	0.3140
Other ILD	1/ 43 (2.3)	3/ 38 (7.9)	37.2	1/ 5 (20.0)	0/ 6 (0.0)	62.8	1.46 (0.32, 6.65)	0.6265	38.6	0.2019
Region										
Europe										
Asia	3/ 76 (3.9)	27/ 79 (34.2)	53.4	2/ 27 (7.4)	18/ 54 (33.3)	46.6	6.72 (2.80,16.12)	<.0001	0.0	0.4764
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	11/331 (3.3)	41/332 (12.3)	90.2	2/ 27 (7.4)	18/ 54 (33.3)	9.8	10.68 (6.72, 14.64)	75.2	0.0446
Age									
<65 years	2/121 (1.7)	17/139 (12.2)	90.2	0/ 9 (0.0)	9/ 25 (36.0)	9.8	12.87 (7.16, 18.58)	77.2	0.0364
>=65 years	9/210 (4.3)	24/193 (12.4)	90.1	2/ 18 (11.1)	9/ 29 (31.0)	9.9	9.32 (3.98, 14.66)	1.7	0.3132
Sex									
Male	6/177 (3.4)	25/179 (14.0)	92.0	2/ 11 (18.2)	7/ 26 (26.9)	8.0	10.43 (4.68, 16.18)	0.0	0.9014
Female	5/154 (3.2)	16/153 (10.5)	87.8	0/ 16 (0.0)	11/ 28 (39.3)	12.2	10.91 (5.47, 16.35)	88.9	0.0027
Baseline FVC percent predicted									
<=70%	8/193 (4.1)	27/196 (13.8)	93.5	0/ 10 (0.0)	7/ 17 (41.2)	6.5	11.50 (6.03, 16.97)	79.1	0.0288
>70%	3/138 (2.2)	14/136 (10.3)	85.5	2/ 17 (11.8)	11/ 37 (29.7)	14.5	9.55 (3.81, 15.29)	0.0	0.3802
Baseline HRCT pattern									
UIP-like	8/206 (3.9)	24/206 (11.7)	87.1	2/ 23 (8.7)	15/ 45 (33.3)	12.9	9.94 (4.92, 14.96)	68.1	0.0765
Other fibrotic patterns	3/125 (2.4)	17/126 (13.5)	95.2	0/ 4 (0.0)	3/ 9 (33.3)	4.8	11.95 (5.48, 18.43)	0.0	0.3526
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	9/ 64 (14.1)	88.0	1/ 7 (14.3)	4/ 11 (36.4)	12.0	13.59 (4.34, 22.83)	0.0	0.6322
Unclassifiable IIP	1/ 50 (2.0)	16/ 64 (25.0)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	21.70 (10.63, 32.77)	0.0	0.4048
HP	5/ 89 (5.6)	6/ 84 (7.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	3/ 88 (3.4)	7/ 82 (8.5)	82.1	0/ 12 (0.0)	14/ 34 (41.2)	17.9	11.27 (4.58, 17.96)	91.7	0.0005
Other ILD	1/ 43 (2.3)	3/ 38 (7.9)	86.2	1/ 5 (20.0)	0/ 6 (0.0)	13.8	2.47 (-7.53, 12.47)	13.3	0.2828
Region									
Europe									
Asia	3/ 76 (3.9)	27/ 79 (34.2)	68.3	2/ 27 (7.4)	18/ 54 (33.3)	31.7	28.86 (19.61, 38.12)	0.0	0.6669
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	11/331 (3.3)	41/332 (12.3)	84.5	2/ 27 (7.4)	18/ 54 (33.3)	15.5	4.43 (2.37, 8.28)	0.0	0.6250
Age									
<65 years	2/121 (1.7)	17/139 (12.2)	88.4	0/ 9 (0.0)	9/ 25 (36.0)	11.6	9.69 (2.43,38.71)	0.0	0.6761
>=65 years	9/210 (4.3)	24/193 (12.4)	81.6	2/ 18 (11.1)	9/ 29 (31.0)	18.4	3.25 (1.59, 6.65)	0.0	0.8930
Sex									
Male	6/177 (3.4)	25/179 (14.0)	71.6	2/ 11 (18.2)	7/ 26 (26.9)	28.4	3.78 (1.69, 8.47)	2.6	0.3109
Female	5/154 (3.2)	16/153 (10.5)	94.1	0/ 16 (0.0)	11/ 28 (39.3)	5.9	5.02 (1.94,13.00)	29.7	0.2330
Baseline FVC percent predicted									
<=70%	8/193 (4.1)	27/196 (13.8)	96.2	0/ 10 (0.0)	7/ 17 (41.2)	3.8	4.31 (1.97, 9.43)	0.0	0.3433
>70%	3/138 (2.2)	14/136 (10.3)	58.1	2/ 17 (11.8)	11/ 37 (29.7)	41.9	4.33 (1.59,11.78)	0.0	0.6449
Baseline HRCT pattern									
UIP-like	8/206 (3.9)	24/206 (11.7)	80.0	2/ 23 (8.7)	15/ 45 (33.3)	20.0	3.66 (1.77, 7.58)	0.0	0.6007
Other fibrotic patterns	3/125 (2.4)	17/126 (13.5)	90.5	0/ 4 (0.0)	3/ 9 (33.3)	9.5	6.47 (1.96,21.35)	0.0	0.9244
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	9/ 64 (14.1)	53.1	1/ 7 (14.3)	4/ 11 (36.4)	46.9	6.82 (1.43,32.59)	0.0	0.5224
Unclassifiable IIP	1/ 50 (2.0)	16/ 64 (25.0)	67.2	0/ 3 (0.0)	0/ 2 (0.0)	32.8	11.30 (2.03,62.82)	23.5	0.2528
HP	5/ 89 (5.6)	6/ 84 (7.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	3/ 88 (3.4)	7/ 82 (8.5)	92.2	0/ 12 (0.0)	14/ 34 (41.2)	7.8	5.06 (1.49,17.21)	29.5	0.2335
Other ILD	1/ 43 (2.3)	3/ 38 (7.9)	37.1	1/ 5 (20.0)	0/ 6 (0.0)	62.9	1.50 (0.28, 7.88)	38.8	0.2010
Region									
Europe									
Asia	3/ 76 (3.9)	27/ 79 (34.2)	53.1	2/ 27 (7.4)	18/ 54 (33.3)	46.9	9.64 (3.67,25.35)	0.0	0.4873
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Infections and infestations

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo			Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk ratio (95% CI)	p-value	I^2	p-value
Overall	218/331 (65.9)	206/332 (62.0)	90.6	17/ 27 (63.0)	29/ 54 (53.7)	9.4	0.93 (0.84, 1.04)	0.2201	0.0	0.6241
Age										
<65 years	77/121 (63.6)	90/139 (64.7)	91.8	5/ 9 (55.6)	16/ 25 (64.0)	8.2	1.03 (0.86, 1.23)	0.7540	0.0	0.7200
>=65 years	141/210 (67.1)	116/193 (60.1)	90.1	12/ 18 (66.7)	13/ 29 (44.8)	9.9	0.87 (0.76, 1.01)	0.0632	7.2	0.2993
Sex										
Male	115/177 (65.0)	109/179 (60.9)	92.2	7/ 11 (63.6)	16/ 26 (61.5)	7.8	0.94 (0.81, 1.10)	0.4249	0.0	0.9133
Female	103/154 (66.9)	97/153 (63.4)	89.0	10/ 16 (62.5)	13/ 28 (46.4)	11.0	0.93 (0.79, 1.08)	0.3331	0.0	0.4050
Baseline FVC percent predicted										
<=70%	139/193 (72.0)	130/196 (66.3)	94.1	7/ 10 (70.0)	9/ 17 (52.9)	5.9	0.91 (0.80, 1.04)	0.1606	0.0	0.5329
>70%	79/138 (57.2)	76/136 (55.9)	85.1	10/ 17 (58.8)	20/ 37 (54.1)	14.9	0.97 (0.80, 1.17)	0.7365	0.0	0.8257
Baseline HRCT pattern										
UIP-like	136/206 (66.0)	131/206 (63.6)	87.3	15/ 23 (65.2)	23/ 45 (51.1)	12.7	0.94 (0.82, 1.08)	0.3707	0.0	0.3550
Other fibrotic patterns	82/125 (65.6)	75/126 (59.5)	96.7	2/ 4 (50.0)	6/ 9 (66.7)	3.3	0.92 (0.76, 1.11)	0.3952	0.0	0.4930
Underlying ILD diagnosis										
iNSIP	37/ 61 (60.7)	33/ 64 (51.6)	88.6	4/ 7 (57.1)	6/ 11 (54.5)	11.4	0.86 (0.64, 1.15)	0.3193	0.0	0.7995
Unclassifiable IIP	32/ 50 (64.0)	37/ 64 (57.8)	94.5	2/ 3 (66.7)	2/ 2 (100.0)	5.5	0.93 (0.70, 1.23)	0.6112	0.0	0.3718
HP	68/ 89 (76.4)	58/ 84 (69.0)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	54/ 88 (61.4)	55/ 82 (67.1)	81.5	8/ 12 (66.7)	17/ 34 (50.0)	18.5	1.03 (0.84, 1.27)	0.7815	40.6	0.1943
Other ILD	27/ 43 (62.8)	23/ 38 (60.5)	88.6	3/ 5 (60.0)	3/ 6 (50.0)	11.4	0.95 (0.68, 1.32)	0.7548	0.0	0.8002
Region										
Europe										
Asia	50/ 76 (65.8)	46/ 79 (58.2)	69.2	17/ 27 (63.0)	29/ 54 (53.7)	30.8	0.88 (0.71, 1.08)	0.2077	0.0	0.8732
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Infections and infestations

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	218/331 (65.9)	206/332 (62.0)	90.2	17/ 27 (63.0)	29/ 54 (53.7)	9.8	-4.35 (-11.30, 2.60)	0.0	0.6525
Age									
<65 years	77/121 (63.6)	90/139 (64.7)	90.7	5/ 9 (55.6)	16/ 25 (64.0)	9.3	1.79 (-9.37, 12.95)	0.0	0.7146
>=65 years	141/210 (67.1)	116/193 (60.1)	90.1	12/ 18 (66.7)	13/ 29 (44.8)	9.9	-8.51 (-17.42, 0.40)	0.0	0.3309
Sex									
Male	115/177 (65.0)	109/179 (60.9)	92.0	7/ 11 (63.6)	16/ 26 (61.5)	8.0	-3.92 (-13.54, 5.70)	0.0	0.9129
Female	103/154 (66.9)	97/153 (63.4)	88.3	10/ 16 (62.5)	13/ 28 (46.4)	11.7	-4.96 (-15.00, 5.09)	0.0	0.4393
Baseline FVC percent predicted									
<=70%	139/193 (72.0)	130/196 (66.3)	93.9	7/ 10 (70.0)	9/ 17 (52.9)	6.1	-6.39 (-15.28, 2.51)	0.0	0.5591
>70%	79/138 (57.2)	76/136 (55.9)	85.5	10/ 17 (58.8)	20/ 37 (54.1)	14.5	-1.86 (-12.71, 8.99)	0.0	0.8279
Baseline HRCT pattern									
UIP-like	136/206 (66.0)	131/206 (63.6)	87.1	15/ 23 (65.2)	23/ 45 (51.1)	12.9	-3.93 (-12.55, 4.69)	0.0	0.3791
Other fibrotic patterns	82/125 (65.6)	75/126 (59.5)	95.8	2/ 4 (50.0)	6/ 9 (66.7)	4.2	-5.11 (-16.82, 6.59)	0.0	0.4507
Underlying ILD diagnosis									
iNSIP	37/ 61 (60.7)	33/ 64 (51.6)	88.0	4/ 7 (57.1)	6/ 11 (54.5)	12.0	-8.31 (-24.57, 7.95)	0.0	0.7994
Unclassifiable IIP	32/ 50 (64.0)	37/ 64 (57.8)	94.4	2/ 3 (66.7)	2/ 2 (100.0)	5.6	-4.49 (-21.82, 12.83)	0.0	0.3620
HP	68/ 89 (76.4)	58/ 84 (69.0)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	54/ 88 (61.4)	55/ 82 (67.1)	82.7	8/ 12 (66.7)	17/ 34 (50.0)	17.3	1.84 (-11.25, 14.93)	37.6	0.2057
Other ILD	27/ 43 (62.8)	23/ 38 (60.5)	88.1	3/ 5 (60.0)	3/ 6 (50.0)	11.9	-3.19 (-23.14, 16.77)	0.0	0.8081
Region									
Europe									
Asia	50/ 76 (65.8)	46/ 79 (58.2)	68.3	17/ 27 (63.0)	29/ 54 (53.7)	31.7	-8.10 (-20.72, 4.52)	0.0	0.9027
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Infections and infestations

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	218/331 (65.9)	206/332 (62.0)	88.8	17/ 27 (63.0)	29/ 54 (53.7)	11.2	0.83 (0.61, 1.12)	0.0	0.6706
Age									
<65 years	77/121 (63.6)	90/139 (64.7)	91.6	5/ 9 (55.6)	16/ 25 (64.0)	8.4	1.08 (0.67, 1.75)	0.0	0.7147
>=65 years	141/210 (67.1)	116/193 (60.1)	86.8	12/ 18 (66.7)	13/ 29 (44.8)	13.2	0.69 (0.47, 1.02)	0.0	0.3649
Sex									
Male	115/177 (65.0)	109/179 (60.9)	92.3	7/ 11 (63.6)	16/ 26 (61.5)	7.7	0.85 (0.56, 1.28)	0.0	0.9125
Female	103/154 (66.9)	97/153 (63.4)	84.6	10/ 16 (62.5)	13/ 28 (46.4)	15.4	0.81 (0.52, 1.25)	0.0	0.4644
Baseline FVC percent predicted									
<=70%	139/193 (72.0)	130/196 (66.3)	91.9	7/ 10 (70.0)	9/ 17 (52.9)	8.1	0.74 (0.49, 1.13)	0.0	0.5964
>70%	79/138 (57.2)	76/136 (55.9)	84.6	10/ 17 (58.8)	20/ 37 (54.1)	15.4	0.93 (0.60, 1.44)	0.0	0.8288
Baseline HRCT pattern									
UIP-like	136/206 (66.0)	131/206 (63.6)	83.6	15/ 23 (65.2)	23/ 45 (51.1)	16.4	0.84 (0.58, 1.23)	0.0	0.4008
Other fibrotic patterns	82/125 (65.6)	75/126 (59.5)	97.3	2/ 4 (50.0)	6/ 9 (66.7)	2.7	0.80 (0.49, 1.33)	0.0	0.4467
Underlying ILD diagnosis									
iNSIP	37/ 61 (60.7)	33/ 64 (51.6)	89.2	4/ 7 (57.1)	6/ 11 (54.5)	10.8	0.71 (0.37, 1.39)	0.0	0.7989
Unclassifiable IIP	32/ 50 (64.0)	37/ 64 (57.8)	98.1	2/ 3 (66.7)	2/ 2 (100.0)	1.9	0.83 (0.39, 1.73)	0.0	0.4379
HP	68/ 89 (76.4)	58/ 84 (69.0)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	54/ 88 (61.4)	55/ 82 (67.1)	74.4	8/ 12 (66.7)	17/ 34 (50.0)	25.6	1.08 (0.61, 1.91)	32.9	0.2223
Other ILD	27/ 43 (62.8)	23/ 38 (60.5)	85.9	3/ 5 (60.0)	3/ 6 (50.0)	14.1	0.87 (0.38, 2.03)	0.0	0.8128
Region									
Europe									
Asia	50/ 76 (65.8)	46/ 79 (58.2)	67.0	17/ 27 (63.0)	29/ 54 (53.7)	33.0	0.71 (0.42, 1.22)	0.0	0.9179
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Injury, poisoning and procedural complications

Subgroup / Category	Trial 1199_0247: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247: Wt	Trial 1199_0434: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434: Wt	Fixed effects: Nin 150bid vs Placebo: Risk ratio (95% CI)	p-value	Heterogeneity: I^2	Heterogeneity: p-value
Overall	56/331 (16.9)	52/332 (15.7)	95.5	2/ 27 (7.4)	2/ 54 (3.7)	4.5	0.91 (0.65, 1.27)	0.5705	0.0	0.5328
Age										
<65 years	13/121 (10.7)	19/139 (13.7)	97.3	0/ 9 (0.0)	1/ 25 (4.0)	2.7	1.30 (0.68, 2.50)	0.4288	0.0	0.7664
>=65 years	43/210 (20.5)	33/193 (17.1)	94.3	2/ 18 (11.1)	1/ 29 (3.4)	5.7	0.81 (0.54, 1.20)	0.2908	0.0	0.4117
Sex										
Male	31/177 (17.5)	22/179 (12.3)	90.6	2/ 11 (18.2)	0/ 26 (0.0)	9.4	0.65 (0.40, 1.06)	0.0819	36.9	0.2079
Female	25/154 (16.2)	30/153 (19.6)	98.2	0/ 16 (0.0)	2/ 28 (7.1)	1.8	1.26 (0.78, 2.03)	0.3390	0.0	0.4836
Baseline FVC percent predicted										
<=70%	36/193 (18.7)	27/196 (13.8)	95.5	1/ 10 (10.0)	0/ 17 (0.0)	4.5	0.72 (0.46, 1.13)	0.1483	0.0	0.5003
>70%	20/138 (14.5)	25/136 (18.4)	93.5	1/ 17 (5.9)	2/ 37 (5.4)	6.5	1.25 (0.74, 2.10)	0.4112	0.0	0.7917
Baseline HRCT pattern										
UIP-like	35/206 (17.0)	30/206 (14.6)	96.4	1/ 23 (4.3)	2/ 45 (4.4)	3.6	0.86 (0.56, 1.34)	0.5121	0.0	0.8851
Other fibrotic patterns	21/125 (16.8)	22/126 (17.5)	92.1	1/ 4 (25.0)	0/ 9 (0.0)	7.9	0.98 (0.58, 1.65)	0.9273	10.6	0.2903
Underlying ILD diagnosis										
iNSIP	4/ 61 (6.6)	6/ 64 (9.4)	89.6	0/ 7 (0.0)	0/ 11 (0.0)	10.4	1.39 (0.43, 4.42)	0.5819	0.0	0.8644
Unclassifiable IIP	10/ 50 (20.0)	10/ 64 (15.6)	95.9	0/ 3 (0.0)	0/ 2 (0.0)	4.1	0.79 (0.36, 1.72)	0.5524	0.0	0.8984
HP	21/ 89 (23.6)	13/ 84 (15.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	14/ 88 (15.9)	17/ 82 (20.7)	97.2	0/ 12 (0.0)	2/ 34 (5.9)	2.8	1.37 (0.73, 2.58)	0.3302	0.0	0.6099
Other ILD	7/ 43 (16.3)	6/ 38 (15.8)	71.0	2/ 5 (40.0)	0/ 6 (0.0)	29.0	0.74 (0.30, 1.83)	0.5179	20.1	0.2632
Region										
Europe										
Asia	11/ 76 (14.5)	13/ 79 (16.5)	80.8	2/ 27 (7.4)	2/ 54 (3.7)	19.2	1.01 (0.51, 2.01)	0.9668	0.0	0.4306
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Injury, poisoning and procedural complications

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	56/331 (16.9)	52/332 (15.7)	90.2	2/ 27 (7.4)	2/ 54 (3.7)	9.8	-1.50 (-6.68, 3.69)	0.0	0.6995
Age									
<65 years	13/121 (10.7)	19/139 (13.7)	90.2	0/ 9 (0.0)	1/ 25 (4.0)	9.8	3.01 (-4.29, 10.30)	0.0	0.9176
>=65 years	43/210 (20.5)	33/193 (17.1)	90.1	2/ 18 (11.1)	1/ 29 (3.4)	9.9	-3.80 (-10.84, 3.24)	0.0	0.6349
Sex									
Male	31/177 (17.5)	22/179 (12.3)	91.6	2/ 11 (18.2)	0/ 26 (0.0)	8.4	-6.23 (-13.28, 0.82)	0.0	0.3422
Female	25/154 (16.2)	30/153 (19.6)	87.8	0/ 16 (0.0)	2/ 28 (7.1)	12.2	3.80 (-3.89, 11.48)	0.0	0.6548
Baseline FVC percent predicted									
<=70%	36/193 (18.7)	27/196 (13.8)	93.5	1/ 10 (10.0)	0/ 17 (0.0)	6.5	-5.17 (-12.15, 1.82)	0.0	0.7036
>70%	20/138 (14.5)	25/136 (18.4)	85.5	1/ 17 (5.9)	2/ 37 (5.4)	14.5	3.25 (-4.49, 11.00)	0.0	0.5920
Baseline HRCT pattern									
UIP-like	35/206 (17.0)	30/206 (14.6)	87.1	1/ 23 (4.3)	2/ 45 (4.4)	12.9	-2.10 (-8.37, 4.17)	0.0	0.6913
Other fibrotic patterns	21/125 (16.8)	22/126 (17.5)	95.2	1/ 4 (25.0)	0/ 9 (0.0)	4.8	-0.42 (-9.54, 8.70)	0.0	0.3287
Underlying ILD diagnosis									
iNSIP	4/ 61 (6.6)	6/ 64 (9.4)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	2.45 (-6.17, 11.06)	0.0	0.7997
Unclassifiable IIP	10/ 50 (20.0)	10/ 64 (15.6)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	-4.13 (-17.87, 9.61)	0.0	0.8756
HP	21/ 89 (23.6)	13/ 84 (15.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	14/ 88 (15.9)	17/ 82 (20.7)	82.1	0/ 12 (0.0)	2/ 34 (5.9)	17.9	4.97 (-4.82, 14.75)	0.0	0.9233
Other ILD	7/ 43 (16.3)	6/ 38 (15.8)	86.2	2/ 5 (40.0)	0/ 6 (0.0)	13.8	-5.08 (-20.18, 10.01)	48.1	0.1652
Region									
Europe									
Asia	11/ 76 (14.5)	13/ 79 (16.5)	68.3	2/ 27 (7.4)	2/ 54 (3.7)	31.7	0.18 (-8.35, 8.70)	0.0	0.4830
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Injury, poisoning and procedural complications

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	56/331 (16.9)	52/332 (15.7)	94.9	2/ 27 (7.4)	2/ 54 (3.7)	5.1	0.89 (0.59, 1.33)	0.0	0.5422
Age									
<65 years	13/121 (10.7)	19/139 (13.7)	97.1	0/ 9 (0.0)	1/ 25 (4.0)	2.9	1.35 (0.65, 2.82)	0.0	0.7722
>=65 years	43/210 (20.5)	33/193 (17.1)	93.5	2/ 18 (11.1)	1/ 29 (3.4)	6.5	0.77 (0.47, 1.25)	0.0	0.4242
Sex									
Male	31/177 (17.5)	22/179 (12.3)	89.7	2/ 11 (18.2)	0/ 26 (0.0)	10.3	0.60 (0.34, 1.07)	37.1	0.2075
Female	25/154 (16.2)	30/153 (19.6)	97.9	0/ 16 (0.0)	2/ 28 (7.1)	2.1	1.32 (0.75, 2.35)	0.0	0.4877
Baseline FVC percent predicted									
<=70%	36/193 (18.7)	27/196 (13.8)	94.9	1/ 10 (10.0)	0/ 17 (0.0)	5.1	0.67 (0.39, 1.15)	0.0	0.5122
>70%	20/138 (14.5)	25/136 (18.4)	92.6	1/ 17 (5.9)	2/ 37 (5.4)	7.4	1.30 (0.70, 2.42)	0.0	0.7742
Baseline HRCT pattern									
UIP-like	35/206 (17.0)	30/206 (14.6)	95.9	1/ 23 (4.3)	2/ 45 (4.4)	4.1	0.84 (0.50, 1.41)	0.0	0.8723
Other fibrotic patterns	21/125 (16.8)	22/126 (17.5)	91.1	1/ 4 (25.0)	0/ 9 (0.0)	8.9	0.97 (0.51, 1.84)	11.7	0.2872
Underlying ILD diagnosis									
iNSIP	4/ 61 (6.6)	6/ 64 (9.4)	89.2	0/ 7 (0.0)	0/ 11 (0.0)	10.8	1.42 (0.41, 4.99)	0.0	0.8606
Unclassifiable IIP	10/ 50 (20.0)	10/ 64 (15.6)	95.8	0/ 3 (0.0)	0/ 2 (0.0)	4.2	0.75 (0.29, 1.93)	0.0	0.8943
HP	21/ 89 (23.6)	13/ 84 (15.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	14/ 88 (15.9)	17/ 82 (20.7)	96.8	0/ 12 (0.0)	2/ 34 (5.9)	3.2	1.46 (0.68, 3.14)	0.0	0.6210
Other ILD	7/ 43 (16.3)	6/ 38 (15.8)	69.1	2/ 5 (40.0)	0/ 6 (0.0)	30.9	0.70 (0.24, 2.06)	31.2	0.2278
Region									
Europe									
Asia	11/ 76 (14.5)	13/ 79 (16.5)	78.5	2/ 27 (7.4)	2/ 54 (3.7)	21.5	1.02 (0.46, 2.26)	0.0	0.4305
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Investigations

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	70/331 (21.1)	130/332 (39.2)	86.8	8/ 27 (29.6)	29/ 54 (53.7)	13.2	1.85 (1.47, 2.32)	<.0001	0.0	0.9509
Age										
<65 years	21/121 (17.4)	55/139 (39.6)	88.4	2/ 9 (22.2)	13/ 25 (52.0)	11.6	2.29 (1.51, 3.47)	<.0001	0.0	0.9699
>=65 years	49/210 (23.3)	75/193 (38.9)	86.4	6/ 18 (33.3)	16/ 29 (55.2)	13.6	1.66 (1.26, 2.20)	0.0004	0.0	0.9878
Sex										
Male	34/177 (19.2)	62/179 (34.6)	92.4	2/ 11 (18.2)	15/ 26 (57.7)	7.6	1.91 (1.34, 2.71)	0.0003	0.0	0.4105
Female	36/154 (23.4)	68/153 (44.4)	82.5	6/ 16 (37.5)	14/ 28 (50.0)	17.5	1.80 (1.33, 2.45)	0.0002	0.0	0.3885
Baseline FVC percent predicted										
<=70%	47/193 (24.4)	74/196 (37.8)	92.6	3/ 10 (30.0)	12/ 17 (70.6)	7.4	1.61 (1.20, 2.16)	0.0014	0.0	0.4324
>70%	23/138 (16.7)	56/136 (41.2)	76.9	5/ 17 (29.4)	17/ 37 (45.9)	23.1	2.26 (1.55, 3.29)	<.0001	0.0	0.3281
Baseline HRCT pattern										
UIP-like	34/206 (16.5)	88/206 (42.7)	81.1	6/ 23 (26.1)	24/ 45 (53.3)	18.9	2.49 (1.82, 3.40)	<.0001	0.0	0.5715
Other fibrotic patterns	36/125 (28.8)	42/126 (33.3)	92.9	2/ 4 (50.0)	5/ 9 (55.6)	7.1	1.15 (0.81, 1.64)	0.4266	0.0	0.9468
Underlying ILD diagnosis										
iNSIP	7/ 61 (11.5)	23/ 64 (35.9)	74.6	2/ 7 (28.6)	5/ 11 (45.5)	25.4	2.74 (1.41, 5.33)	0.0030	0.0	0.3899
Unclassifiable IIP	15/ 50 (30.0)	23/ 64 (35.9)	97.2	0/ 3 (0.0)	1/ 2 (50.0)	2.8	1.26 (0.75, 2.12)	0.3819	0.0	0.4318
HP	26/ 89 (29.2)	34/ 84 (40.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	14/ 88 (15.9)	37/ 82 (45.1)	75.3	3/ 12 (25.0)	20/ 34 (58.8)	24.7	2.72 (1.69, 4.37)	<.0001	0.0	0.7506
Other ILD	8/ 43 (18.6)	13/ 38 (34.2)	69.6	3/ 5 (60.0)	3/ 6 (50.0)	30.4	1.53 (0.82, 2.88)	0.1841	27.8	0.2393
Region										
Europe										
Asia	15/ 76 (19.7)	43/ 79 (54.4)	58.9	8/ 27 (29.6)	29/ 54 (53.7)	41.1	2.37 (1.61, 3.49)	<.0001	4.6	0.3059
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Investigations

Subgroup / Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo: Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	70/331 (21.1)	130/332 (39.2)	90.2	8/ 27 (29.6)	29/ 54 (53.7)	9.8	18.60 (12.07, 25.14)	0.0	0.6023
Age									
<65 years	21/121 (17.4)	55/139 (39.6)	90.7	2/ 9 (22.2)	13/ 25 (52.0)	9.3	22.92 (12.84, 32.99)	0.0	0.6728
>=65 years	49/210 (23.3)	75/193 (38.9)	90.1	6/ 18 (33.3)	16/ 29 (55.2)	9.9	16.15 (7.62, 24.69)	0.0	0.6770
Sex									
Male	34/177 (19.2)	62/179 (34.6)	92.0	2/ 11 (18.2)	15/ 26 (57.7)	8.0	17.35 (8.68, 26.03)	56.8	0.1281
Female	36/154 (23.4)	68/153 (44.4)	88.3	6/ 16 (37.5)	14/ 28 (50.0)	11.7	20.06 (10.29, 29.84)	0.0	0.5977
Baseline FVC percent predicted									
<=70%	47/193 (24.4)	74/196 (37.8)	93.9	3/ 10 (30.0)	12/ 17 (70.6)	6.1	15.06 (6.24, 23.87)	52.1	0.1483
>70%	23/138 (16.7)	56/136 (41.2)	85.5	5/ 17 (29.4)	17/ 37 (45.9)	14.5	23.35 (13.68, 33.02)	0.0	0.5883
Baseline HRCT pattern									
UIP-like	34/206 (16.5)	88/206 (42.7)	87.1	6/ 23 (26.1)	24/ 45 (53.3)	12.9	26.35 (18.41, 34.28)	0.0	0.9345
Other fibrotic patterns	36/125 (28.8)	42/126 (33.3)	95.8	2/ 4 (50.0)	5/ 9 (55.6)	4.2	4.58 (-6.65, 15.81)	0.0	0.9733
Underlying ILD diagnosis									
iNSIP	7/ 61 (11.5)	23/ 64 (35.9)	88.0	2/ 7 (28.6)	5/ 11 (45.5)	12.0	23.55 (9.94, 37.16)	0.0	0.7508
Unclassifiable IIP	15/ 50 (30.0)	23/ 64 (35.9)	94.4	0/ 3 (0.0)	1/ 2 (50.0)	5.6	7.62 (-9.15, 24.39)	0.0	0.4020
HP	26/ 89 (29.2)	34/ 84 (40.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	14/ 88 (15.9)	37/ 82 (45.1)	82.7	3/ 12 (25.0)	20/ 34 (58.8)	17.3	30.01 (17.95, 42.07)	0.0	0.7802
Other ILD	8/ 43 (18.6)	13/ 38 (34.2)	88.1	3/ 5 (60.0)	3/ 6 (50.0)	11.9	12.56 (-5.62, 30.73)	0.0	0.4160
Region									
Europe									
Asia	15/ 76 (19.7)	43/ 79 (54.4)	68.3	8/ 27 (29.6)	29/ 54 (53.7)	31.7	31.32 (19.44, 43.21)	0.0	0.4228
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Investigations

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	70/331 (21.1)	130/332 (39.2)	89.6	8/ 27 (29.6)	29/ 54 (53.7)	10.4	2.44 (1.76, 3.37)	0.0	0.7951
Age									
<65 years	21/121 (17.4)	55/139 (39.6)	90.6	2/ 9 (22.2)	13/ 25 (52.0)	9.4	3.18 (1.83, 5.52)	0.0	0.8358
>=65 years	49/210 (23.3)	75/193 (38.9)	89.6	6/ 18 (33.3)	16/ 29 (55.2)	10.4	2.13 (1.42, 3.19)	0.0	0.8038
Sex									
Male	34/177 (19.2)	62/179 (34.6)	94.9	2/ 11 (18.2)	15/ 26 (57.7)	5.1	2.43 (1.53, 3.86)	19.1	0.2662
Female	36/154 (23.4)	68/153 (44.4)	83.9	6/ 16 (37.5)	14/ 28 (50.0)	16.1	2.47 (1.56, 3.90)	0.0	0.5096
Baseline FVC percent predicted									
<=70%	47/193 (24.4)	74/196 (37.8)	96.4	3/ 10 (30.0)	12/ 17 (70.6)	3.6	2.02 (1.32, 3.08)	31.8	0.2260
>70%	23/138 (16.7)	56/136 (41.2)	78.4	5/ 17 (29.4)	17/ 37 (45.9)	21.6	3.18 (1.91, 5.31)	0.0	0.4333
Baseline HRCT pattern									
UIP-like	34/206 (16.5)	88/206 (42.7)	84.0	6/ 23 (26.1)	24/ 45 (53.3)	16.0	3.69 (2.41, 5.64)	0.0	0.8016
Other fibrotic patterns	36/125 (28.8)	42/126 (33.3)	95.1	2/ 4 (50.0)	5/ 9 (55.6)	4.9	1.24 (0.73, 2.09)	0.0	0.9928
Underlying ILD diagnosis									
iNSIP	7/ 61 (11.5)	23/ 64 (35.9)	77.5	2/ 7 (28.6)	5/ 11 (45.5)	22.5	3.82 (1.64, 8.91)	0.0	0.5208
Unclassifiable IIP	15/ 50 (30.0)	23/ 64 (35.9)	97.8	0/ 3 (0.0)	1/ 2 (50.0)	2.2	1.41 (0.65, 3.04)	0.0	0.4181
HP	26/ 89 (29.2)	34/ 84 (40.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	14/ 88 (15.9)	37/ 82 (45.1)	80.2	3/ 12 (25.0)	20/ 34 (58.8)	19.8	4.33 (2.27, 8.27)	0.0	0.9867
Other ILD	8/ 43 (18.6)	13/ 38 (34.2)	75.1	3/ 5 (60.0)	3/ 6 (50.0)	24.9	1.87 (0.74, 4.73)	0.0	0.3563
Region									
Europe									
Asia	15/ 76 (19.7)	43/ 79 (54.4)	58.5	8/ 27 (29.6)	29/ 54 (53.7)	41.5	3.99 (2.24, 7.10)	0.0	0.3615
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Metabolism and nutrition disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	58/331 (17.5)	81/332 (24.4)	89.7	5/ 27 (18.5)	14/ 54 (25.9)	10.3	1.39 (1.05, 1.85)	0.0229	0.0	0.9911
Age										
<65 years	14/121 (11.6)	28/139 (20.1)	83.6	2/ 9 (22.2)	3/ 25 (12.0)	16.4	1.54 (0.89, 2.67)	0.1216	43.5	0.1833
>=65 years	44/210 (21.0)	53/193 (27.5)	91.9	3/ 18 (16.7)	11/ 29 (37.9)	8.1	1.39 (1.00, 1.94)	0.0531	0.0	0.3616
Sex										
Male	33/177 (18.6)	44/179 (24.6)	95.9	1/ 11 (9.1)	10/ 26 (38.5)	4.1	1.44 (0.97, 2.13)	0.0701	25.5	0.2466
Female	25/154 (16.2)	37/153 (24.2)	83.0	4/ 16 (25.0)	4/ 28 (14.3)	17.0	1.33 (0.87, 2.04)	0.1817	50.4	0.1558
Baseline FVC percent predicted										
<=70%	42/193 (21.8)	47/196 (24.0)	97.1	1/ 10 (10.0)	7/ 17 (41.2)	2.9	1.19 (0.83, 1.70)	0.3424	41.4	0.1916
>70%	16/138 (11.6)	34/136 (25.0)	74.3	4/ 17 (23.5)	7/ 37 (18.9)	25.7	1.81 (1.12, 2.92)	0.0154	60.5	0.1116
Baseline HRCT pattern										
UIP-like	36/206 (17.5)	55/206 (26.7)	84.5	5/ 23 (21.7)	13/ 45 (28.9)	15.5	1.50 (1.06, 2.11)	0.0218	0.0	0.7792
Other fibrotic patterns	22/125 (17.6)	26/126 (20.6)	98.1	0/ 4 (0.0)	1/ 9 (11.1)	1.9	1.20 (0.72, 1.98)	0.4872	0.0	0.6984
Underlying ILD diagnosis										
iNSIP	5/ 61 (8.2)	13/ 64 (20.3)	91.5	0/ 7 (0.0)	2/ 11 (18.2)	8.5	2.63 (1.04, 6.67)	0.0416	0.0	0.7527
Unclassifiable IIP	12/ 50 (24.0)	21/ 64 (32.8)	96.6	0/ 3 (0.0)	0/ 2 (0.0)	3.4	1.35 (0.75, 2.46)	0.3192	0.0	0.8703
HP	24/ 89 (27.0)	14/ 84 (16.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	9/ 88 (10.2)	21/ 82 (25.6)	66.2	3/ 12 (25.0)	10/ 34 (29.4)	33.8	2.06 (1.13, 3.74)	0.0182	20.1	0.2632
Other ILD	8/ 43 (18.6)	12/ 38 (31.6)	77.5	2/ 5 (40.0)	2/ 6 (33.3)	22.5	1.50 (0.75, 3.01)	0.2502	0.0	0.4241
Region										
Europe										
Asia	21/ 76 (27.6)	29/ 79 (36.7)	76.3	5/ 27 (18.5)	14/ 54 (25.9)	23.7	1.35 (0.89, 2.04)	0.1617	0.0	0.9200
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Metabolism and nutrition disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	58/331 (17.5)	81/332 (24.4)	90.2	5/ 27 (18.5)	14/ 54 (25.9)	9.8	6.93 (1.06, 12.79)	0.0	0.9578
Age									
<65 years	14/121 (11.6)	28/139 (20.1)	90.7	2/ 9 (22.2)	3/ 25 (12.0)	9.3	6.83 (-1.60, 15.26)	28.0	0.2385
>=65 years	44/210 (21.0)	53/193 (27.5)	90.1	3/ 18 (16.7)	11/ 29 (37.9)	9.9	7.98 (0.06, 15.90)	18.9	0.2668
Sex									
Male	33/177 (18.6)	44/179 (24.6)	92.0	1/ 11 (9.1)	10/ 26 (38.5)	8.0	7.81 (-0.29, 15.91)	66.3	0.0850
Female	25/154 (16.2)	37/153 (24.2)	88.3	4/ 16 (25.0)	4/ 28 (14.3)	11.7	5.76 (-2.65, 14.18)	47.8	0.1662
Baseline FVC percent predicted									
<=70%	42/193 (21.8)	47/196 (24.0)	93.9	1/ 10 (10.0)	7/ 17 (41.2)	6.1	3.98 (-4.07, 12.02)	70.1	0.0674
>70%	16/138 (11.6)	34/136 (25.0)	85.5	4/ 17 (23.5)	7/ 37 (18.9)	14.5	10.79 (2.33, 19.24)	48.1	0.1652
Baseline HRCT pattern									
UIP-like	36/206 (17.5)	55/206 (26.7)	87.1	5/ 23 (21.7)	13/ 45 (28.9)	12.9	8.96 (1.49, 16.42)	0.0	0.8589
Other fibrotic patterns	22/125 (17.6)	26/126 (20.6)	95.2	0/ 4 (0.0)	1/ 9 (11.1)	4.8	3.35 (-6.02, 12.73)	0.0	0.6989
Underlying ILD diagnosis									
iNSIP	5/ 61 (8.2)	13/ 64 (20.3)	86.8	0/ 7 (0.0)	2/ 11 (18.2)	13.2	12.68 (1.62, 23.73)	0.0	0.7822
Unclassifiable IIP	12/ 50 (24.0)	21/ 64 (32.8)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	8.31 (-7.54, 24.17)	0.0	0.7553
HP	24/ 89 (27.0)	14/ 84 (16.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	9/ 88 (10.2)	21/ 82 (25.6)	82.7	3/ 12 (25.0)	10/ 34 (29.4)	17.3	13.49 (2.84, 24.14)	0.0	0.4886
Other ILD	8/ 43 (18.6)	12/ 38 (31.6)	88.1	2/ 5 (40.0)	2/ 6 (33.3)	11.9	10.64 (-7.28, 28.55)	0.0	0.5223
Region									
Europe									
Asia	21/ 76 (27.6)	29/ 79 (36.7)	68.3	5/ 27 (18.5)	14/ 54 (25.9)	31.7	8.55 (-3.08, 20.17)	0.0	0.8905
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Metabolism and nutrition disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	58/331 (17.5)	81/332 (24.4)	89.9	5/ 27 (18.5)	14/ 54 (25.9)	10.1	1.52 (1.06, 2.18)	0.0	0.9822
Age									
<65 years	14/121 (11.6)	28/139 (20.1)	82.2	2/ 9 (22.2)	3/ 25 (12.0)	17.8	1.67 (0.87, 3.20)	41.1	0.1924
>=65 years	44/210 (21.0)	53/193 (27.5)	93.0	3/ 18 (16.7)	11/ 29 (37.9)	7.0	1.54 (1.00, 2.38)	0.0	0.3267
Sex									
Male	33/177 (18.6)	44/179 (24.6)	96.7	1/ 11 (9.1)	10/ 26 (38.5)	3.3	1.58 (0.97, 2.58)	39.3	0.1992
Female	25/154 (16.2)	37/153 (24.2)	81.2	4/ 16 (25.0)	4/ 28 (14.3)	18.8	1.43 (0.84, 2.43)	50.1	0.1569
Baseline FVC percent predicted									
<=70%	42/193 (21.8)	47/196 (24.0)	97.7	1/ 10 (10.0)	7/ 17 (41.2)	2.3	1.25 (0.79, 1.98)	52.0	0.1491
>70%	16/138 (11.6)	34/136 (25.0)	72.8	4/ 17 (23.5)	7/ 37 (18.9)	27.2	2.06 (1.15, 3.69)	58.1	0.1224
Baseline HRCT pattern									
UIP-like	36/206 (17.5)	55/206 (26.7)	84.9	5/ 23 (21.7)	13/ 45 (28.9)	15.1	1.68 (1.08, 2.61)	0.0	0.8029
Other fibrotic patterns	22/125 (17.6)	26/126 (20.6)	98.0	0/ 4 (0.0)	1/ 9 (11.1)	2.0	1.25 (0.67, 2.32)	0.0	0.6972
Underlying ILD diagnosis									
iNSIP	5/ 61 (8.2)	13/ 64 (20.3)	91.6	0/ 7 (0.0)	2/ 11 (18.2)	8.4	3.05 (1.07, 8.67)	0.0	0.7518
Unclassifiable IIP	12/ 50 (24.0)	21/ 64 (32.8)	95.7	0/ 3 (0.0)	0/ 2 (0.0)	4.3	1.52 (0.67, 3.45)	0.0	0.8460
HP	24/ 89 (27.0)	14/ 84 (16.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	9/ 88 (10.2)	21/ 82 (25.6)	67.4	3/ 12 (25.0)	10/ 34 (29.4)	32.6	2.44 (1.17, 5.11)	0.7	0.3157
Other ILD	8/ 43 (18.6)	12/ 38 (31.6)	77.9	2/ 5 (40.0)	2/ 6 (33.3)	22.1	1.74 (0.68, 4.46)	0.0	0.4676
Region									
Europe									
Asia	21/ 76 (27.6)	29/ 79 (36.7)	73.3	5/ 27 (18.5)	14/ 54 (25.9)	26.7	1.52 (0.85, 2.74)	0.0	0.9839
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Musculoskeletal and connective tissue disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	108/331 (32.6)	98/332 (29.5)	96.4	3/ 27 (11.1)	6/ 54 (11.1)	3.6	0.91 (0.73, 1.14)	0.3989	0.0	0.8823
Age										
<65 years	44/121 (36.4)	41/139 (29.5)	94.1	2/ 9 (22.2)	4/ 25 (16.0)	5.9	0.81 (0.57, 1.13)	0.2131	0.0	0.8807
>=65 years	64/210 (30.5)	57/193 (29.5)	98.0	1/ 18 (5.6)	2/ 29 (6.9)	2.0	0.97 (0.72, 1.31)	0.8642	0.0	0.8361
Sex										
Male	59/177 (33.3)	52/179 (29.1)	99.3	0/ 11 (0.0)	2/ 26 (7.7)	0.7	0.89 (0.66, 1.21)	0.4692	0.0	0.4362
Female	49/154 (31.8)	46/153 (30.1)	92.7	3/ 16 (18.8)	4/ 28 (14.3)	7.3	0.93 (0.67, 1.29)	0.6693	0.0	0.7640
Baseline FVC percent predicted										
<=70%	66/193 (34.2)	60/196 (30.6)	95.7	2/ 10 (20.0)	0/ 17 (0.0)	4.3	0.86 (0.65, 1.15)	0.3118	38.2	0.2034
>70%	42/138 (30.4)	38/136 (27.9)	96.8	1/ 17 (5.9)	6/ 37 (16.2)	3.2	0.98 (0.68, 1.40)	0.8983	7.7	0.2980
Baseline HRCT pattern										
UIP-like	57/206 (27.7)	63/206 (30.6)	93.5	3/ 23 (13.0)	5/ 45 (11.1)	6.5	1.09 (0.81, 1.46)	0.5715	0.0	0.7102
Other fibrotic patterns	51/125 (40.8)	35/126 (27.8)	99.2	0/ 4 (0.0)	1/ 9 (11.1)	0.8	0.70 (0.49, 0.99)	0.0419	0.0	0.4981
Underlying ILD diagnosis										
iNSIP	12/ 61 (19.7)	11/ 64 (17.2)	96.3	0/ 7 (0.0)	2/ 11 (18.2)	3.7	1.00 (0.49, 2.04)	0.9994	0.0	0.3502
Unclassifiable IIP	13/ 50 (26.0)	19/ 64 (29.7)	96.8	0/ 3 (0.0)	0/ 2 (0.0)	3.2	1.14 (0.63, 2.06)	0.6707	0.0	0.9448
HP	34/ 89 (38.2)	31/ 84 (36.9)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	35/ 88 (39.8)	25/ 82 (30.5)	91.9	2/ 12 (16.7)	4/ 34 (11.8)	8.1	0.76 (0.51, 1.14)	0.1847	0.0	0.9205
Other ILD	14/ 43 (32.6)	12/ 38 (31.6)	89.2	1/ 5 (20.0)	0/ 6 (0.0)	10.8	0.90 (0.48, 1.67)	0.7356	0.0	0.4567
Region										
Europe										
Asia	24/ 76 (31.6)	23/ 79 (29.1)	85.9	3/ 27 (11.1)	6/ 54 (11.1)	14.1	0.93 (0.59, 1.46)	0.7623	0.0	0.9088
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Musculoskeletal and connective tissue disorders

Subgroup / Category	Trial 1199_0247: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247: Nin 150bid n / N (%)	Trial 1199_0247: Wt	Trial 1199_0434: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434: Nin 150bid n / N (%)	Trial 1199_0434: Wt	Fixed effects: Nin 150bid vs Placebo: Risk difference (95% CI)	Heterogeneity: I^2	Heterogeneity: p-value
Overall	108/331 (32.6)	98/332 (29.5)	90.2	3/ 27 (11.1)	6/ 54 (11.1)	9.8	-2.81 (-9.31, 3.70)	0.0	0.7056
Age									
<65 years	44/121 (36.4)	41/139 (29.5)	90.7	2/ 9 (22.2)	4/ 25 (16.0)	9.3	-6.81 (-17.57, 3.96)	0.0	0.9692
>=65 years	64/210 (30.5)	57/193 (29.5)	90.1	1/ 18 (5.6)	2/ 29 (6.9)	9.9	-0.72 (-8.90, 7.47)	0.0	0.7881
Sex									
Male	59/177 (33.3)	52/179 (29.1)	91.6	0/ 11 (0.0)	2/ 26 (7.7)	8.4	-3.31 (-12.20, 5.58)	41.8	0.1899
Female	49/154 (31.8)	46/153 (30.1)	88.3	3/ 16 (18.8)	4/ 28 (14.3)	11.7	-2.07 (-11.59, 7.45)	0.0	0.8337
Baseline FVC percent predicted									
<=70%	66/193 (34.2)	60/196 (30.6)	93.5	2/ 10 (20.0)	0/ 17 (0.0)	6.5	-4.56 (-13.42, 4.29)	11.2	0.2887
>70%	42/138 (30.4)	38/136 (27.9)	85.5	1/ 17 (5.9)	6/ 37 (16.2)	14.5	-0.63 (-10.13, 8.87)	39.6	0.1983
Baseline HRCT pattern									
UIP-like	57/206 (27.7)	63/206 (30.6)	87.1	3/ 23 (13.0)	5/ 45 (11.1)	12.9	2.29 (-5.64, 10.22)	0.0	0.6121
Other fibrotic patterns	51/125 (40.8)	35/126 (27.8)	95.2	0/ 4 (0.0)	1/ 9 (11.1)	4.8	-11.92 (-23.10, -0.74)	41.3	0.1920
Underlying ILD diagnosis									
iNSIP	12/ 61 (19.7)	11/ 64 (17.2)	86.8	0/ 7 (0.0)	2/ 11 (18.2)	13.2	0.00 (-12.35, 12.36)	30.6	0.2301
Unclassifiable IIP	13/ 50 (26.0)	19/ 64 (29.7)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	3.48 (-12.40, 19.36)	0.0	0.8963
HP	34/ 89 (38.2)	31/ 84 (36.9)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	35/ 88 (39.8)	25/ 82 (30.5)	82.7	2/ 12 (16.7)	4/ 34 (11.8)	17.3	-8.53 (-21.03, 3.97)	0.0	0.7562
Other ILD	14/ 43 (32.6)	12/ 38 (31.6)	86.2	1/ 5 (20.0)	0/ 6 (0.0)	13.8	-3.18 (-21.57, 15.22)	0.0	0.4853
Region									
Europe									
Asia	24/ 76 (31.6)	23/ 79 (29.1)	68.3	3/ 27 (11.1)	6/ 54 (11.1)	31.7	-1.68 (-12.59, 9.22)	0.0	0.8137
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Musculoskeletal and connective tissue disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	108/331 (32.6)	98/332 (29.5)	95.5	3/ 27 (11.1)	6/ 54 (11.1)	4.5	0.87 (0.63, 1.20)	0.0	0.8500
Age									
<65 years	44/121 (36.4)	41/139 (29.5)	93.1	2/ 9 (22.2)	4/ 25 (16.0)	6.9	0.73 (0.44, 1.20)	0.0	0.9258
>=65 years	64/210 (30.5)	57/193 (29.5)	97.4	1/ 18 (5.6)	2/ 29 (6.9)	2.6	0.96 (0.63, 1.47)	0.0	0.8299
Sex									
Male	59/177 (33.3)	52/179 (29.1)	99.1	0/ 11 (0.0)	2/ 26 (7.7)	0.9	0.85 (0.54, 1.32)	0.0	0.4116
Female	49/154 (31.8)	46/153 (30.1)	91.3	3/ 16 (18.8)	4/ 28 (14.3)	8.7	0.90 (0.57, 1.44)	0.0	0.7805
Baseline FVC percent predicted									
<=70%	66/193 (34.2)	60/196 (30.6)	94.1	2/ 10 (20.0)	0/ 17 (0.0)	5.9	0.81 (0.53, 1.22)	38.6	0.2020
>70%	42/138 (30.4)	38/136 (27.9)	96.3	1/ 17 (5.9)	6/ 37 (16.2)	3.7	0.97 (0.59, 1.60)	14.9	0.2784
Baseline HRCT pattern									
UIP-like	57/206 (27.7)	63/206 (30.6)	91.8	3/ 23 (13.0)	5/ 45 (11.1)	8.2	1.13 (0.75, 1.70)	0.0	0.6895
Other fibrotic patterns	51/125 (40.8)	35/126 (27.8)	99.0	0/ 4 (0.0)	1/ 9 (11.1)	1.0	0.58 (0.34, 0.97)	0.0	0.4423
Underlying ILD diagnosis									
iNSIP	12/ 61 (19.7)	11/ 64 (17.2)	96.5	0/ 7 (0.0)	2/ 11 (18.2)	3.5	1.00 (0.43, 2.35)	0.0	0.3277
Unclassifiable IIP	13/ 50 (26.0)	19/ 64 (29.7)	96.1	0/ 3 (0.0)	0/ 2 (0.0)	3.9	1.19 (0.53, 2.69)	0.0	0.9348
HP	34/ 89 (38.2)	31/ 84 (36.9)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	35/ 88 (39.8)	25/ 82 (30.5)	90.0	2/ 12 (16.7)	4/ 34 (11.8)	10.0	0.66 (0.36, 1.21)	0.0	0.9970
Other ILD	14/ 43 (32.6)	12/ 38 (31.6)	86.0	1/ 5 (20.0)	0/ 6 (0.0)	14.0	0.86 (0.35, 2.09)	0.0	0.4551
Region									
Europe									
Asia	24/ 76 (31.6)	23/ 79 (29.1)	83.0	3/ 27 (11.1)	6/ 54 (11.1)	17.0	0.91 (0.49, 1.69)	0.0	0.8879
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	17/331 (5.1)	17/332 (5.1)	90.5	1/ 27 (3.7)	0/ 54 (0.0)	9.5	0.93 (0.49, 1.74)	0.8123	0.0	0.3625
Age										
<65 years	4/121 (3.3)	6/139 (4.3)	91.7	0/ 9 (0.0)	0/ 25 (0.0)	8.3	1.28 (0.39, 4.22)	0.6850	0.0	0.9086
>=65 years	13/210 (6.2)	11/193 (5.7)	87.9	1/ 18 (5.6)	0/ 29 (0.0)	12.1	0.84 (0.40, 1.77)	0.6530	0.0	0.4395
Sex										
Male	12/177 (6.8)	13/179 (7.3)	96.7	0/ 11 (0.0)	0/ 26 (0.0)	3.3	1.07 (0.51, 2.25)	0.8609	0.0	0.9750
Female	5/154 (3.2)	4/153 (2.6)	74.2	1/ 16 (6.3)	0/ 28 (0.0)	25.8	0.67 (0.21, 2.12)	0.4920	0.0	0.4970
Baseline FVC percent predicted										
<=70%	9/193 (4.7)	8/196 (4.1)	95.1	0/ 10 (0.0)	0/ 17 (0.0)	4.9	0.88 (0.36, 2.18)	0.7849	0.0	0.9492
>70%	8/138 (5.8)	9/136 (6.6)	81.5	1/ 17 (5.9)	0/ 37 (0.0)	18.5	0.97 (0.41, 2.29)	0.9532	3.3	0.3092
Baseline HRCT pattern										
UIP-like	11/206 (5.3)	13/206 (6.3)	86.1	1/ 23 (4.3)	0/ 45 (0.0)	13.9	1.05 (0.50, 2.20)	0.8910	1.1	0.3146
Other fibrotic patterns	6/125 (4.8)	4/126 (3.2)	93.4	0/ 4 (0.0)	0/ 9 (0.0)	6.6	0.68 (0.21, 2.24)	0.5298	0.0	0.8500
Underlying ILD diagnosis										
iNSIP	0/ 61 (0.0)	3/ 64 (4.7)	22.7	1/ 7 (14.3)	0/ 11 (0.0)	77.3	1.78 (0.36, 8.75)	0.4800	56.5	0.1294
Unclassifiable IIP	1/ 50 (2.0)	1/ 64 (1.6)	70.1	0/ 3 (0.0)	0/ 2 (0.0)	29.9	0.85 (0.09, 7.69)	0.8826	0.0	0.9164
HP	6/ 89 (6.7)	6/ 84 (7.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	5/ 88 (5.7)	4/ 82 (4.9)	92.6	0/ 12 (0.0)	0/ 34 (0.0)	7.4	0.87 (0.25, 2.97)	0.8228	0.0	0.9482
Other ILD	5/ 43 (11.6)	3/ 38 (7.9)	90.4	0/ 5 (0.0)	0/ 6 (0.0)	9.6	0.71 (0.20, 2.55)	0.5994	0.0	0.8503
Region										
Europe										
Asia	3/ 76 (3.9)	5/ 79 (6.3)	63.2	1/ 27 (3.7)	0/ 54 (0.0)	36.8	1.11 (0.34, 3.59)	0.8671	21.7	0.2584
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	17/331 (5.1)	17/332 (5.1)	90.0	1/ 27 (3.7)	0/ 54 (0.0)	10.0	-0.38 (-3.51, 2.76)	0.0	0.4394
Age									
<65 years	4/121 (3.3)	6/139 (4.3)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	0.91 (-3.44, 5.27)	0.0	0.8791
>=65 years	13/210 (6.2)	11/193 (5.7)	89.7	1/ 18 (5.6)	0/ 29 (0.0)	10.3	-0.99 (-5.34, 3.36)	0.0	0.4874
Sex									
Male	12/177 (6.8)	13/179 (7.3)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	0.44 (-4.50, 5.39)	0.0	0.9376
Female	5/154 (3.2)	4/153 (2.6)	87.8	1/ 16 (6.3)	0/ 28 (0.0)	12.2	-1.28 (-5.02, 2.45)	0.0	0.4739
Baseline FVC percent predicted									
<=70%	9/193 (4.7)	8/196 (4.1)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-0.54 (-4.45, 3.36)	0.0	0.9366
>70%	8/138 (5.8)	9/136 (6.6)	85.0	1/ 17 (5.9)	0/ 37 (0.0)	15.0	-0.15 (-5.38, 5.08)	0.0	0.3689
Baseline HRCT pattern									
UIP-like	11/206 (5.3)	13/206 (6.3)	86.8	1/ 23 (4.3)	0/ 45 (0.0)	13.2	0.29 (-3.85, 4.42)	0.0	0.3500
Other fibrotic patterns	6/125 (4.8)	4/126 (3.2)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-1.55 (-6.34, 3.24)	0.0	0.9087
Underlying ILD diagnosis									
iNSIP	0/ 61 (0.0)	3/ 64 (4.7)	87.0	1/ 7 (14.3)	0/ 11 (0.0)	13.0	2.34 (-4.09, 8.77)	22.5	0.2560
Unclassifiable IIP	1/ 50 (2.0)	1/ 64 (1.6)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	-0.41 (-5.94, 5.11)	0.0	0.9871
HP	6/ 89 (6.7)	6/ 84 (7.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	5/ 88 (5.7)	4/ 82 (4.9)	82.1	0/ 12 (0.0)	0/ 34 (0.0)	17.9	-0.66 (-6.42, 5.10)	0.0	0.8900
Other ILD	5/ 43 (11.6)	3/ 38 (7.9)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	-3.22 (-15.01, 8.57)	0.0	0.8181
Region									
Europe									
Asia	3/ 76 (3.9)	5/ 79 (6.3)	67.7	1/ 27 (3.7)	0/ 54 (0.0)	32.3	0.45 (-4.98, 5.88)	13.2	0.2832
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	17/331 (5.1)	17/332 (5.1)	90.2	1/ 27 (3.7)	0/ 54 (0.0)	9.8	0.92 (0.47, 1.80)	0.0	0.3622
Age									
<65 years	4/121 (3.3)	6/139 (4.3)	91.5	0/ 9 (0.0)	0/ 25 (0.0)	8.5	1.29 (0.37, 4.47)	0.0	0.9077
>=65 years	13/210 (6.2)	11/193 (5.7)	87.5	1/ 18 (5.6)	0/ 29 (0.0)	12.5	0.83 (0.38, 1.85)	0.0	0.4386
Sex									
Male	12/177 (6.8)	13/179 (7.3)	96.5	0/ 11 (0.0)	0/ 26 (0.0)	3.5	1.07 (0.48, 2.39)	0.0	0.9738
Female	5/154 (3.2)	4/153 (2.6)	74.1	1/ 16 (6.3)	0/ 28 (0.0)	25.9	0.66 (0.20, 2.20)	0.0	0.4928
Baseline FVC percent predicted									
<=70%	9/193 (4.7)	8/196 (4.1)	95.1	0/ 10 (0.0)	0/ 17 (0.0)	4.9	0.88 (0.34, 2.26)	0.0	0.9487
>70%	8/138 (5.8)	9/136 (6.6)	80.7	1/ 17 (5.9)	0/ 37 (0.0)	19.3	0.97 (0.39, 2.44)	3.7	0.3083
Baseline HRCT pattern									
UIP-like	11/206 (5.3)	13/206 (6.3)	85.5	1/ 23 (4.3)	0/ 45 (0.0)	14.5	1.06 (0.48, 2.32)	1.8	0.3129
Other fibrotic patterns	6/125 (4.8)	4/126 (3.2)	93.6	0/ 4 (0.0)	0/ 9 (0.0)	6.4	0.67 (0.20, 2.31)	0.0	0.8539
Underlying ILD diagnosis									
iNSIP	0/ 61 (0.0)	3/ 64 (4.7)	22.7	1/ 7 (14.3)	0/ 11 (0.0)	77.3	1.82 (0.33,10.14)	56.8	0.1280
Unclassifiable IIP	1/ 50 (2.0)	1/ 64 (1.6)	72.9	0/ 3 (0.0)	0/ 2 (0.0)	27.1	0.84 (0.08, 8.81)	0.0	0.9238
HP	6/ 89 (6.7)	6/ 84 (7.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	5/ 88 (5.7)	4/ 82 (4.9)	92.4	0/ 12 (0.0)	0/ 34 (0.0)	7.6	0.86 (0.24, 3.14)	0.0	0.9466
Other ILD	5/ 43 (11.6)	3/ 38 (7.9)	90.4	0/ 5 (0.0)	0/ 6 (0.0)	9.6	0.68 (0.17, 2.80)	0.0	0.8474
Region									
Europe									
Asia	3/ 76 (3.9)	5/ 79 (6.3)	62.0	1/ 27 (3.7)	0/ 54 (0.0)	38.0	1.11 (0.32, 3.91)	22.3	0.2566
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Nervous system disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	71/331 (21.5)	79/332 (23.8)	96.4	2/ 27 (7.4)	9/ 54 (16.7)	3.6	1.15 (0.87, 1.52)	0.3210	0.0	0.3516
Age										
<65 years	23/121 (19.0)	27/139 (19.4)	98.4	0/ 9 (0.0)	3/ 25 (12.0)	1.6	1.09 (0.66, 1.78)	0.7464	0.0	0.4208
>=65 years	48/210 (22.9)	52/193 (26.9)	94.9	2/ 18 (11.1)	6/ 29 (20.7)	5.1	1.21 (0.87, 1.69)	0.2528	0.0	0.5572
Sex										
Male	36/177 (20.3)	35/179 (19.6)	98.9	0/ 11 (0.0)	3/ 26 (11.5)	1.1	1.01 (0.67, 1.53)	0.9604	0.0	0.3670
Female	35/154 (22.7)	44/153 (28.8)	93.2	2/ 16 (12.5)	6/ 28 (21.4)	6.8	1.30 (0.89, 1.88)	0.1715	0.0	0.6967
Baseline FVC percent predicted										
<=70%	43/193 (22.3)	46/196 (23.5)	98.9	0/ 10 (0.0)	3/ 17 (17.6)	1.1	1.10 (0.77, 1.58)	0.5936	0.9	0.3151
>70%	28/138 (20.3)	33/136 (24.3)	91.0	2/ 17 (11.8)	6/ 37 (16.2)	9.0	1.21 (0.79, 1.86)	0.3763	0.0	0.8583
Baseline HRCT pattern										
UIP-like	45/206 (21.8)	43/206 (20.9)	94.4	2/ 23 (8.7)	9/ 45 (20.0)	5.6	1.03 (0.72, 1.47)	0.8704	24.7	0.2492
Other fibrotic patterns	26/125 (20.8)	36/126 (28.6)	98.4	0/ 4 (0.0)	0/ 9 (0.0)	1.6	1.37 (0.88, 2.12)	0.1604	0.0	0.8801
Underlying ILD diagnosis										
iNSIP	9/ 61 (14.8)	10/ 64 (15.6)	95.1	0/ 7 (0.0)	2/ 11 (18.2)	4.9	1.22 (0.55, 2.69)	0.6284	0.0	0.4146
Unclassifiable IIP	13/ 50 (26.0)	20/ 64 (31.3)	96.8	0/ 3 (0.0)	0/ 2 (0.0)	3.2	1.20 (0.67, 2.15)	0.5496	0.0	0.9234
HP	25/ 89 (28.1)	20/ 84 (23.8)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	15/ 88 (17.0)	19/ 82 (23.2)	90.7	1/ 12 (8.3)	6/ 34 (17.6)	9.3	1.43 (0.80, 2.56)	0.2292	0.0	0.6793
Other ILD	9/ 43 (20.9)	10/ 38 (26.3)	84.2	1/ 5 (20.0)	0/ 6 (0.0)	15.8	1.11 (0.52, 2.34)	0.7883	0.0	0.3661
Region										
Europe										
Asia	13/ 76 (17.1)	10/ 79 (12.7)	83.2	2/ 27 (7.4)	9/ 54 (16.7)	16.8	0.99 (0.51, 1.92)	0.9833	42.9	0.1859
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Nervous system disorders

Subgroup / Category	Trial 1199_0247: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247: Wt	Trial 1199_0434: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434: Wt	Fixed effects: Nin 150bid vs Placebo: Risk difference (95% CI)	Heterogeneity: I^2	Heterogeneity: p-value
Overall	71/331 (21.5)	79/332 (23.8)	90.2	2/ 27 (7.4)	9/ 54 (16.7)	9.8	3.02 (-2.88, 8.93)	0.0	0.3786
Age									
<65 years	23/121 (19.0)	27/139 (19.4)	90.2	0/ 9 (0.0)	3/ 25 (12.0)	9.8	1.48 (-7.33, 10.30)	17.7	0.2704
>=65 years	48/210 (22.9)	52/193 (26.9)	90.1	2/ 18 (11.1)	6/ 29 (20.7)	9.9	4.63 (-3.25, 12.52)	0.0	0.6301
Sex									
Male	36/177 (20.3)	35/179 (19.6)	91.6	0/ 11 (0.0)	3/ 26 (11.5)	8.4	0.20 (-7.52, 7.92)	40.3	0.1954
Female	35/154 (22.7)	44/153 (28.8)	88.3	2/ 16 (12.5)	6/ 28 (21.4)	11.7	6.37 (-2.63, 15.37)	0.0	0.8150
Baseline FVC percent predicted									
<=70%	43/193 (22.3)	46/196 (23.5)	93.5	0/ 10 (0.0)	3/ 17 (17.6)	6.5	2.18 (-5.75, 10.11)	41.3	0.1918
>70%	28/138 (20.3)	33/136 (24.3)	85.5	2/ 17 (11.8)	6/ 37 (16.2)	14.5	4.04 (-4.83, 12.92)	0.0	0.9657
Baseline HRCT pattern									
UIP-like	45/206 (21.8)	43/206 (20.9)	87.1	2/ 23 (8.7)	9/ 45 (20.0)	12.9	0.61 (-6.60, 7.82)	42.7	0.1866
Other fibrotic patterns	26/125 (20.8)	36/126 (28.6)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	7.39 (-2.80, 17.59)	0.0	0.6037
Underlying ILD diagnosis									
iNSIP	9/ 61 (14.8)	10/ 64 (15.6)	86.8	0/ 7 (0.0)	2/ 11 (18.2)	13.2	2.92 (-8.60, 14.43)	0.1	0.3170
Unclassifiable IIP	13/ 50 (26.0)	20/ 64 (31.3)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	4.95 (-11.03, 20.93)	0.0	0.8528
HP	25/ 89 (28.1)	20/ 84 (23.8)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	15/ 88 (17.0)	19/ 82 (23.2)	82.7	1/ 12 (8.3)	6/ 34 (17.6)	17.3	6.68 (-3.88, 17.24)	0.0	0.7906
Other ILD	9/ 43 (20.9)	10/ 38 (26.3)	86.2	1/ 5 (20.0)	0/ 6 (0.0)	13.8	2.31 (-14.59, 19.22)	0.0	0.3202
Region									
Europe									
Asia	13/ 76 (17.1)	10/ 79 (12.7)	68.3	2/ 27 (7.4)	9/ 54 (16.7)	31.7	-0.10 (-8.94, 8.75)	55.4	0.1343
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Nervous system disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	71/331 (21.5)	79/332 (23.8)	96.1	2/ 27 (7.4)	9/ 54 (16.7)	3.9	1.20 (0.84, 1.70)	0.0	0.3525
Age									
<65 years	23/121 (19.0)	27/139 (19.4)	98.3	0/ 9 (0.0)	3/ 25 (12.0)	1.7	1.11 (0.60, 2.02)	0.0	0.4060
>=65 years	48/210 (22.9)	52/193 (26.9)	94.5	2/ 18 (11.1)	6/ 29 (20.7)	5.5	1.29 (0.83, 2.00)	0.0	0.5696
Sex									
Male	36/177 (20.3)	35/179 (19.6)	98.8	0/ 11 (0.0)	3/ 26 (11.5)	1.2	1.01 (0.61, 1.69)	0.0	0.3500
Female	35/154 (22.7)	44/153 (28.8)	92.6	2/ 16 (12.5)	6/ 28 (21.4)	7.4	1.41 (0.86, 2.31)	0.0	0.7208
Baseline FVC percent predicted									
<=70%	43/193 (22.3)	46/196 (23.5)	98.9	0/ 10 (0.0)	3/ 17 (17.6)	1.1	1.14 (0.71, 1.81)	8.6	0.2955
>70%	28/138 (20.3)	33/136 (24.3)	90.2	2/ 17 (11.8)	6/ 37 (16.2)	9.8	1.28 (0.74, 2.19)	0.0	0.8771
Baseline HRCT pattern									
UIP-like	45/206 (21.8)	43/206 (20.9)	94.4	2/ 23 (8.7)	9/ 45 (20.0)	5.6	1.04 (0.66, 1.62)	28.9	0.2358
Other fibrotic patterns	26/125 (20.8)	36/126 (28.6)	97.9	0/ 4 (0.0)	0/ 9 (0.0)	2.1	1.51 (0.85, 2.69)	0.0	0.8525
Underlying ILD diagnosis									
iNSIP	9/ 61 (14.8)	10/ 64 (15.6)	95.4	0/ 7 (0.0)	2/ 11 (18.2)	4.6	1.26 (0.50, 3.16)	0.0	0.3964
Unclassifiable IIP	13/ 50 (26.0)	20/ 64 (31.3)	96.1	0/ 3 (0.0)	0/ 2 (0.0)	3.9	1.28 (0.57, 2.88)	0.0	0.9087
HP	25/ 89 (28.1)	20/ 84 (23.8)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	15/ 88 (17.0)	19/ 82 (23.2)	90.1	1/ 12 (8.3)	6/ 34 (17.6)	9.9	1.56 (0.76, 3.17)	0.0	0.6932
Other ILD	9/ 43 (20.9)	10/ 38 (26.3)	80.9	1/ 5 (20.0)	0/ 6 (0.0)	19.1	1.14 (0.43, 3.00)	0.0	0.3500
Region									
Europe									
Asia	13/ 76 (17.1)	10/ 79 (12.7)	83.9	2/ 27 (7.4)	9/ 54 (16.7)	16.1	0.99 (0.47, 2.09)	45.4	0.1761
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Psychiatric disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	42/331 (12.7)	40/332 (12.0)	96.9	1/ 27 (3.7)	1/ 54 (1.9)	3.1	0.94 (0.63, 1.40)	0.7450	0.0	0.6491
Age										
<65 years	15/121 (12.4)	19/139 (13.7)	97.6	0/ 9 (0.0)	1/ 25 (4.0)	2.4	1.13 (0.61, 2.11)	0.6960	0.0	0.7141
>=65 years	27/210 (12.9)	21/193 (10.9)	93.8	1/ 18 (5.6)	0/ 29 (0.0)	6.2	0.81 (0.48, 1.37)	0.4337	0.0	0.4645
Sex										
Male	18/177 (10.2)	20/179 (11.2)	97.7	0/ 11 (0.0)	0/ 26 (0.0)	2.3	1.10 (0.60, 1.99)	0.7620	0.0	0.9656
Female	24/154 (15.6)	20/153 (13.1)	94.9	1/ 16 (6.3)	1/ 28 (3.6)	5.1	0.83 (0.48, 1.41)	0.4844	0.0	0.7851
Baseline FVC percent predicted										
<=70%	30/193 (15.5)	28/196 (14.3)	98.5	0/ 10 (0.0)	0/ 17 (0.0)	1.5	0.92 (0.57, 1.48)	0.7300	0.0	0.9671
>70%	12/138 (8.7)	12/136 (8.8)	89.7	1/ 17 (5.9)	1/ 37 (2.7)	10.3	0.96 (0.46, 1.99)	0.9072	0.0	0.5815
Baseline HRCT pattern										
UIP-like	26/206 (12.6)	30/206 (14.6)	93.6	1/ 23 (4.3)	0/ 45 (0.0)	6.4	1.10 (0.68, 1.77)	0.7056	2.1	0.3121
Other fibrotic patterns	16/125 (12.8)	10/126 (7.9)	97.4	0/ 4 (0.0)	1/ 9 (11.1)	2.6	0.67 (0.32, 1.38)	0.2758	0.0	0.4742
Underlying ILD diagnosis										
iNSIP	5/ 61 (8.2)	7/ 64 (10.9)	91.5	0/ 7 (0.0)	1/ 11 (9.1)	8.5	1.44 (0.51, 4.07)	0.4864	0.0	0.7075
Unclassifiable IIP	5/ 50 (10.0)	10/ 64 (15.6)	92.1	0/ 3 (0.0)	0/ 2 (0.0)	7.9	1.52 (0.57, 4.01)	0.3994	0.0	0.8197
HP	15/ 89 (16.9)	9/ 84 (10.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	12/ 88 (13.6)	9/ 82 (11.0)	86.1	1/ 12 (8.3)	0/ 34 (0.0)	13.9	0.72 (0.34, 1.55)	0.4042	0.0	0.3607
Other ILD	5/ 43 (11.6)	5/ 38 (13.2)	90.4	0/ 5 (0.0)	0/ 6 (0.0)	9.6	1.12 (0.37, 3.39)	0.8425	0.0	0.9512
Region										
Europe										
Asia	10/ 76 (13.2)	11/ 79 (13.9)	88.4	1/ 27 (3.7)	1/ 54 (1.9)	11.6	0.99 (0.46, 2.13)	0.9869	0.0	0.6057
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Psychiatric disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	42/331 (12.7)	40/332 (12.0)	90.2	1/ 27 (3.7)	1/ 54 (1.9)	9.8	-0.76 (-5.35, 3.83)	0.0	0.8011
Age									
<65 years	15/121 (12.4)	19/139 (13.7)	90.2	0/ 9 (0.0)	1/ 25 (4.0)	9.8	1.52 (-6.00, 9.03)	0.0	0.7629
>=65 years	27/210 (12.9)	21/193 (10.9)	89.7	1/ 18 (5.6)	0/ 29 (0.0)	10.3	-2.32 (-8.13, 3.49)	0.0	0.6462
Sex									
Male	18/177 (10.2)	20/179 (11.2)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	0.92 (-5.03, 6.86)	0.0	0.8760
Female	24/154 (15.6)	20/153 (13.1)	88.3	1/ 16 (6.3)	1/ 28 (3.6)	11.7	-2.53 (-9.63, 4.57)	0.0	0.9836
Baseline FVC percent predicted									
<=70%	30/193 (15.5)	28/196 (14.3)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-1.18 (-7.86, 5.50)	0.0	0.8733
>70%	12/138 (8.7)	12/136 (8.8)	85.5	1/ 17 (5.9)	1/ 37 (2.7)	14.5	-0.35 (-6.35, 5.64)	0.0	0.6444
Baseline HRCT pattern									
UIP-like	26/206 (12.6)	30/206 (14.6)	86.8	1/ 23 (4.3)	0/ 45 (0.0)	13.2	1.13 (-4.76, 7.02)	2.8	0.3105
Other fibrotic patterns	16/125 (12.8)	10/126 (7.9)	95.2	0/ 4 (0.0)	1/ 9 (11.1)	4.8	-4.16 (-11.48, 3.16)	0.0	0.3872
Underlying ILD diagnosis									
iNSIP	5/ 61 (8.2)	7/ 64 (10.9)	86.8	0/ 7 (0.0)	1/ 11 (9.1)	13.2	3.46 (-6.03, 12.95)	0.0	0.6869
Unclassifiable IIP	5/ 50 (10.0)	10/ 64 (15.6)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	5.31 (-6.56, 17.18)	0.0	0.8391
HP	15/ 89 (16.9)	9/ 84 (10.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	12/ 88 (13.6)	9/ 82 (11.0)	82.1	1/ 12 (8.3)	0/ 34 (0.0)	17.9	-3.61 (-12.28, 5.05)	0.0	0.6004
Other ILD	5/ 43 (11.6)	5/ 38 (13.2)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	1.32 (-11.73, 14.36)	0.0	0.9264
Region									
Europe									
Asia	10/ 76 (13.2)	11/ 79 (13.9)	68.3	1/ 27 (3.7)	1/ 54 (1.9)	31.7	-0.06 (-7.84, 7.71)	0.0	0.7019
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Psychiatric disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	42/331 (12.7)	40/332 (12.0)	96.6	1/ 27 (3.7)	1/ 54 (1.9)	3.4	0.93 (0.59, 1.46)	0.0	0.6532
Age									
<65 years	15/121 (12.4)	19/139 (13.7)	97.4	0/ 9 (0.0)	1/ 25 (4.0)	2.6	1.15 (0.57, 2.35)	0.0	0.7152
>=65 years	27/210 (12.9)	21/193 (10.9)	93.2	1/ 18 (5.6)	0/ 29 (0.0)	6.8	0.79 (0.44, 1.43)	0.0	0.4695
Sex									
Male	18/177 (10.2)	20/179 (11.2)	97.5	0/ 11 (0.0)	0/ 26 (0.0)	2.5	1.11 (0.57, 2.16)	0.0	0.9625
Female	24/154 (15.6)	20/153 (13.1)	94.4	1/ 16 (6.3)	1/ 28 (3.6)	5.6	0.80 (0.43, 1.50)	0.0	0.7969
Baseline FVC percent predicted									
<=70%	30/193 (15.5)	28/196 (14.3)	98.3	0/ 10 (0.0)	0/ 17 (0.0)	1.7	0.91 (0.52, 1.58)	0.0	0.9628
>70%	12/138 (8.7)	12/136 (8.8)	89.1	1/ 17 (5.9)	1/ 37 (2.7)	10.9	0.95 (0.43, 2.13)	0.0	0.5834
Baseline HRCT pattern									
UIP-like	26/206 (12.6)	30/206 (14.6)	92.7	1/ 23 (4.3)	0/ 45 (0.0)	7.3	1.11 (0.64, 1.93)	4.1	0.3071
Other fibrotic patterns	16/125 (12.8)	10/126 (7.9)	97.6	0/ 4 (0.0)	1/ 9 (11.1)	2.4	0.64 (0.29, 1.42)	0.0	0.4627
Underlying ILD diagnosis									
iNSIP	5/ 61 (8.2)	7/ 64 (10.9)	91.7	0/ 7 (0.0)	1/ 11 (9.1)	8.3	1.50 (0.48, 4.67)	0.0	0.7040
Unclassifiable IIP	5/ 50 (10.0)	10/ 64 (15.6)	92.0	0/ 3 (0.0)	0/ 2 (0.0)	8.0	1.61 (0.54, 4.86)	0.0	0.8228
HP	15/ 89 (16.9)	9/ 84 (10.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	12/ 88 (13.6)	9/ 82 (11.0)	85.0	1/ 12 (8.3)	0/ 34 (0.0)	15.0	0.69 (0.29, 1.66)	0.0	0.3700
Other ILD	5/ 43 (11.6)	5/ 38 (13.2)	89.9	0/ 5 (0.0)	0/ 6 (0.0)	10.1	1.14 (0.32, 4.01)	0.0	0.9488
Region									
Europe									
Asia	10/ 76 (13.2)	11/ 79 (13.9)	87.0	1/ 27 (3.7)	1/ 54 (1.9)	13.0	0.99 (0.41, 2.38)	0.0	0.6064
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Renal and urinary disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	18/331 (5.4)	30/332 (9.0)	81.8	3/ 27 (11.1)	6/ 54 (11.1)	18.2	1.54 (0.92, 2.58)	0.1003	0.0	0.4844
Age										
<65 years	5/121 (4.1)	11/139 (7.9)	78.4	1/ 9 (11.1)	1/ 25 (4.0)	21.6	1.58 (0.62, 4.00)	0.3351	24.0	0.2515
>=65 years	13/210 (6.2)	19/193 (9.8)	83.5	2/ 18 (11.1)	5/ 29 (17.2)	16.5	1.58 (0.85, 2.94)	0.1459	0.0	0.9771
Sex										
Male	8/177 (4.5)	20/179 (11.2)	95.1	0/ 11 (0.0)	4/ 26 (15.4)	4.9	2.68 (1.23, 5.83)	0.0130	0.0	0.6005
Female	10/154 (6.5)	10/153 (6.5)	72.3	3/ 16 (18.8)	2/ 28 (7.1)	27.7	0.83 (0.40, 1.75)	0.6306	2.3	0.3116
Baseline FVC percent predicted										
<=70%	14/193 (7.3)	17/196 (8.7)	96.8	0/ 10 (0.0)	1/ 17 (5.9)	3.2	1.24 (0.64, 2.41)	0.5257	0.0	0.6701
>70%	4/138 (2.9)	13/136 (9.6)	49.1	3/ 17 (17.6)	5/ 37 (13.5)	50.9	2.01 (0.90, 4.49)	0.0884	64.4	0.0939
Baseline HRCT pattern										
UIP-like	8/206 (3.9)	19/206 (9.2)	66.8	3/ 23 (13.0)	6/ 45 (13.3)	33.2	1.93 (0.98, 3.77)	0.0561	15.3	0.2773
Other fibrotic patterns	10/125 (8.0)	11/126 (8.7)	95.9	0/ 4 (0.0)	0/ 9 (0.0)	4.1	1.09 (0.49, 2.43)	0.8379	0.0	0.9674
Underlying ILD diagnosis										
iNSIP	0/ 61 (0.0)	6/ 64 (9.4)	51.3	0/ 7 (0.0)	1/ 11 (9.1)	48.7	7.80 (0.94,64.95)	0.0574	0.0	0.4882
Unclassifiable IIP	0/ 50 (0.0)	6/ 64 (9.4)	50.6	0/ 3 (0.0)	0/ 2 (0.0)	49.4	6.41 (0.71,57.69)	0.0973	1.2	0.3143
HP	10/ 89 (11.2)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	4/ 88 (4.5)	6/ 82 (7.3)	46.5	3/ 12 (25.0)	4/ 34 (11.8)	53.5	1.00 (0.42, 2.41)	0.9989	42.9	0.1857
Other ILD	4/ 43 (9.3)	5/ 38 (13.2)	88.3	0/ 5 (0.0)	1/ 6 (16.7)	11.7	1.58 (0.50, 4.97)	0.4338	0.0	0.6852
Region										
Europe										
Asia	4/ 76 (5.3)	9/ 79 (11.4)	50.5	3/ 27 (11.1)	6/ 54 (11.1)	49.5	1.59 (0.68, 3.69)	0.2825	0.0	0.3818
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Renal and urinary disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	18/331 (5.4)	30/332 (9.0)	90.2	3/ 27 (11.1)	6/ 54 (11.1)	9.8	3.25 (-0.58, 7.07)	0.0	0.6392
Age									
<65 years	5/121 (4.1)	11/139 (7.9)	90.7	1/ 9 (11.1)	1/ 25 (4.0)	9.3	2.77 (-2.80, 8.34)	0.0	0.3460
>=65 years	13/210 (6.2)	19/193 (9.8)	90.1	2/ 18 (11.1)	5/ 29 (17.2)	9.9	3.90 (-1.29, 9.09)	0.0	0.8145
Sex									
Male	8/177 (4.5)	20/179 (11.2)	91.6	0/ 11 (0.0)	4/ 26 (15.4)	8.4	7.32 (2.05, 12.58)	0.0	0.3787
Female	10/154 (6.5)	10/153 (6.5)	88.3	3/ 16 (18.8)	2/ 28 (7.1)	11.7	-1.32 (-6.80, 4.16)	6.5	0.3010
Baseline FVC percent predicted									
<=70%	14/193 (7.3)	17/196 (8.7)	93.5	0/ 10 (0.0)	1/ 17 (5.9)	6.5	1.68 (-3.46, 6.83)	0.0	0.6562
>70%	4/138 (2.9)	13/136 (9.6)	85.5	3/ 17 (17.6)	5/ 37 (13.5)	14.5	5.09 (-0.66, 10.84)	0.0	0.3352
Baseline HRCT pattern									
UIP-like	8/206 (3.9)	19/206 (9.2)	87.1	3/ 23 (13.0)	6/ 45 (13.3)	12.9	4.69 (0.01, 9.37)	0.0	0.5744
Other fibrotic patterns	10/125 (8.0)	11/126 (8.7)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	0.69 (-5.96, 7.35)	0.0	0.9595
Underlying ILD diagnosis									
iNSIP	0/ 61 (0.0)	6/ 64 (9.4)	87.0	0/ 7 (0.0)	1/ 11 (9.1)	13.0	9.09 (1.74, 16.44)	0.0	0.9361
Unclassifiable IIP	0/ 50 (0.0)	6/ 64 (9.4)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	8.70 (0.82, 16.58)	0.0	0.7356
HP	10/ 89 (11.2)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	6/ 82 (7.3)	82.7	3/ 12 (25.0)	4/ 34 (11.8)	17.3	0.00 (-7.49, 7.50)	21.9	0.2577
Other ILD	4/ 43 (9.3)	5/ 38 (13.2)	86.2	0/ 5 (0.0)	1/ 6 (16.7)	13.8	5.27 (-7.70, 18.24)	0.0	0.6129
Region									
Europe									
Asia	4/ 76 (5.3)	9/ 79 (11.4)	68.3	3/ 27 (11.1)	6/ 54 (11.1)	31.7	4.18 (-3.29, 11.66)	0.0	0.4768
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Renal and urinary disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	18/331 (5.4)	30/332 (9.0)	82.2	3/ 27 (11.1)	6/ 54 (11.1)	17.8	1.60 (0.91, 2.80)	0.0	0.5004
Age									
<65 years	5/121 (4.1)	11/139 (7.9)	77.7	1/ 9 (11.1)	1/ 25 (4.0)	22.3	1.62 (0.60, 4.41)	22.7	0.2555
>=65 years	13/210 (6.2)	19/193 (9.8)	84.6	2/ 18 (11.1)	5/ 29 (17.2)	15.4	1.66 (0.84, 3.26)	0.0	0.9941
Sex									
Male	8/177 (4.5)	20/179 (11.2)	95.4	0/ 11 (0.0)	4/ 26 (15.4)	4.6	2.90 (1.27, 6.59)	0.0	0.5822
Female	10/154 (6.5)	10/153 (6.5)	72.4	3/ 16 (18.8)	2/ 28 (7.1)	27.6	0.82 (0.36, 1.85)	4.9	0.3052
Baseline FVC percent predicted									
<=70%	14/193 (7.3)	17/196 (8.7)	96.8	0/ 10 (0.0)	1/ 17 (5.9)	3.2	1.26 (0.62, 2.59)	0.0	0.6679
>70%	4/138 (2.9)	13/136 (9.6)	50.2	3/ 17 (17.6)	5/ 37 (13.5)	49.8	2.14 (0.87, 5.25)	60.8	0.1102
Baseline HRCT pattern									
UIP-like	8/206 (3.9)	19/206 (9.2)	67.8	3/ 23 (13.0)	6/ 45 (13.3)	32.2	2.04 (0.98, 4.24)	5.1	0.3048
Other fibrotic patterns	10/125 (8.0)	11/126 (8.7)	95.8	0/ 4 (0.0)	0/ 9 (0.0)	4.2	1.10 (0.46, 2.63)	0.0	0.9668
Underlying ILD diagnosis									
iNSIP	0/ 61 (0.0)	6/ 64 (9.4)	52.1	0/ 7 (0.0)	1/ 11 (9.1)	47.9	8.69 (0.95,79.57)	0.0	0.5062
Unclassifiable IIP	0/ 50 (0.0)	6/ 64 (9.4)	51.8	0/ 3 (0.0)	0/ 2 (0.0)	48.2	7.16 (0.76,67.32)	0.0	0.3451
HP	10/ 89 (11.2)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	6/ 82 (7.3)	47.8	3/ 12 (25.0)	4/ 34 (11.8)	52.2	1.00 (0.36, 2.75)	42.2	0.1886
Other ILD	4/ 43 (9.3)	5/ 38 (13.2)	89.4	0/ 5 (0.0)	1/ 6 (16.7)	10.6	1.68 (0.46, 6.04)	0.0	0.6717
Region									
Europe									
Asia	4/ 76 (5.3)	9/ 79 (11.4)	50.4	3/ 27 (11.1)	6/ 54 (11.1)	49.6	1.66 (0.65, 4.23)	0.0	0.3897
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Reproductive system and breast disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	13/331 (3.9)	3/332 (0.9)	96.7	0/ 27 (0.0)	0/ 54 (0.0)	3.3	0.26 (0.08, 0.83)	0.0228	0.0	0.5046
Age										
<65 years	2/121 (1.7)	2/139 (1.4)	84.6	0/ 9 (0.0)	0/ 25 (0.0)	15.4	0.89 (0.15, 5.26)	0.8982	0.0	0.9548
>=65 years	11/210 (5.2)	1/193 (0.5)	95.7	0/ 18 (0.0)	0/ 29 (0.0)	4.3	0.14 (0.02, 0.77)	0.0236	2.4	0.3116
Sex										
Male	9/177 (5.1)	1/179 (0.6)	95.6	0/ 11 (0.0)	0/ 26 (0.0)	4.4	0.15 (0.03, 0.86)	0.0335	0.0	0.3576
Female	4/154 (2.6)	2/153 (1.3)	89.6	0/ 16 (0.0)	0/ 28 (0.0)	10.4	0.55 (0.12, 2.59)	0.4541	0.0	0.7580
Baseline FVC percent predicted										
<=70%	11/193 (5.7)	3/196 (1.5)	96.0	0/ 10 (0.0)	0/ 17 (0.0)	4.0	0.30 (0.09, 0.98)	0.0455	0.0	0.5379
>70%	2/138 (1.4)	0/136 (0.0)	85.2	0/ 17 (0.0)	0/ 37 (0.0)	14.8	0.32 (0.03, 3.27)	0.3363	0.0	0.5431
Baseline HRCT pattern										
UIP-like										
Other fibrotic patterns										
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	2/ 76 (2.6)	1/ 79 (1.3)	82.1	0/ 27 (0.0)	0/ 54 (0.0)	17.9	0.57 (0.07, 4.40)	0.5933	0.0	0.7636
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Reproductive system and breast disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	13/331 (3.9)	3/332 (0.9)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	-2.72 (-4.87, -0.57)	14.0	0.2809
Age									
<65 years	2/121 (1.7)	2/139 (1.4)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	-0.19 (-3.16, 2.77)	0.0	0.9733
>=65 years	11/210 (5.2)	1/193 (0.5)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	-4.23 (-7.20, -1.26)	10.7	0.2900
Sex									
Male	9/177 (5.1)	1/179 (0.6)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-4.15 (-7.41, -0.89)	0.0	0.4356
Female	4/154 (2.6)	2/153 (1.3)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	-1.13 (-4.05, 1.78)	0.0	0.7855
Baseline FVC percent predicted									
<=70%	11/193 (5.7)	3/196 (1.5)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-3.90 (-7.47, -0.33)	0.0	0.5661
>70%	2/138 (1.4)	0/136 (0.0)	85.1	0/ 17 (0.0)	0/ 37 (0.0)	14.9	-1.22 (-3.57, 1.12)	0.0	0.7195
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	2/ 76 (2.6)	1/ 79 (1.3)	67.7	0/ 27 (0.0)	0/ 54 (0.0)	32.3	-0.93 (-4.29, 2.44)	0.0	0.6859
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Reproductive system and breast disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	13/331 (3.9)	3/332 (0.9)	96.7	0/ 27 (0.0)	0/ 54 (0.0)	3.3	0.25 (0.08, 0.81)	0.0	0.5010
Age									
<65 years	2/121 (1.7)	2/139 (1.4)	84.8	0/ 9 (0.0)	0/ 25 (0.0)	15.2	0.89 (0.15, 5.40)	0.0	0.9552
>=65 years	11/210 (5.2)	1/193 (0.5)	95.8	0/ 18 (0.0)	0/ 29 (0.0)	4.2	0.13 (0.02, 0.73)	2.8	0.3103
Sex									
Male	9/177 (5.1)	1/179 (0.6)	95.7	0/ 11 (0.0)	0/ 26 (0.0)	4.3	0.14 (0.03, 0.81)	0.0	0.3587
Female	4/154 (2.6)	2/153 (1.3)	89.7	0/ 16 (0.0)	0/ 28 (0.0)	10.3	0.55 (0.12, 2.61)	0.0	0.7585
Baseline FVC percent predicted									
<=70%	11/193 (5.7)	3/196 (1.5)	96.0	0/ 10 (0.0)	0/ 17 (0.0)	4.0	0.29 (0.09, 0.96)	0.0	0.5386
>70%	2/138 (1.4)	0/136 (0.0)	85.4	0/ 17 (0.0)	0/ 37 (0.0)	14.6	0.32 (0.03, 3.08)	0.0	0.5450
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	2/ 76 (2.6)	1/ 79 (1.3)	82.1	0/ 27 (0.0)	0/ 54 (0.0)	17.9	0.57 (0.07, 4.41)	0.0	0.7623
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	181/331 (54.7)	154/332 (46.4)	91.3	13/ 27 (48.1)	15/ 54 (27.8)	8.7	0.82 (0.71, 0.95)	0.0099	36.7	0.2087
Age										
<65 years	63/121 (52.1)	59/139 (42.4)	88.4	6/ 9 (66.7)	6/ 25 (24.0)	11.6	0.76 (0.60, 0.97)	0.0303	70.1	0.0673
>=65 years	118/210 (56.2)	95/193 (49.2)	92.9	7/ 18 (38.9)	9/ 29 (31.0)	7.1	0.87 (0.73, 1.04)	0.1352	0.0	0.8227
Sex										
Male	100/177 (56.5)	98/179 (54.7)	94.7	4/ 11 (36.4)	9/ 26 (34.6)	5.3	0.97 (0.81, 1.16)	0.7284	0.0	0.9710
Female	81/154 (52.6)	56/153 (36.6)	87.6	9/ 16 (56.3)	6/ 28 (21.4)	12.4	0.66 (0.51, 0.84)	0.0008	45.8	0.1744
Baseline FVC percent predicted										
<=70%	123/193 (63.7)	94/196 (48.0)	95.2	5/ 10 (50.0)	4/ 17 (23.5)	4.8	0.74 (0.62, 0.88)	0.0009	0.0	0.3911
>70%	58/138 (42.0)	60/136 (44.1)	84.0	8/ 17 (47.1)	11/ 37 (29.7)	16.0	0.98 (0.76, 1.27)	0.8935	42.1	0.1889
Baseline HRCT pattern										
UIP-like	112/206 (54.4)	97/206 (47.1)	88.5	11/ 23 (47.8)	11/ 45 (24.4)	11.5	0.83 (0.69, 0.99)	0.0404	54.8	0.1368
Other fibrotic patterns	69/125 (55.2)	57/126 (45.2)	96.2	2/ 4 (50.0)	4/ 9 (44.4)	3.8	0.82 (0.64, 1.05)	0.1154	0.0	0.8984
Underlying ILD diagnosis										
iNSIP	27/ 61 (44.3)	21/ 64 (32.8)	85.0	4/ 7 (57.1)	2/ 11 (18.2)	15.0	0.68 (0.44, 1.04)	0.0729	20.5	0.2621
Unclassifiable IIP	34/ 50 (68.0)	37/ 64 (57.8)	96.0	2/ 3 (66.7)	1/ 2 (50.0)	4.0	0.85 (0.64, 1.12)	0.2401	0.0	0.8798
HP	57/ 89 (64.0)	48/ 84 (57.1)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	41/ 88 (46.6)	24/ 82 (29.3)	84.3	5/ 12 (41.7)	9/ 34 (26.5)	15.7	0.63 (0.44, 0.91)	0.0134	0.0	0.9817
Other ILD	22/ 43 (51.2)	24/ 38 (63.2)	90.4	2/ 5 (40.0)	2/ 6 (33.3)	9.6	1.20 (0.83, 1.73)	0.3435	0.0	0.6314
Region										
Europe										
Asia	46/ 76 (60.5)	35/ 79 (44.3)	73.0	13/ 27 (48.1)	15/ 54 (27.8)	27.0	0.69 (0.53, 0.91)	0.0075	0.0	0.4780
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders

Subgroup / Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo: Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	181/331 (54.7)	154/332 (46.4)	90.2	13/ 27 (48.1)	15/ 54 (27.8)	9.8	-9.48 (-16.66, -2.30)	0.8	0.3154
Age									
<65 years	63/121 (52.1)	59/139 (42.4)	90.7	6/ 9 (66.7)	6/ 25 (24.0)	9.3	-12.69 (-24.15, -1.23)	67.2	0.0807
>=65 years	118/210 (56.2)	95/193 (49.2)	90.1	7/ 18 (38.9)	9/ 29 (31.0)	9.9	-7.06 (-16.26, 2.15)	0.0	0.9534
Sex									
Male	100/177 (56.5)	98/179 (54.7)	92.0	4/ 11 (36.4)	9/ 26 (34.6)	8.0	-1.75 (-11.62, 8.12)	0.0	1.0000
Female	81/154 (52.6)	56/153 (36.6)	88.3	9/ 16 (56.3)	6/ 28 (21.4)	11.7	-18.20 (-28.46, -7.95)	30.8	0.2294
Baseline FVC percent predicted									
<=70%	123/193 (63.7)	94/196 (48.0)	93.9	5/ 10 (50.0)	4/ 17 (23.5)	6.1	-16.42 (-25.84, -7.00)	0.0	0.5834
>70%	58/138 (42.0)	60/136 (44.1)	85.5	8/ 17 (47.1)	11/ 37 (29.7)	14.5	-0.73 (-11.54, 10.08)	36.7	0.2089
Baseline HRCT pattern									
UIP-like	112/206 (54.4)	97/206 (47.1)	87.1	11/ 23 (47.8)	11/ 45 (24.4)	12.9	-9.35 (-18.29, -0.42)	33.0	0.2218
Other fibrotic patterns	69/125 (55.2)	57/126 (45.2)	95.8	2/ 4 (50.0)	4/ 9 (44.4)	4.2	-9.78 (-21.82, 2.27)	0.0	0.8856
Underlying ILD diagnosis									
iNSIP	27/ 61 (44.3)	21/ 64 (32.8)	88.0	4/ 7 (57.1)	2/ 11 (18.2)	12.0	-14.76 (-30.56, 1.03)	26.0	0.2450
Unclassifiable IIP	34/ 50 (68.0)	37/ 64 (57.8)	95.9	2/ 3 (66.7)	1/ 2 (50.0)	4.1	-10.45 (-27.81, 6.90)	0.0	0.8868
HP	57/ 89 (64.0)	48/ 84 (57.1)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	41/ 88 (46.6)	24/ 82 (29.3)	82.7	5/ 12 (41.7)	9/ 34 (26.5)	17.3	-16.96 (-30.01, -3.90)	0.0	0.9044
Other ILD	22/ 43 (51.2)	24/ 38 (63.2)	88.1	2/ 5 (40.0)	2/ 6 (33.3)	11.9	9.77 (-10.28, 29.82)	0.0	0.5490
Region									
Europe									
Asia	46/ 76 (60.5)	35/ 79 (44.3)	68.3	13/ 27 (48.1)	15/ 54 (27.8)	31.7	-17.54 (-30.28, -4.80)	0.0	0.7648
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	181/331 (54.7)	154/332 (46.4)	88.6	13/ 27 (48.1)	15/ 54 (27.8)	11.4	0.68 (0.51, 0.91)	12.0	0.2864
Age									
<65 years	63/121 (52.1)	59/139 (42.4)	85.3	6/ 9 (66.7)	6/ 25 (24.0)	14.7	0.60 (0.38, 0.96)	63.3	0.0990
>=65 years	118/210 (56.2)	95/193 (49.2)	90.6	7/ 18 (38.9)	9/ 29 (31.0)	9.4	0.75 (0.52, 1.09)	0.0	0.9196
Sex									
Male	100/177 (56.5)	98/179 (54.7)	92.5	4/ 11 (36.4)	9/ 26 (34.6)	7.5	0.93 (0.62, 1.39)	0.0	0.9943
Female	81/154 (52.6)	56/153 (36.6)	85.0	9/ 16 (56.3)	6/ 28 (21.4)	15.0	0.47 (0.31, 0.73)	35.4	0.2135
Baseline FVC percent predicted									
<=70%	123/193 (63.7)	94/196 (48.0)	93.1	5/ 10 (50.0)	4/ 17 (23.5)	6.9	0.51 (0.34, 0.76)	0.0	0.5433
>70%	58/138 (42.0)	60/136 (44.1)	80.7	8/ 17 (47.1)	11/ 37 (29.7)	19.3	0.97 (0.62, 1.51)	37.9	0.2043
Baseline HRCT pattern									
UIP-like	112/206 (54.4)	97/206 (47.1)	84.3	11/ 23 (47.8)	11/ 45 (24.4)	15.7	0.69 (0.48, 0.99)	40.6	0.1943
Other fibrotic patterns	69/125 (55.2)	57/126 (45.2)	96.1	2/ 4 (50.0)	4/ 9 (44.4)	3.9	0.68 (0.42, 1.10)	0.0	0.8858
Underlying ILD diagnosis									
iNSIP	27/ 61 (44.3)	21/ 64 (32.8)	82.3	4/ 7 (57.1)	2/ 11 (18.2)	17.7	0.54 (0.27, 1.06)	21.9	0.2579
Unclassifiable IIP	34/ 50 (68.0)	37/ 64 (57.8)	95.3	2/ 3 (66.7)	1/ 2 (50.0)	4.7	0.64 (0.30, 1.36)	0.0	0.8941
HP	57/ 89 (64.0)	48/ 84 (57.1)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	41/ 88 (46.6)	24/ 82 (29.3)	83.7	5/ 12 (41.7)	9/ 34 (26.5)	16.3	0.48 (0.27, 0.85)	0.0	0.9375
Other ILD	22/ 43 (51.2)	24/ 38 (63.2)	83.9	2/ 5 (40.0)	2/ 6 (33.3)	16.1	1.49 (0.65, 3.44)	0.0	0.5598
Region									
Europe									
Asia	46/ 76 (60.5)	35/ 79 (44.3)	67.6	13/ 27 (48.1)	15/ 54 (27.8)	32.4	0.48 (0.28, 0.83)	0.0	0.7024
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Skin and subcutaneous tissue disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	56/331 (16.9)	76/332 (22.9)	91.3	4/ 27 (14.8)	3/ 54 (5.6)	8.7	1.27 (0.94, 1.71)	0.1205	66.4	0.0844
Age										
<65 years	17/121 (14.0)	36/139 (25.9)	90.7	1/ 9 (11.1)	0/ 25 (0.0)	9.3	1.69 (1.02, 2.80)	0.0406	56.1	0.1313
>=65 years	39/210 (18.6)	40/193 (20.7)	91.0	3/ 18 (16.7)	3/ 29 (10.3)	9.0	1.07 (0.73, 1.57)	0.7231	0.0	0.4553
Sex										
Male	28/177 (15.8)	37/179 (20.7)	95.2	1/ 11 (9.1)	1/ 26 (3.8)	4.8	1.26 (0.82, 1.96)	0.2922	0.0	0.4160
Female	28/154 (18.2)	39/153 (25.5)	88.0	3/ 16 (18.8)	2/ 28 (7.1)	12.0	1.28 (0.85, 1.93)	0.2415	53.9	0.1410
Baseline FVC percent predicted										
<=70%	30/193 (15.5)	52/196 (26.5)	96.0	1/ 10 (10.0)	1/ 17 (5.9)	4.0	1.66 (1.12, 2.47)	0.0122	0.0	0.4376
>70%	26/138 (18.8)	24/136 (17.6)	86.3	3/ 17 (17.6)	2/ 37 (5.4)	13.7	0.85 (0.53, 1.37)	0.5029	34.9	0.2151
Baseline HRCT pattern										
UIP-like	36/206 (17.5)	46/206 (22.3)	87.2	4/ 23 (17.4)	3/ 45 (6.7)	12.8	1.16 (0.80, 1.69)	0.4261	61.5	0.1068
Other fibrotic patterns	20/125 (16.0)	30/126 (23.8)	97.9	0/ 4 (0.0)	0/ 9 (0.0)	2.1	1.48 (0.89, 2.45)	0.1294	0.0	0.8505
Underlying ILD diagnosis										
iNSIP	7/ 61 (11.5)	15/ 64 (23.4)	93.8	0/ 7 (0.0)	0/ 11 (0.0)	6.2	1.98 (0.88, 4.43)	0.0972	0.0	0.7267
Unclassifiable IIP	9/ 50 (18.0)	17/ 64 (26.6)	95.5	0/ 3 (0.0)	0/ 2 (0.0)	4.5	1.45 (0.72, 2.94)	0.2977	0.0	0.8398
HP	21/ 89 (23.6)	16/ 84 (19.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	17/ 88 (19.3)	23/ 82 (28.0)	78.7	3/ 12 (25.0)	3/ 34 (8.8)	21.3	1.22 (0.74, 2.01)	0.4407	68.4	0.0754
Other ILD	2/ 43 (4.7)	5/ 38 (13.2)	54.2	1/ 5 (20.0)	0/ 6 (0.0)	45.8	1.68 (0.48, 5.87)	0.4193	41.1	0.1928
Region										
Europe										
Asia	20/ 76 (26.3)	25/ 79 (31.6)	79.3	4/ 27 (14.8)	3/ 54 (5.6)	20.7	1.03 (0.65, 1.63)	0.8969	56.4	0.1299
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Skin and subcutaneous tissue disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	56/331 (16.9)	76/332 (22.9)	90.2	4/ 27 (14.8)	3/ 54 (5.6)	9.8	4.48 (-1.17, 10.14)	71.5	0.0608
Age									
<65 years	17/121 (14.0)	36/139 (25.9)	90.2	1/ 9 (11.1)	0/ 25 (0.0)	9.8	9.67 (0.77, 18.57)	69.0	0.0725
>=65 years	39/210 (18.6)	40/193 (20.7)	90.1	3/ 18 (16.7)	3/ 29 (10.3)	9.9	1.31 (-5.98, 8.60)	0.0	0.4481
Sex									
Male	28/177 (15.8)	37/179 (20.7)	92.0	1/ 11 (9.1)	1/ 26 (3.8)	8.0	4.04 (-3.47, 11.56)	0.0	0.3269
Female	28/154 (18.2)	39/153 (25.5)	88.3	3/ 16 (18.8)	2/ 28 (7.1)	11.7	5.09 (-3.41, 13.60)	60.6	0.1111
Baseline FVC percent predicted									
<=70%	30/193 (15.5)	52/196 (26.5)	93.9	1/ 10 (10.0)	1/ 17 (5.9)	6.1	10.07 (2.42, 17.72)	38.9	0.2007
>70%	26/138 (18.8)	24/136 (17.6)	85.5	3/ 17 (17.6)	2/ 37 (5.4)	14.5	-2.80 (-11.11, 5.52)	0.8	0.3153
Baseline HRCT pattern									
UIP-like	36/206 (17.5)	46/206 (22.3)	87.1	4/ 23 (17.4)	3/ 45 (6.7)	12.9	2.85 (-4.21, 9.91)	62.2	0.1038
Other fibrotic patterns	20/125 (16.0)	30/126 (23.8)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	7.43 (-2.02, 16.88)	0.0	0.5984
Underlying ILD diagnosis									
iNSIP	7/ 61 (11.5)	15/ 64 (23.4)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	10.38 (-1.28, 22.04)	0.0	0.3199
Unclassifiable IIP	9/ 50 (18.0)	17/ 64 (26.6)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	8.08 (-6.55, 22.71)	0.0	0.7605
HP	21/ 89 (23.6)	16/ 84 (19.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	17/ 88 (19.3)	23/ 82 (28.0)	82.7	3/ 12 (25.0)	3/ 34 (8.8)	17.3	4.43 (-7.06, 15.91)	64.2	0.0948
Other ILD	2/ 43 (4.7)	5/ 38 (13.2)	86.2	1/ 5 (20.0)	0/ 6 (0.0)	13.8	5.00 (-7.06, 17.07)	29.7	0.2330
Region									
Europe									
Asia	20/ 76 (26.3)	25/ 79 (31.6)	68.3	4/ 27 (14.8)	3/ 54 (5.6)	31.7	0.70 (-10.09, 11.50)	48.6	0.1630
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Skin and subcutaneous tissue disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	56/331 (16.9)	76/332 (22.9)	89.6	4/ 27 (14.8)	3/ 54 (5.6)	10.4	1.34 (0.92, 1.95)	67.9	0.0775
Age									
<65 years	17/121 (14.0)	36/139 (25.9)	88.2	1/ 9 (11.1)	0/ 25 (0.0)	11.8	1.91 (1.03, 3.53)	59.4	0.1168
>=65 years	39/210 (18.6)	40/193 (20.7)	89.9	3/ 18 (16.7)	3/ 29 (10.3)	10.1	1.09 (0.68, 1.75)	0.0	0.4524
Sex									
Male	28/177 (15.8)	37/179 (20.7)	94.3	1/ 11 (9.1)	1/ 26 (3.8)	5.7	1.33 (0.78, 2.26)	0.0	0.4037
Female	28/154 (18.2)	39/153 (25.5)	85.4	3/ 16 (18.8)	2/ 28 (7.1)	14.6	1.36 (0.81, 2.30)	56.1	0.1311
Baseline FVC percent predicted									
<=70%	30/193 (15.5)	52/196 (26.5)	94.9	1/ 10 (10.0)	1/ 17 (5.9)	5.1	1.89 (1.15, 3.10)	0.0	0.4038
>70%	26/138 (18.8)	24/136 (17.6)	84.5	3/ 17 (17.6)	2/ 37 (5.4)	15.5	0.82 (0.46, 1.47)	33.1	0.2214
Baseline HRCT pattern									
UIP-like	36/206 (17.5)	46/206 (22.3)	85.0	4/ 23 (17.4)	3/ 45 (6.7)	15.0	1.20 (0.76, 1.91)	62.5	0.1026
Other fibrotic patterns	20/125 (16.0)	30/126 (23.8)	97.5	0/ 4 (0.0)	0/ 9 (0.0)	2.5	1.62 (0.87, 3.03)	0.0	0.8270
Underlying ILD diagnosis									
iNSIP	7/ 61 (11.5)	15/ 64 (23.4)	92.4	0/ 7 (0.0)	0/ 11 (0.0)	7.6	2.26 (0.87, 5.84)	0.0	0.6911
Unclassifiable IIP	9/ 50 (18.0)	17/ 64 (26.6)	94.7	0/ 3 (0.0)	0/ 2 (0.0)	5.3	1.61 (0.66, 3.93)	0.0	0.8246
HP	21/ 89 (23.6)	16/ 84 (19.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	17/ 88 (19.3)	23/ 82 (28.0)	74.5	3/ 12 (25.0)	3/ 34 (8.8)	25.5	1.29 (0.67, 2.48)	68.3	0.0759
Other ILD	2/ 43 (4.7)	5/ 38 (13.2)	52.7	1/ 5 (20.0)	0/ 6 (0.0)	47.3	1.76 (0.44, 7.04)	41.5	0.1910
Region									
Europe									
Asia	20/ 76 (26.3)	25/ 79 (31.6)	73.5	4/ 27 (14.8)	3/ 54 (5.6)	26.5	1.04 (0.55, 1.96)	57.2	0.1264
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Vascular disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	43/331 (13.0)	37/332 (11.1)	97.0	1/ 27 (3.7)	4/ 54 (7.4)	3.0	0.89 (0.60, 1.34)	0.5797	0.0	0.4469
Age										
<65 years	15/121 (12.4)	15/139 (10.8)	91.6	1/ 9 (11.1)	2/ 25 (8.0)	8.4	0.86 (0.45, 1.64)	0.6414	0.0	0.8755
>=65 years	28/210 (13.3)	22/193 (11.4)	98.3	0/ 18 (0.0)	2/ 29 (6.9)	1.7	0.91 (0.55, 1.53)	0.7296	0.0	0.3534
Sex										
Male	20/177 (11.3)	16/179 (8.9)	98.0	0/ 11 (0.0)	2/ 26 (7.7)	2.0	0.85 (0.46, 1.57)	0.6100	0.0	0.4118
Female	23/154 (14.9)	21/153 (13.7)	94.7	1/ 16 (6.3)	2/ 28 (7.1)	5.3	0.93 (0.55, 1.59)	0.7920	0.0	0.8578
Baseline FVC percent predicted										
<=70%	29/193 (15.0)	23/196 (11.7)	94.4	1/ 10 (10.0)	0/ 17 (0.0)	5.6	0.75 (0.46, 1.24)	0.2649	0.0	0.4781
>70%	14/138 (10.1)	14/136 (10.3)	97.0	0/ 17 (0.0)	4/ 37 (10.8)	3.0	1.19 (0.60, 2.35)	0.6157	5.6	0.3033
Baseline HRCT pattern										
UIP-like	22/206 (10.7)	22/206 (10.7)	94.3	1/ 23 (4.3)	4/ 45 (8.9)	5.7	1.06 (0.62, 1.82)	0.8341	0.0	0.5250
Other fibrotic patterns	21/125 (16.8)	15/126 (11.9)	98.0	0/ 4 (0.0)	0/ 9 (0.0)	2.0	0.71 (0.39, 1.31)	0.2780	0.0	0.8707
Underlying ILD diagnosis										
iNSIP	7/ 61 (11.5)	5/ 64 (7.8)	85.4	1/ 7 (14.3)	2/ 11 (18.2)	14.6	0.77 (0.29, 2.03)	0.5928	0.0	0.6183
Unclassifiable IIP	7/ 50 (14.0)	6/ 64 (9.4)	94.2	0/ 3 (0.0)	0/ 2 (0.0)	5.8	0.69 (0.26, 1.85)	0.4590	0.0	0.8380
HP	10/ 89 (11.2)	13/ 84 (15.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	11/ 88 (12.5)	8/ 82 (9.8)	96.5	0/ 12 (0.0)	2/ 34 (5.9)	3.5	0.88 (0.39, 2.03)	0.7691	0.0	0.4516
Other ILD	8/ 43 (18.6)	5/ 38 (13.2)	93.8	0/ 5 (0.0)	0/ 6 (0.0)	6.2	0.73 (0.27, 1.96)	0.5257	0.0	0.8625
Region										
Europe										
Asia	3/ 76 (3.9)	9/ 79 (11.4)	69.6	1/ 27 (3.7)	4/ 54 (7.4)	30.4	2.62 (0.88, 7.77)	0.0830	0.0	0.7728
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Vascular disorders

Subgroup / Category	Trial 1199_0247: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247: Wt	Trial 1199_0434: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434: Wt	Fixed effects: Nin 150bid vs Placebo: Risk difference (95% CI)	Heterogeneity: I^2	Heterogeneity: p-value
Overall	43/331 (13.0)	37/332 (11.1)	90.2	1/ 27 (3.7)	4/ 54 (7.4)	9.8	-1.30 (-5.88, 3.27)	0.0	0.3289
Age									
<65 years	15/121 (12.4)	15/139 (10.8)	90.7	1/ 9 (11.1)	2/ 25 (8.0)	9.3	-1.75 (-9.15, 5.66)	0.0	0.9038
>=65 years	28/210 (13.3)	22/193 (11.4)	89.7	0/ 18 (0.0)	2/ 29 (6.9)	10.3	-1.05 (-6.94, 4.84)	35.0	0.2150
Sex									
Male	20/177 (11.3)	16/179 (8.9)	91.6	0/ 11 (0.0)	2/ 26 (7.7)	8.4	-1.55 (-7.41, 4.31)	31.2	0.2280
Female	23/154 (14.9)	21/153 (13.7)	88.3	1/ 16 (6.3)	2/ 28 (7.1)	11.7	-0.96 (-8.11, 6.18)	0.0	0.8098
Baseline FVC percent predicted									
<=70%	29/193 (15.0)	23/196 (11.7)	93.5	1/ 10 (10.0)	0/ 17 (0.0)	6.5	-3.68 (-10.16, 2.79)	0.0	0.6028
>70%	14/138 (10.1)	14/136 (10.3)	85.0	0/ 17 (0.0)	4/ 37 (10.8)	15.0	1.69 (-4.67, 8.05)	51.4	0.1513
Baseline HRCT pattern									
UIP-like	22/206 (10.7)	22/206 (10.7)	87.1	1/ 23 (4.3)	4/ 45 (8.9)	12.9	0.58 (-4.83, 6.00)	0.0	0.5001
Other fibrotic patterns	21/125 (16.8)	15/126 (11.9)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-4.66 (-13.00, 3.68)	0.0	0.7380
Underlying ILD diagnosis									
iNSIP	7/ 61 (11.5)	5/ 64 (7.8)	88.0	1/ 7 (14.3)	2/ 11 (18.2)	12.0	-2.75 (-12.76, 7.26)	0.0	0.6810
Unclassifiable IIP	7/ 50 (14.0)	6/ 64 (9.4)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	-4.36 (-16.05, 7.33)	0.0	0.8673
HP	10/ 89 (11.2)	13/ 84 (15.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	11/ 88 (12.5)	8/ 82 (9.8)	82.1	0/ 12 (0.0)	2/ 34 (5.9)	17.9	-1.24 (-9.27, 6.79)	15.2	0.2774
Other ILD	8/ 43 (18.6)	5/ 38 (13.2)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	-4.70 (-18.93, 9.53)	0.0	0.7472
Region									
Europe									
Asia	3/ 76 (3.9)	9/ 79 (11.4)	68.3	1/ 27 (3.7)	4/ 54 (7.4)	31.7	6.26 (-0.21, 12.73)	0.0	0.5713
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

SOC: Vascular disorders

Subgroup / Category	Trial 1199_0247: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247: Wt	Trial 1199_0434: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434: Wt	Fixed effects: Nin 150bid vs Placebo: Odds ratio (95% CI)	Heterogeneity: I^2	Heterogeneity: p-value
Overall	43/331 (13.0)	37/332 (11.1)	96.9	1/ 27 (3.7)	4/ 54 (7.4)	3.1	0.88 (0.56, 1.39)	0.0	0.4378
Age									
<65 years	15/121 (12.4)	15/139 (10.8)	91.4	1/ 9 (11.1)	2/ 25 (8.0)	8.6	0.84 (0.41, 1.74)	0.0	0.8786
>=65 years	28/210 (13.3)	22/193 (11.4)	98.2	0/ 18 (0.0)	2/ 29 (6.9)	1.8	0.90 (0.51, 1.61)	0.0	0.3420
Sex									
Male	20/177 (11.3)	16/179 (8.9)	98.0	0/ 11 (0.0)	2/ 26 (7.7)	2.0	0.84 (0.43, 1.64)	0.0	0.3986
Female	23/154 (14.9)	21/153 (13.7)	94.4	1/ 16 (6.3)	2/ 28 (7.1)	5.6	0.92 (0.50, 1.71)	0.0	0.8534
Baseline FVC percent predicted									
<=70%	29/193 (15.0)	23/196 (11.7)	93.9	1/ 10 (10.0)	0/ 17 (0.0)	6.1	0.72 (0.41, 1.28)	0.0	0.4831
>70%	14/138 (10.1)	14/136 (10.3)	97.1	0/ 17 (0.0)	4/ 37 (10.8)	2.9	1.21 (0.58, 2.54)	10.7	0.2898
Baseline HRCT pattern									
UIP-like	22/206 (10.7)	22/206 (10.7)	94.2	1/ 23 (4.3)	4/ 45 (8.9)	5.8	1.07 (0.59, 1.94)	0.0	0.5218
Other fibrotic patterns	21/125 (16.8)	15/126 (11.9)	97.9	0/ 4 (0.0)	0/ 9 (0.0)	2.1	0.68 (0.33, 1.37)	0.0	0.8597
Underlying ILD diagnosis									
iNSIP	7/ 61 (11.5)	5/ 64 (7.8)	86.9	1/ 7 (14.3)	2/ 11 (18.2)	13.1	0.74 (0.25, 2.19)	0.0	0.6274
Unclassifiable IIP	7/ 50 (14.0)	6/ 64 (9.4)	94.5	0/ 3 (0.0)	0/ 2 (0.0)	5.5	0.66 (0.21, 2.01)	0.0	0.8426
HP	10/ 89 (11.2)	13/ 84 (15.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	11/ 88 (12.5)	8/ 82 (9.8)	96.4	0/ 12 (0.0)	2/ 34 (5.9)	3.6	0.87 (0.35, 2.16)	0.0	0.4399
Other ILD	8/ 43 (18.6)	5/ 38 (13.2)	93.4	0/ 5 (0.0)	0/ 6 (0.0)	6.6	0.68 (0.21, 2.19)	0.0	0.8504
Region									
Europe									
Asia	3/ 76 (3.9)	9/ 79 (11.4)	68.7	1/ 27 (3.7)	4/ 54 (7.4)	31.3	2.80 (0.88, 8.91)	0.0	0.7597
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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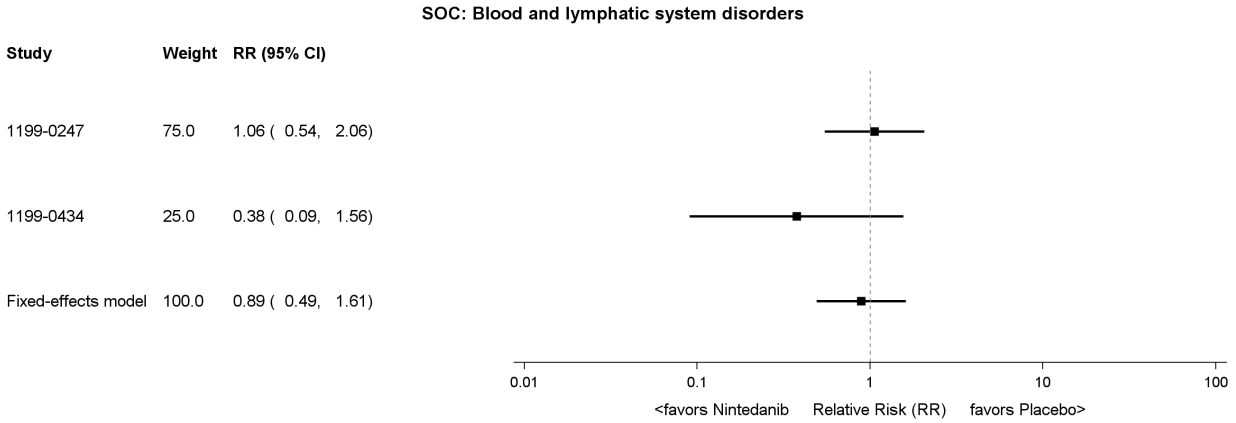

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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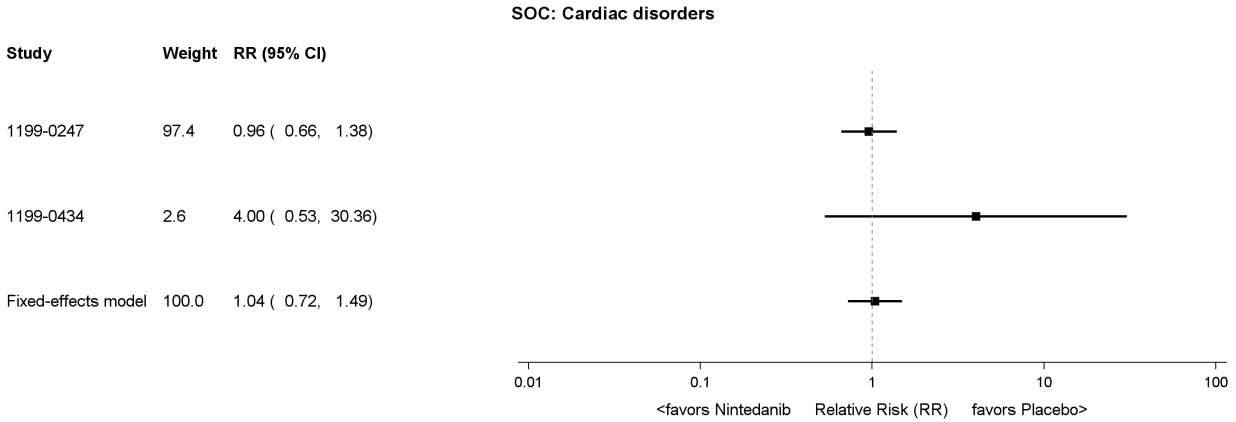

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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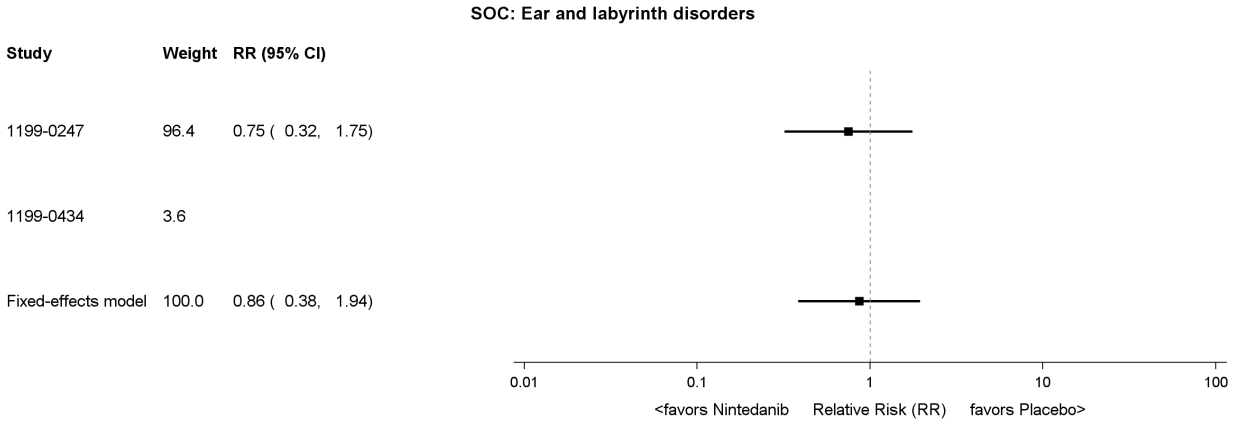

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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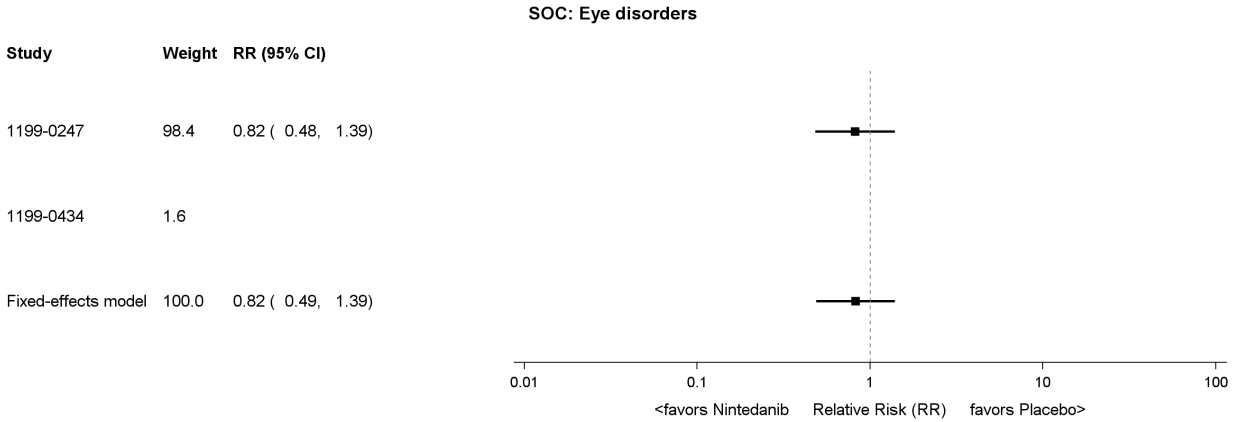

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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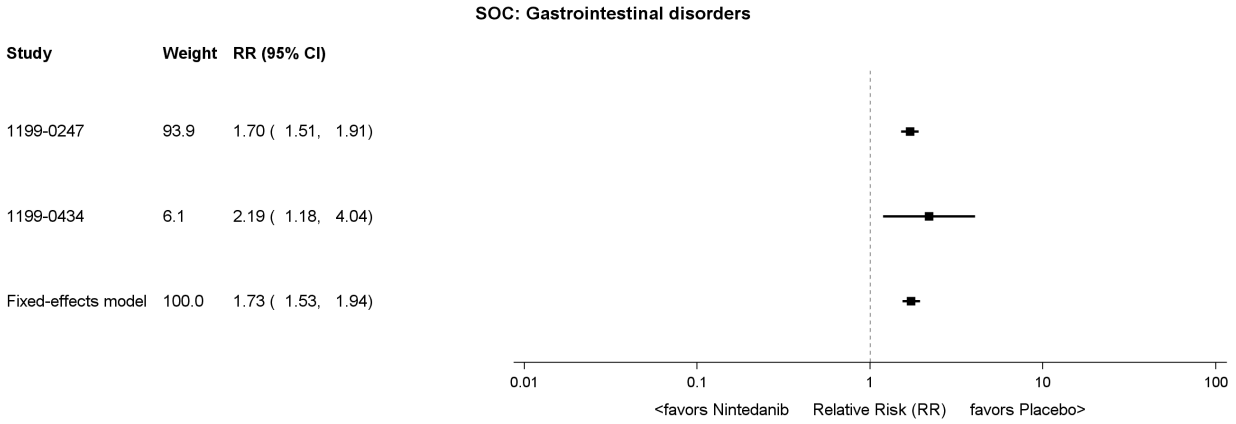

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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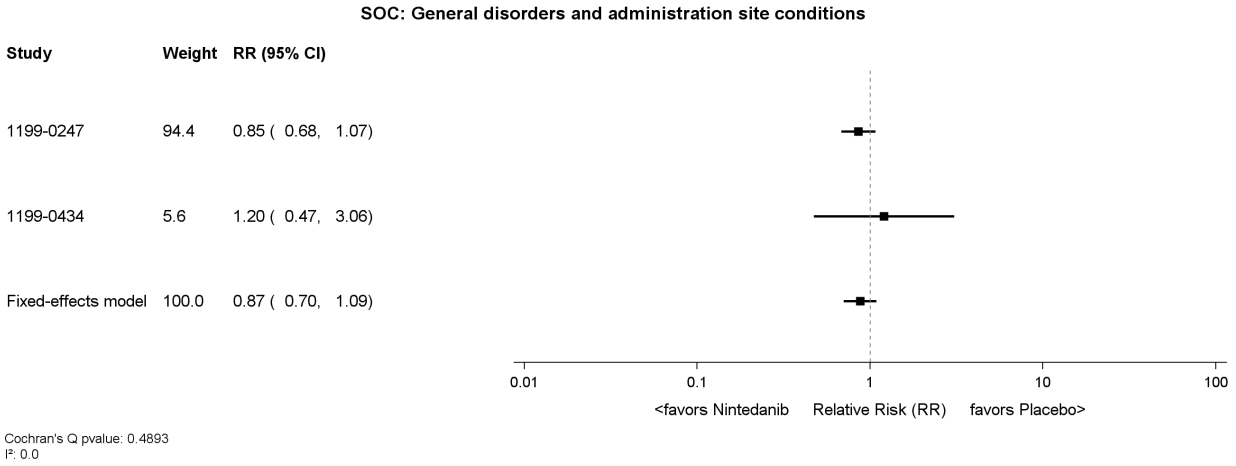

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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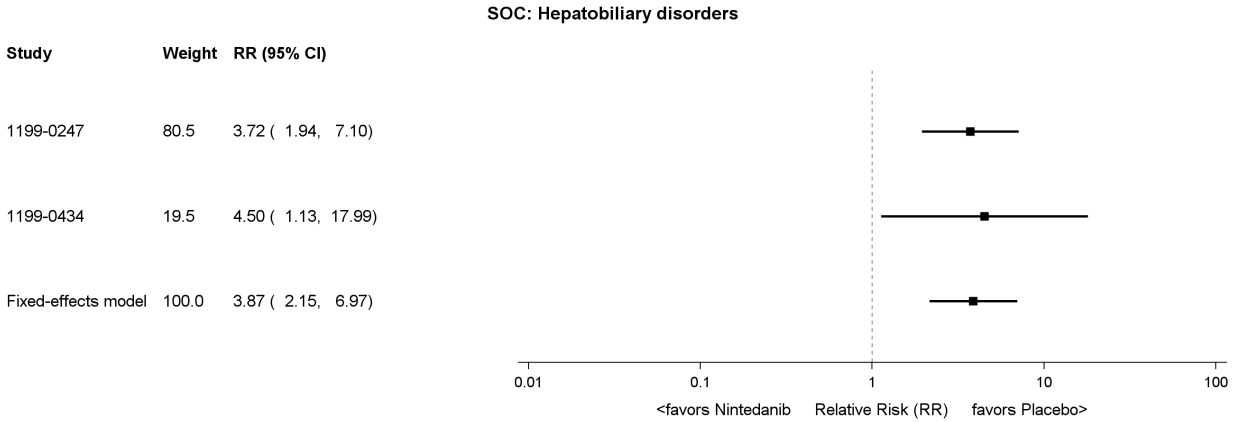

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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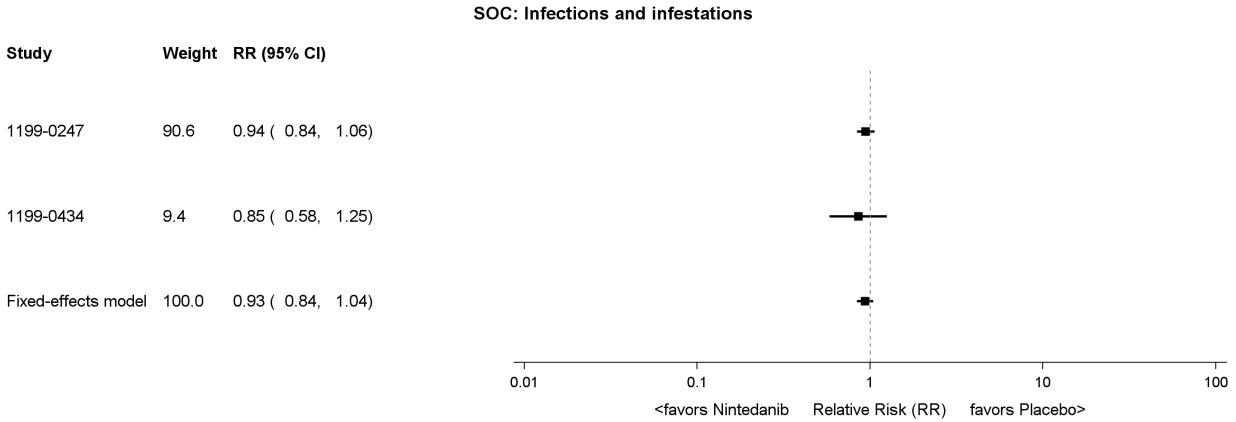

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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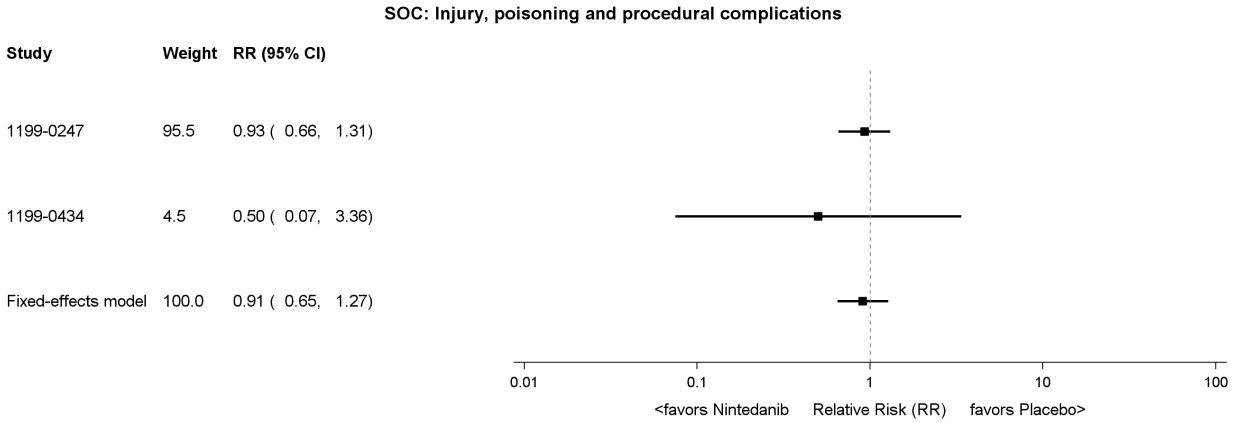

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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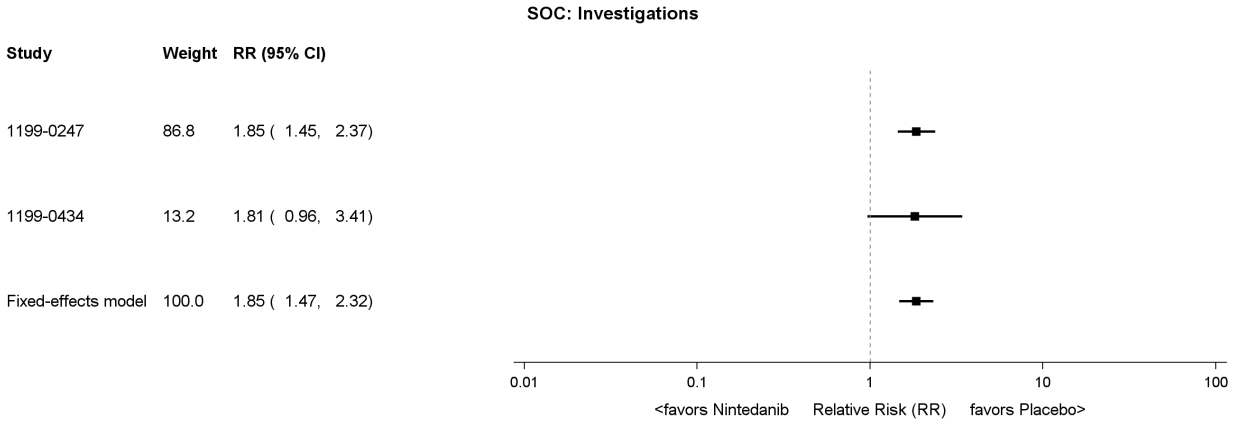

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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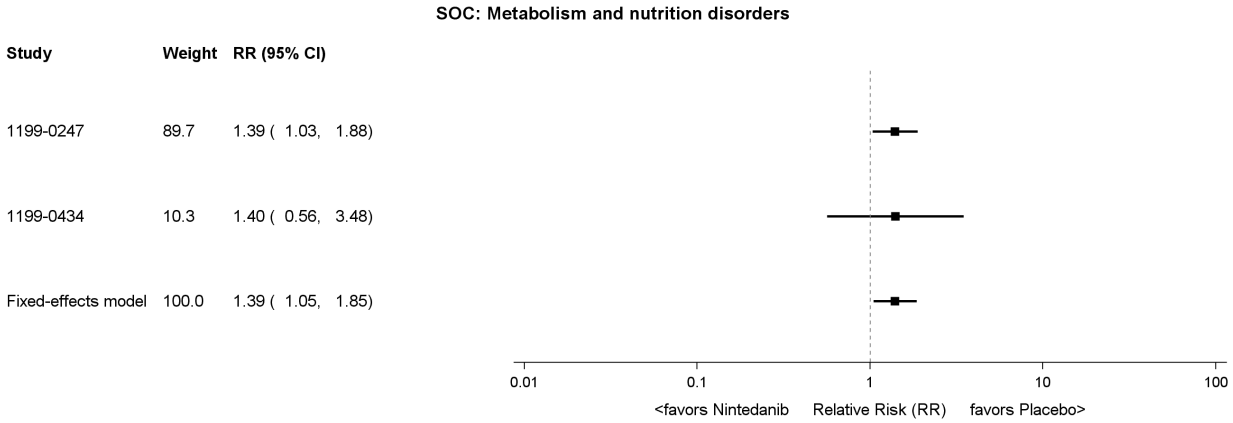

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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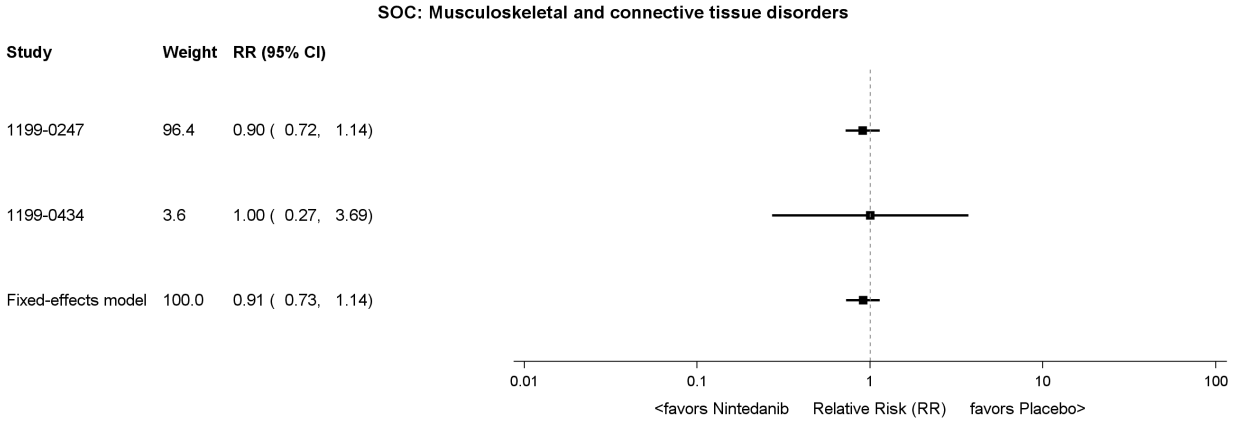

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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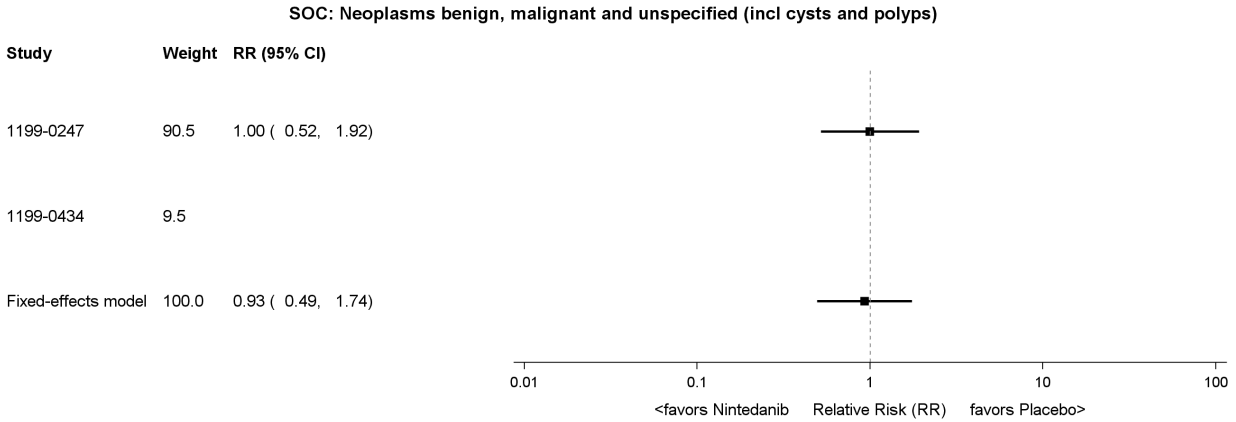

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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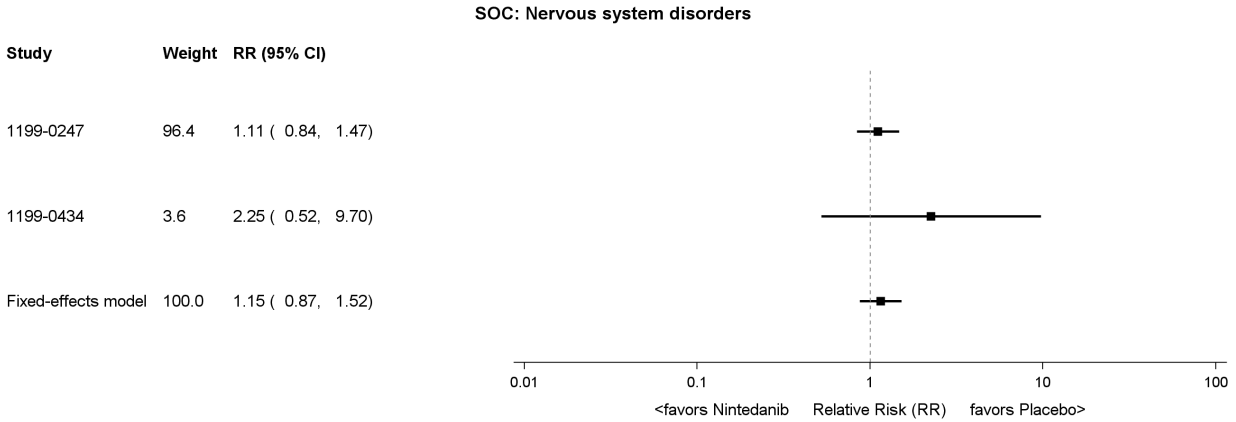

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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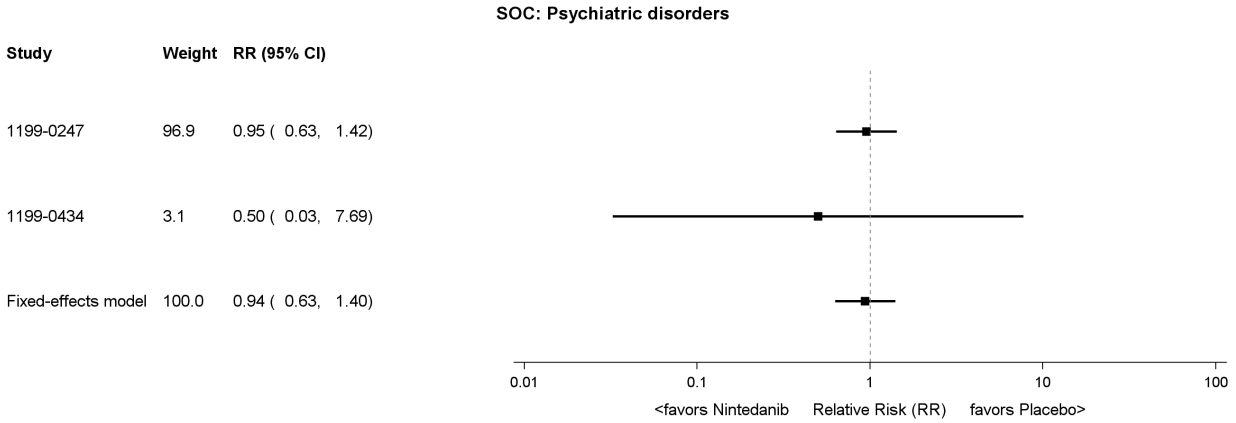

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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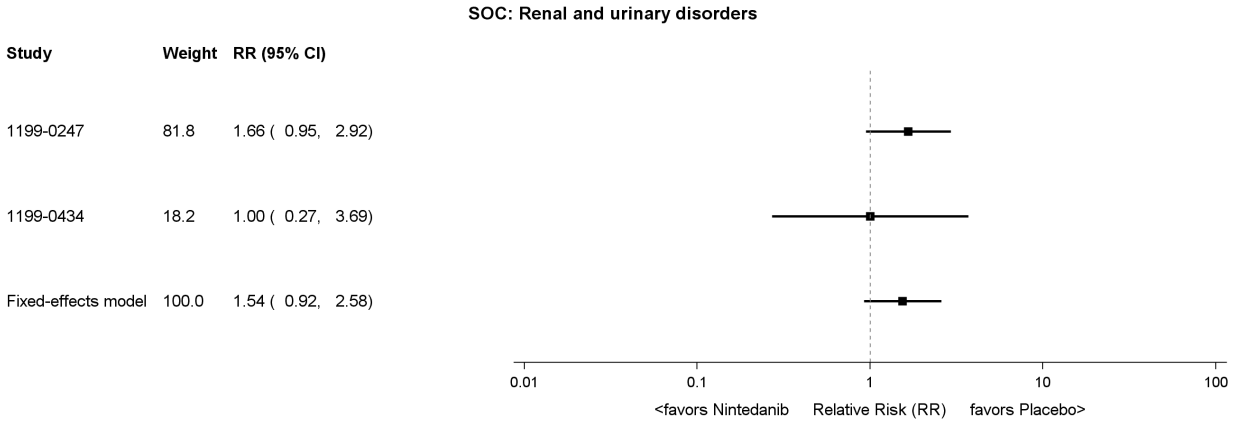

Cochran's Q pvalue: 0.4844
I²: 0.0

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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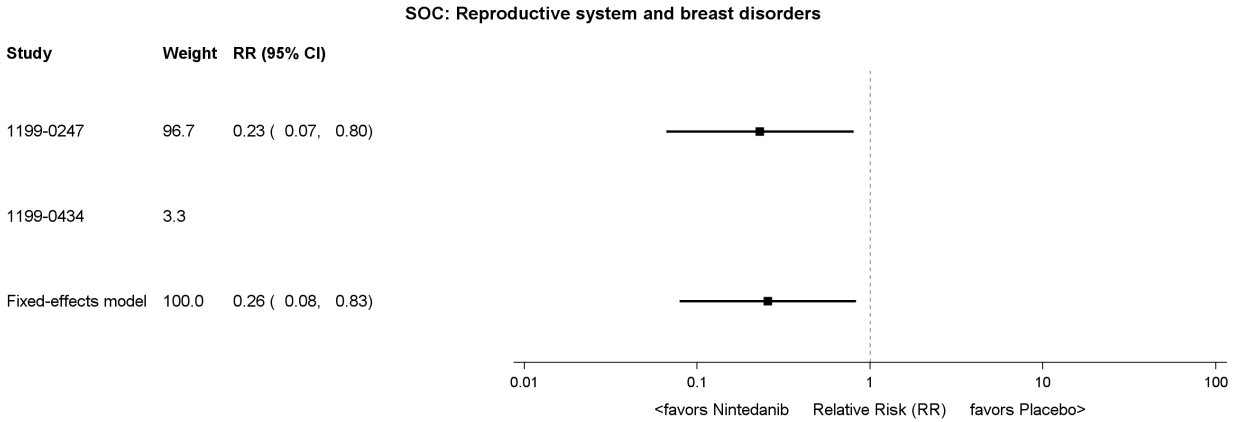

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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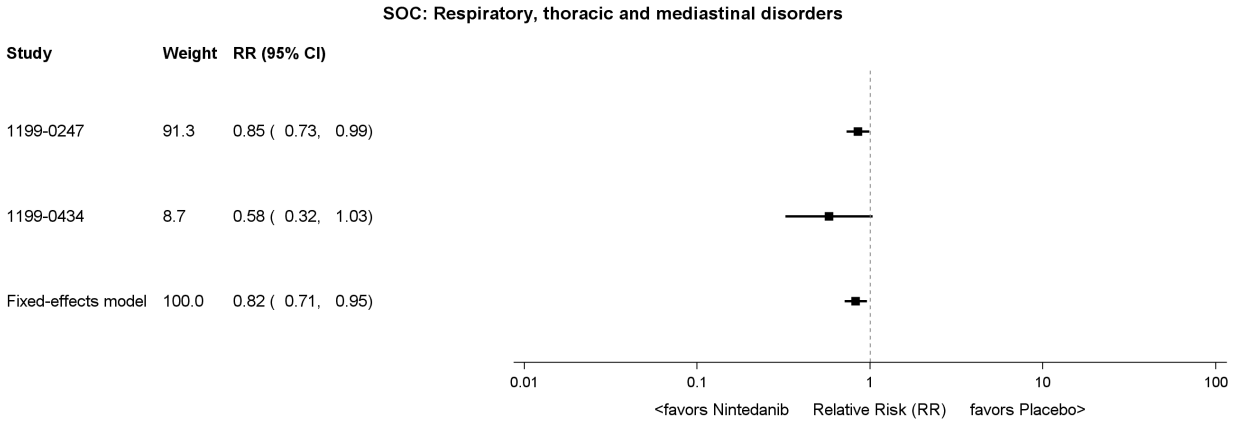

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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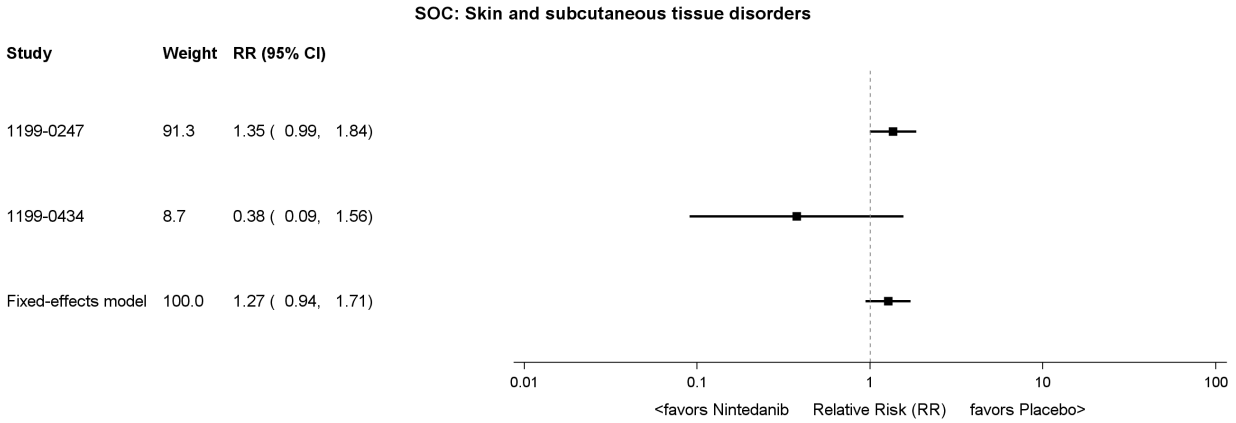

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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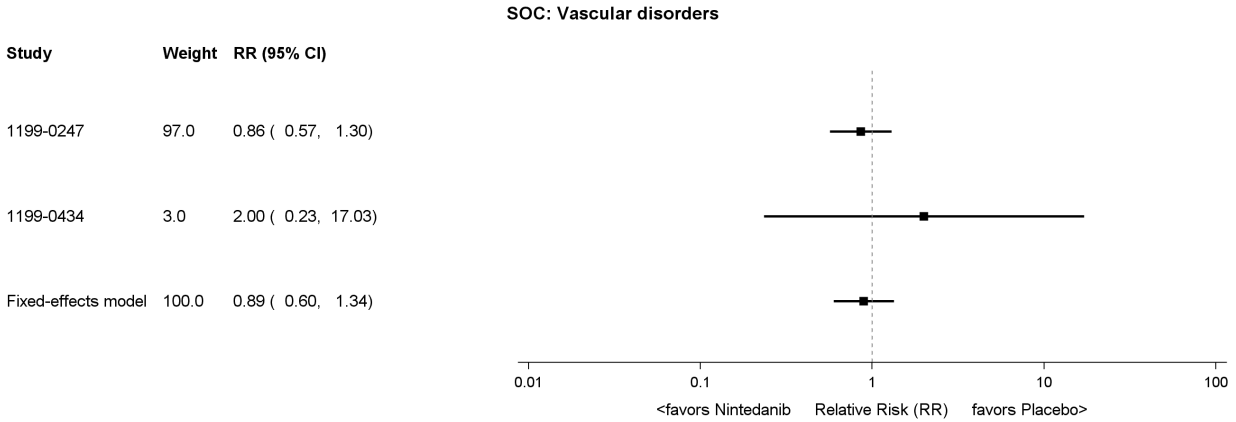

Figure M.2.2.1.3: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC over the whole trial

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Cardiac disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	24/331 (7.3)	23/332 (6.9)	94.7	1/ 27 (3.7)	4/ 54 (7.4)	5.3	1.01 (0.59, 1.72)	0.9698	0.0	0.5127
Age										
<65 years	4/121 (3.3)	3/139 (2.2)	91.7	0/ 9 (0.0)	1/ 25 (4.0)	8.3	0.80 (0.20, 3.09)	0.7406	0.0	0.5567
>=65 years	20/210 (9.5)	20/193 (10.4)	93.9	1/ 18 (5.6)	3/ 29 (10.3)	6.1	1.13 (0.64, 2.00)	0.6617	0.0	0.6417
Sex										
Male	19/177 (10.7)	17/179 (9.5)	93.1	1/ 11 (9.1)	2/ 26 (7.7)	6.9	0.88 (0.48, 1.61)	0.6814	0.0	0.9707
Female	5/154 (3.2)	6/153 (3.9)	91.5	0/ 16 (0.0)	2/ 28 (7.1)	8.5	1.46 (0.49, 4.32)	0.4973	0.0	0.5032
Baseline FVC percent predicted										
<=70%	17/193 (8.8)	12/196 (6.1)	97.3	0/ 10 (0.0)	1/ 17 (5.9)	2.7	0.75 (0.37, 1.49)	0.4043	0.0	0.4691
>70%	7/138 (5.1)	11/136 (8.1)	83.5	1/ 17 (5.9)	3/ 37 (8.1)	16.5	1.56 (0.67, 3.63)	0.3037	0.0	0.9043
Baseline HRCT pattern										
UIP-like	16/206 (7.8)	17/206 (8.3)	92.4	1/ 23 (4.3)	4/ 45 (8.9)	7.6	1.14 (0.61, 2.12)	0.6857	0.0	0.5653
Other fibrotic patterns	8/125 (6.4)	6/126 (4.8)	95.0	0/ 4 (0.0)	0/ 9 (0.0)	5.0	0.76 (0.28, 2.05)	0.5843	0.0	0.8910
Underlying ILD diagnosis										
iNSIP	0/ 61 (0.0)	5/ 64 (7.8)	51.3	0/ 7 (0.0)	1/ 11 (9.1)	48.7	6.80 (0.80,57.64)	0.0787	0.0	0.5365
Unclassifiable IIP	4/ 50 (8.0)	5/ 64 (7.8)	90.3	0/ 3 (0.0)	0/ 2 (0.0)	9.7	0.98 (0.30, 3.23)	0.9720	0.0	0.9905
HP	11/ 89 (12.4)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	4/ 88 (4.5)	6/ 82 (7.3)	90.9	0/ 12 (0.0)	3/ 34 (8.8)	9.1	1.92 (0.59, 6.22)	0.2749	0.0	0.5845
Other ILD	5/ 43 (11.6)	2/ 38 (5.3)	74.7	1/ 5 (20.0)	0/ 6 (0.0)	25.3	0.42 (0.10, 1.67)	0.2163	0.0	0.8266
Region										
Europe										
Asia	5/ 76 (6.6)	6/ 79 (7.6)	79.3	1/ 27 (3.7)	4/ 54 (7.4)	20.7	1.33 (0.49, 3.63)	0.5785	0.0	0.6574
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Cardiac disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	24/331 (7.3)	23/332 (6.9)	90.2	1/ 27 (3.7)	4/ 54 (7.4)	9.8	0.07 (-3.59, 3.73)	0.0	0.4614
Age									
<65 years	4/121 (3.3)	3/139 (2.2)	90.2	0/ 9 (0.0)	1/ 25 (4.0)	9.8	-0.67 (-4.53, 3.19)	0.0	0.5091
>=65 years	20/210 (9.5)	20/193 (10.4)	90.1	1/ 18 (5.6)	3/ 29 (10.3)	9.9	1.23 (-4.25, 6.72)	0.0	0.6369
Sex									
Male	19/177 (10.7)	17/179 (9.5)	92.0	1/ 11 (9.1)	2/ 26 (7.7)	8.0	-1.25 (-7.23, 4.73)	0.0	0.9879
Female	5/154 (3.2)	6/153 (3.9)	87.8	0/ 16 (0.0)	2/ 28 (7.1)	12.2	1.42 (-2.53, 5.38)	0.0	0.3598
Baseline FVC percent predicted									
<=70%	17/193 (8.8)	12/196 (6.1)	93.5	0/ 10 (0.0)	1/ 17 (5.9)	6.5	-2.16 (-7.16, 2.85)	0.0	0.3691
>70%	7/138 (5.1)	11/136 (8.1)	85.5	1/ 17 (5.9)	3/ 37 (8.1)	14.5	2.90 (-2.52, 8.32)	0.0	0.9199
Baseline HRCT pattern									
UIP-like	16/206 (7.8)	17/206 (8.3)	87.1	1/ 23 (4.3)	4/ 45 (8.9)	12.9	1.01 (-3.80, 5.82)	0.0	0.5374
Other fibrotic patterns	8/125 (6.4)	6/126 (4.8)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-1.56 (-7.12, 4.00)	0.0	0.9085
Underlying ILD diagnosis									
iNSIP	0/ 61 (0.0)	5/ 64 (7.8)	87.0	0/ 7 (0.0)	1/ 11 (9.1)	13.0	7.75 (0.80, 14.71)	0.0	0.9697
Unclassifiable IIP	4/ 50 (8.0)	5/ 64 (7.8)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	-0.18 (-10.06, 9.71)	0.0	0.9946
HP	11/ 89 (12.4)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	6/ 82 (7.3)	82.1	0/ 12 (0.0)	3/ 34 (8.8)	17.9	3.79 (-2.49, 10.07)	0.0	0.4478
Other ILD	5/ 43 (11.6)	2/ 38 (5.3)	86.2	1/ 5 (20.0)	0/ 6 (0.0)	13.8	-7.82 (-19.48, 3.84)	0.0	0.6191
Region									
Europe									
Asia	5/ 76 (6.6)	6/ 79 (7.6)	68.3	1/ 27 (3.7)	4/ 54 (7.4)	31.7	1.87 (-4.49, 8.23)	0.0	0.6815
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Cardiac disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	24/331 (7.3)	23/332 (6.9)	94.8	1/ 27 (3.7)	4/ 54 (7.4)	5.2	1.01 (0.57, 1.79)	0.0	0.5090
Age									
<65 years	4/121 (3.3)	3/139 (2.2)	92.0	0/ 9 (0.0)	1/ 25 (4.0)	8.0	0.79 (0.20, 3.12)	0.0	0.5541
>=65 years	20/210 (9.5)	20/193 (10.4)	93.9	1/ 18 (5.6)	3/ 29 (10.3)	6.1	1.15 (0.62, 2.15)	0.0	0.6404
Sex									
Male	19/177 (10.7)	17/179 (9.5)	93.0	1/ 11 (9.1)	2/ 26 (7.7)	7.0	0.87 (0.45, 1.69)	0.0	0.9723
Female	5/154 (3.2)	6/153 (3.9)	91.9	0/ 16 (0.0)	2/ 28 (7.1)	8.1	1.48 (0.49, 4.50)	0.0	0.4944
Baseline FVC percent predicted									
<=70%	17/193 (8.8)	12/196 (6.1)	97.4	0/ 10 (0.0)	1/ 17 (5.9)	2.6	0.73 (0.35, 1.53)	0.0	0.4614
>70%	7/138 (5.1)	11/136 (8.1)	83.5	1/ 17 (5.9)	3/ 37 (8.1)	16.5	1.61 (0.65, 3.97)	0.0	0.9053
Baseline HRCT pattern									
UIP-like	16/206 (7.8)	17/206 (8.3)	92.4	1/ 23 (4.3)	4/ 45 (8.9)	7.6	1.15 (0.59, 2.25)	0.0	0.5625
Other fibrotic patterns	8/125 (6.4)	6/126 (4.8)	95.1	0/ 4 (0.0)	0/ 9 (0.0)	4.9	0.74 (0.26, 2.14)	0.0	0.8922
Underlying ILD diagnosis									
iNSIP	0/ 61 (0.0)	5/ 64 (7.8)	52.6	0/ 7 (0.0)	1/ 11 (9.1)	47.4	7.50 (0.80,70.01)	0.0	0.5578
Unclassifiable IIP	4/ 50 (8.0)	5/ 64 (7.8)	91.0	0/ 3 (0.0)	0/ 2 (0.0)	9.0	0.98 (0.26, 3.61)	0.0	0.9911
HP	11/ 89 (12.4)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	6/ 82 (7.3)	91.2	0/ 12 (0.0)	3/ 34 (8.8)	8.8	2.00 (0.59, 6.73)	0.0	0.5762
Other ILD	5/ 43 (11.6)	2/ 38 (5.3)	75.2	1/ 5 (20.0)	0/ 6 (0.0)	24.8	0.38 (0.08, 1.73)	0.0	0.7922
Region									
Europe									
Asia	5/ 76 (6.6)	6/ 79 (7.6)	79.2	1/ 27 (3.7)	4/ 54 (7.4)	20.8	1.36 (0.47, 3.94)	0.0	0.6579
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	6/331 (1.8)	15/332 (4.5)	93.1	0/ 27 (0.0)	1/ 54 (1.9)	6.9	2.49 (1.01, 6.17)	0.0483	0.0	0.9988
Age										
<65 years	1/121 (0.8)	5/139 (3.6)	73.3	0/ 9 (0.0)	1/ 25 (4.0)	26.7	3.82 (0.59,24.80)	0.1601	0.0	0.7922
>=65 years	5/210 (2.4)	10/193 (5.2)	91.0	0/ 18 (0.0)	0/ 29 (0.0)	9.0	2.07 (0.75, 5.72)	0.1603	0.0	0.7120
Sex										
Male	6/177 (3.4)	9/179 (5.0)	93.5	0/ 11 (0.0)	1/ 26 (3.8)	6.5	1.54 (0.58, 4.11)	0.3841	0.0	0.8084
Female	0/154 (0.0)	6/153 (3.9)	51.9	0/ 16 (0.0)	0/ 28 (0.0)	48.1	7.25 (0.87,60.40)	0.0670	3.5	0.3086
Baseline FVC percent predicted										
<=70%	5/193 (2.6)	10/196 (5.1)	91.5	0/ 10 (0.0)	0/ 17 (0.0)	8.5	1.89 (0.68, 5.22)	0.2207	0.0	0.7475
>70%	1/138 (0.7)	5/136 (3.7)	69.7	0/ 17 (0.0)	1/ 37 (2.7)	30.3	4.28 (0.68,26.83)	0.1204	0.0	0.7429
Baseline HRCT pattern										
UIP-like	4/206 (1.9)	7/206 (3.4)	89.9	0/ 23 (0.0)	1/ 45 (2.2)	10.1	1.83 (0.58, 5.78)	0.3054	0.0	0.8545
Other fibrotic patterns	2/125 (1.6)	8/126 (6.3)	82.5	0/ 4 (0.0)	0/ 9 (0.0)	17.5	3.45 (0.84,14.09)	0.0848	0.0	0.5372
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	0/ 76 (0.0)	1/ 79 (1.3)	52.9	0/ 27 (0.0)	1/ 54 (1.9)	47.1	2.74 (0.24,30.87)	0.4136	0.0	0.9458
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	6/331 (1.8)	15/332 (4.5)	90.0	0/ 27 (0.0)	1/ 54 (1.9)	10.0	2.62 (0.15, 5.08)	0.0	0.7904
Age									
<65 years	1/121 (0.8)	5/139 (3.6)	90.2	0/ 9 (0.0)	1/ 25 (4.0)	9.8	2.87 (-0.57, 6.31)	0.0	0.8916
>=65 years	5/210 (2.4)	10/193 (5.2)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	2.51 (-0.95, 5.97)	0.0	0.5403
Sex									
Male	6/177 (3.4)	9/179 (5.0)	91.6	0/ 11 (0.0)	1/ 26 (3.8)	8.4	1.81 (-2.16, 5.77)	0.0	0.7701
Female	0/154 (0.0)	6/153 (3.9)	87.9	0/ 16 (0.0)	0/ 28 (0.0)	12.1	3.42 (0.34, 6.51)	0.0	0.4146
Baseline FVC percent predicted									
<=70%	5/193 (2.6)	10/196 (5.1)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	2.35 (-1.32, 6.02)	0.0	0.7301
>70%	1/138 (0.7)	5/136 (3.7)	85.0	0/ 17 (0.0)	1/ 37 (2.7)	15.0	2.90 (-0.34, 6.14)	0.0	0.9438
Baseline HRCT pattern									
UIP-like	4/206 (1.9)	7/206 (3.4)	86.8	0/ 23 (0.0)	1/ 45 (2.2)	13.2	1.55 (-1.31, 4.41)	0.0	0.8603
Other fibrotic patterns	2/125 (1.6)	8/126 (6.3)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	4.52 (-0.23, 9.27)	0.0	0.7375
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	0/ 76 (0.0)	1/ 79 (1.3)	68.0	0/ 27 (0.0)	1/ 54 (1.9)	32.0	1.43 (-1.63, 4.48)	0.0	0.8758
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	6/331 (1.8)	15/332 (4.5)	93.0	0/ 27 (0.0)	1/ 54 (1.9)	7.0	2.56 (1.01, 6.49)	0.0	0.9974
Age									
<65 years	1/121 (0.8)	5/139 (3.6)	73.9	0/ 9 (0.0)	1/ 25 (4.0)	26.1	3.95 (0.58,26.92)	0.0	0.8016
>=65 years	5/210 (2.4)	10/193 (5.2)	90.7	0/ 18 (0.0)	0/ 29 (0.0)	9.3	2.13 (0.74, 6.10)	0.0	0.7078
Sex									
Male	6/177 (3.4)	9/179 (5.0)	93.6	0/ 11 (0.0)	1/ 26 (3.8)	6.4	1.57 (0.57, 4.34)	0.0	0.8065
Female	0/154 (0.0)	6/153 (3.9)	51.4	0/ 16 (0.0)	0/ 28 (0.0)	48.6	7.46 (0.83,67.09)	3.3	0.3093
Baseline FVC percent predicted									
<=70%	5/193 (2.6)	10/196 (5.1)	91.4	0/ 10 (0.0)	0/ 17 (0.0)	8.6	1.93 (0.67, 5.55)	0.0	0.7468
>70%	1/138 (0.7)	5/136 (3.7)	69.9	0/ 17 (0.0)	1/ 37 (2.7)	30.1	4.41 (0.67,29.03)	0.0	0.7467
Baseline HRCT pattern									
UIP-like	4/206 (1.9)	7/206 (3.4)	90.0	0/ 23 (0.0)	1/ 45 (2.2)	10.0	1.86 (0.57, 6.02)	0.0	0.8544
Other fibrotic patterns	2/125 (1.6)	8/126 (6.3)	82.5	0/ 4 (0.0)	0/ 9 (0.0)	17.5	3.62 (0.83,15.67)	0.0	0.5488
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	0/ 76 (0.0)	1/ 79 (1.3)	53.2	0/ 27 (0.0)	1/ 54 (1.9)	46.8	2.79 (0.24,32.52)	0.0	0.9483
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: General disorders and administration site conditions

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	10/331 (3.0)	4/332 (1.2)	84.9	1/ 27 (3.7)	0/ 54 (0.0)	15.1	0.38 (0.13, 1.09)	0.0725	0.0	0.7695
Age										
<65 years										
>=65 years										
Sex										
Male	7/177 (4.0)	3/179 (1.7)	79.4	1/ 11 (9.1)	0/ 26 (0.0)	20.6	0.38 (0.12, 1.28)	0.1184	0.0	0.6995
Female	3/154 (1.9)	1/153 (0.7)	86.6	0/ 16 (0.0)	0/ 28 (0.0)	13.4	0.42 (0.06, 2.90)	0.3823	0.0	0.6429
Baseline FVC percent predicted										
<=70%	8/193 (4.1)	4/196 (2.0)	94.5	0/ 10 (0.0)	0/ 17 (0.0)	5.5	0.52 (0.17, 1.61)	0.2568	0.0	0.7385
>70%	2/138 (1.4)	0/136 (0.0)	58.0	1/ 17 (5.9)	0/ 37 (0.0)	42.0	0.22 (0.03, 1.80)	0.1568	0.0	0.9348
Baseline HRCT pattern										
UIP-like										
Other fibrotic patterns										
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: General disorders and administration site conditions

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	10/331 (3.0)	4/332 (1.2)	90.0	1/ 27 (3.7)	0/ 54 (0.0)	10.0	-2.00 (-4.14, 0.15)	0.0	0.6874
Age									
<65 years									
>=65 years									
Sex									
Male	7/177 (4.0)	3/179 (1.7)	91.6	1/ 11 (9.1)	0/ 26 (0.0)	8.4	-2.81 (-6.34, 0.72)	0.0	0.5213
Female	3/154 (1.9)	1/153 (0.7)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	-1.14 (-3.60, 1.33)	0.0	0.7808
Baseline FVC percent predicted									
<=70%	8/193 (4.1)	4/196 (2.0)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-1.97 (-5.30, 1.37)	0.0	0.7711
>70%	2/138 (1.4)	0/136 (0.0)	85.1	1/ 17 (5.9)	0/ 37 (0.0)	14.9	-2.07 (-4.90, 0.76)	0.0	0.5291
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: General disorders and administration site conditions

Subgroup / Category	Trial 1199_0247: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247: Wt	Trial 1199_0434: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434: Wt	Fixed effects: Nin 150bid vs Placebo: Odds ratio (95% CI)	Heterogeneity: I²	Heterogeneity: p-value
Overall	10/331 (3.0)	4/332 (1.2)	84.9	1/ 27 (3.7)	0/ 54 (0.0)	15.1	0.37 (0.12, 1.10)	0.0	0.7660
Age									
<65 years									
>=65 years									
Sex									
Male	7/177 (4.0)	3/179 (1.7)	79.6	1/ 11 (9.1)	0/ 26 (0.0)	20.4	0.37 (0.11, 1.30)	0.0	0.6836
Female	3/154 (1.9)	1/153 (0.7)	86.8	0/ 16 (0.0)	0/ 28 (0.0)	13.2	0.42 (0.06, 2.87)	0.0	0.6453
Baseline FVC percent predicted									
<=70%	8/193 (4.1)	4/196 (2.0)	94.6	0/ 10 (0.0)	0/ 17 (0.0)	5.4	0.51 (0.16, 1.62)	0.0	0.7396
>70%	2/138 (1.4)	0/136 (0.0)	58.3	1/ 17 (5.9)	0/ 37 (0.0)	41.7	0.21 (0.02, 1.80)	0.0	0.9527
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	4/331 (1.2)	12/332 (3.6)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	2.79 (0.95, 8.17)	0.0608	0.0	0.6160
Age										
<65 years										
>=65 years										
Sex										
Male										
Female										
Baseline FVC percent predicted										
<=70%										
>70%										
Baseline HRCT pattern										
UIP-like										
Other fibrotic patterns										
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	4/331 (1.2)	12/332 (3.6)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	2.17 (0.01, 4.32)	0.0	0.3909
Age									
<65 years									
>=65 years									
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	4/331 (1.2)	12/332 (3.6)	89.8	0/ 27 (0.0)	0/ 54 (0.0)	10.2	2.85 (0.95, 8.56)	0.0	0.6126
Age									
<65 years									
>=65 years									
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Infections and infestations

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	46/331 (13.9)	49/332 (14.8)	87.4	5/ 27 (18.5)	12/ 54 (22.2)	12.6	1.08 (0.76, 1.53)	0.6649	0.0	0.8120
Age										
<65 years	13/121 (10.7)	15/139 (10.8)	82.5	2/ 9 (22.2)	3/ 25 (12.0)	17.5	0.92 (0.49, 1.75)	0.8074	0.0	0.4906
>=65 years	33/210 (15.7)	34/193 (17.6)	89.5	3/ 18 (16.7)	9/ 29 (31.0)	10.5	1.20 (0.80, 1.80)	0.3839	0.0	0.4248
Sex										
Male	24/177 (13.6)	31/179 (17.3)	85.1	3/ 11 (27.3)	9/ 26 (34.6)	14.9	1.28 (0.81, 2.00)	0.2869	0.0	0.9918
Female	22/154 (14.3)	18/153 (11.8)	89.6	2/ 16 (12.5)	3/ 28 (10.7)	10.4	0.83 (0.48, 1.43)	0.4981	0.0	0.9648
Baseline FVC percent predicted										
<=70%	35/193 (18.1)	37/196 (18.9)	96.6	1/ 10 (10.0)	4/ 17 (23.5)	3.4	1.09 (0.72, 1.63)	0.6911	0.0	0.4443
>70%	11/138 (8.0)	12/136 (8.8)	66.6	4/ 17 (23.5)	8/ 37 (21.6)	33.4	1.04 (0.56, 1.96)	0.8932	0.0	0.7811
Baseline HRCT pattern										
UIP-like	30/206 (14.6)	33/206 (16.0)	81.9	5/ 23 (21.7)	10/ 45 (22.2)	18.1	1.09 (0.72, 1.64)	0.6938	0.0	0.8914
Other fibrotic patterns	16/125 (12.8)	16/126 (12.7)	97.4	0/ 4 (0.0)	2/ 9 (22.2)	2.6	1.07 (0.57, 2.01)	0.8411	0.0	0.4599
Underlying ILD diagnosis										
iNSIP	11/ 61 (18.0)	5/ 64 (7.8)	96.0	0/ 7 (0.0)	4/ 11 (36.4)	4.0	0.72 (0.31, 1.68)	0.4502	65.3	0.0898
Unclassifiable IIP	2/ 50 (4.0)	11/ 64 (17.2)	82.4	0/ 3 (0.0)	0/ 2 (0.0)	17.6	3.72 (0.98,14.16)	0.0544	0.0	0.4730
HP	14/ 89 (15.7)	13/ 84 (15.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	15/ 88 (17.0)	17/ 82 (20.7)	76.5	3/ 12 (25.0)	7/ 34 (20.6)	23.5	1.12 (0.65, 1.95)	0.6777	0.0	0.5676
Other ILD	4/ 43 (9.3)	3/ 38 (7.9)	63.2	2/ 5 (40.0)	1/ 6 (16.7)	36.8	0.69 (0.21, 2.22)	0.5333	0.0	0.5816
Region										
Europe										
Asia	12/ 76 (15.8)	15/ 79 (19.0)	64.7	5/ 27 (18.5)	12/ 54 (22.2)	35.3	1.20 (0.69, 2.09)	0.5170	0.0	0.9972
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Infections and infestations

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	46/331 (13.9)	49/332 (14.8)	90.2	5/ 27 (18.5)	12/ 54 (22.2)	9.8	1.14 (-4.00, 6.28)	0.0	0.7710
Age									
<65 years	13/121 (10.7)	15/139 (10.8)	90.7	2/ 9 (22.2)	3/ 25 (12.0)	9.3	-0.91 (-8.30, 6.49)	0.0	0.5153
>=65 years	33/210 (15.7)	34/193 (17.6)	90.1	3/ 18 (16.7)	9/ 29 (31.0)	9.9	3.14 (-3.84, 10.13)	0.0	0.3315
Sex									
Male	24/177 (13.6)	31/179 (17.3)	92.0	3/ 11 (27.3)	9/ 26 (34.6)	8.0	4.05 (-3.31, 11.40)	0.0	0.8310
Female	22/154 (14.3)	18/153 (11.8)	88.3	2/ 16 (12.5)	3/ 28 (10.7)	11.7	-2.43 (-9.47, 4.60)	0.0	0.9459
Baseline FVC percent predicted									
<=70%	35/193 (18.1)	37/196 (18.9)	93.9	1/ 10 (10.0)	4/ 17 (23.5)	6.1	1.52 (-5.92, 8.96)	0.0	0.3791
>70%	11/138 (8.0)	12/136 (8.8)	85.5	4/ 17 (23.5)	8/ 37 (21.6)	14.5	0.45 (-6.17, 7.07)	0.0	0.8288
Baseline HRCT pattern									
UIP-like	30/206 (14.6)	33/206 (16.0)	87.1	5/ 23 (21.7)	10/ 45 (22.2)	12.9	1.33 (-5.29, 7.95)	0.0	0.9306
Other fibrotic patterns	16/125 (12.8)	16/126 (12.7)	95.2	0/ 4 (0.0)	2/ 9 (22.2)	4.8	0.84 (-7.20, 8.87)	10.0	0.2919
Underlying ILD diagnosis									
iNSIP	11/ 61 (18.0)	5/ 64 (7.8)	86.8	0/ 7 (0.0)	4/ 11 (36.4)	13.2	-4.55 (-15.49, 6.39)	84.3	0.0115
Unclassifiable IIP	2/ 50 (4.0)	11/ 64 (17.2)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	12.44 (1.90, 22.99)	0.0	0.6321
HP	14/ 89 (15.7)	13/ 84 (15.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	15/ 88 (17.0)	17/ 82 (20.7)	82.7	3/ 12 (25.0)	7/ 34 (20.6)	17.3	2.29 (-8.59, 13.17)	0.0	0.6015
Other ILD	4/ 43 (9.3)	3/ 38 (7.9)	88.1	2/ 5 (40.0)	1/ 6 (16.7)	11.9	-4.02 (-16.44, 8.40)	0.0	0.4234
Region									
Europe									
Asia	12/ 76 (15.8)	15/ 79 (19.0)	68.3	5/ 27 (18.5)	12/ 54 (22.2)	31.7	3.36 (-6.65, 13.37)	0.0	0.9639
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Infections and infestations

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	46/331 (13.9)	49/332 (14.8)	88.3	5/ 27 (18.5)	12/ 54 (22.2)	11.7	1.09 (0.73, 1.64)	0.0	0.8024
Age									
<65 years	13/121 (10.7)	15/139 (10.8)	82.7	2/ 9 (22.2)	3/ 25 (12.0)	17.3	0.91 (0.44, 1.90)	0.0	0.4935
>=65 years	33/210 (15.7)	34/193 (17.6)	91.1	3/ 18 (16.7)	9/ 29 (31.0)	8.9	1.25 (0.76, 2.03)	0.0	0.3969
Sex									
Male	24/177 (13.6)	31/179 (17.3)	87.9	3/ 11 (27.3)	9/ 26 (34.6)	12.1	1.34 (0.78, 2.31)	0.0	0.9475
Female	22/154 (14.3)	18/153 (11.8)	89.5	2/ 16 (12.5)	3/ 28 (10.7)	10.5	0.80 (0.43, 1.51)	0.0	0.9622
Baseline FVC percent predicted									
<=70%	35/193 (18.1)	37/196 (18.9)	96.7	1/ 10 (10.0)	4/ 17 (23.5)	3.3	1.11 (0.67, 1.82)	0.0	0.4296
>70%	11/138 (8.0)	12/136 (8.8)	69.9	4/ 17 (23.5)	8/ 37 (21.6)	30.1	1.05 (0.51, 2.17)	0.0	0.7890
Baseline HRCT pattern									
UIP-like	30/206 (14.6)	33/206 (16.0)	83.0	5/ 23 (21.7)	10/ 45 (22.2)	17.0	1.10 (0.68, 1.80)	0.0	0.9010
Other fibrotic patterns	16/125 (12.8)	16/126 (12.7)	97.8	0/ 4 (0.0)	2/ 9 (22.2)	2.2	1.08 (0.52, 2.21)	0.0	0.4314
Underlying ILD diagnosis									
iNSIP	11/ 61 (18.0)	5/ 64 (7.8)	97.2	0/ 7 (0.0)	4/ 11 (36.4)	2.8	0.69 (0.27, 1.76)	70.7	0.0647
Unclassifiable IIP	2/ 50 (4.0)	11/ 64 (17.2)	81.9	0/ 3 (0.0)	0/ 2 (0.0)	18.1	4.26 (1.03,17.69)	0.0	0.4932
HP	14/ 89 (15.7)	13/ 84 (15.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	15/ 88 (17.0)	17/ 82 (20.7)	76.5	3/ 12 (25.0)	7/ 34 (20.6)	23.5	1.16 (0.58, 2.31)	0.0	0.5768
Other ILD	4/ 43 (9.3)	3/ 38 (7.9)	65.5	2/ 5 (40.0)	1/ 6 (16.7)	34.5	0.65 (0.17, 2.52)	0.0	0.5307
Region									
Europe									
Asia	12/ 76 (15.8)	15/ 79 (19.0)	65.6	5/ 27 (18.5)	12/ 54 (22.2)	34.4	1.25 (0.64, 2.47)	0.0	0.9938
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Injury, poisoning and procedural complications

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	10/331 (3.0)	9/332 (2.7)	95.8	0/ 27 (0.0)	1/ 54 (1.9)	4.2	0.97 (0.41, 2.28)	0.9358	0.0	0.5968
Age										
<65 years	1/121 (0.8)	3/139 (2.2)	73.3	0/ 9 (0.0)	1/ 25 (4.0)	26.7	2.54 (0.36,18.16)	0.3516	0.0	0.9656
>=65 years	9/210 (4.3)	6/193 (3.1)	94.8	0/ 18 (0.0)	0/ 29 (0.0)	5.2	0.74 (0.28, 1.98)	0.5474	0.0	0.8785
Sex										
Male	6/177 (3.4)	2/179 (1.1)	93.5	0/ 11 (0.0)	0/ 26 (0.0)	6.5	0.37 (0.09, 1.61)	0.1872	0.0	0.6304
Female	4/154 (2.6)	7/153 (4.6)	89.6	0/ 16 (0.0)	1/ 28 (3.6)	10.4	1.85 (0.59, 5.79)	0.2934	0.0	0.8430
Baseline FVC percent predicted										
<=70%	8/193 (4.1)	6/196 (3.1)	94.5	0/ 10 (0.0)	0/ 17 (0.0)	5.5	0.75 (0.28, 2.06)	0.5799	0.0	0.8854
>70%	2/138 (1.4)	3/136 (2.2)	82.1	0/ 17 (0.0)	1/ 37 (2.7)	17.9	1.69 (0.34, 8.39)	0.5214	0.0	0.8211
Baseline HRCT pattern										
UIP-like	8/206 (3.9)	5/206 (2.4)	94.7	0/ 23 (0.0)	1/ 45 (2.2)	5.3	0.72 (0.26, 2.04)	0.5417	0.0	0.4761
Other fibrotic patterns	2/125 (1.6)	4/126 (3.2)	82.5	0/ 4 (0.0)	0/ 9 (0.0)	17.5	1.81 (0.39, 8.49)	0.4508	0.0	0.7619
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	4/ 76 (5.3)	1/ 79 (1.3)	90.2	0/ 27 (0.0)	1/ 54 (1.9)	9.8	0.46 (0.09, 2.39)	0.3577	13.0	0.2837
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Injury, poisoning and procedural complications

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	10/331 (3.0)	9/332 (2.7)	90.0	0/ 27 (0.0)	1/ 54 (1.9)	10.0	-0.10 (-2.46, 2.27)	0.0	0.5280
Age									
<65 years	1/121 (0.8)	3/139 (2.2)	90.2	0/ 9 (0.0)	1/ 25 (4.0)	9.8	1.57 (-1.39, 4.53)	0.0	0.7385
>=65 years	9/210 (4.3)	6/193 (3.1)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	-1.06 (-4.46, 2.34)	0.0	0.7963
Sex									
Male	6/177 (3.4)	2/179 (1.1)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-2.08 (-5.05, 0.88)	0.0	0.6930
Female	4/154 (2.6)	7/153 (4.6)	87.8	0/ 16 (0.0)	1/ 28 (3.6)	12.2	2.15 (-1.73, 6.04)	0.0	0.8085
Baseline FVC percent predicted									
<=70%	8/193 (4.1)	6/196 (3.1)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-1.01 (-4.59, 2.56)	0.0	0.8814
>70%	2/138 (1.4)	3/136 (2.2)	85.0	0/ 17 (0.0)	1/ 37 (2.7)	15.0	1.03 (-1.98, 4.05)	0.0	0.7029
Baseline HRCT pattern									
UIP-like	8/206 (3.9)	5/206 (2.4)	86.8	0/ 23 (0.0)	1/ 45 (2.2)	13.2	-0.98 (-4.06, 2.10)	0.0	0.3717
Other fibrotic patterns	2/125 (1.6)	4/126 (3.2)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	1.50 (-2.33, 5.32)	0.0	0.9110
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	4/ 76 (5.3)	1/ 79 (1.3)	67.7	0/ 27 (0.0)	1/ 54 (1.9)	32.3	-2.12 (-6.39, 2.14)	47.4	0.1680
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Injury, poisoning and procedural complications

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	10/331 (3.0)	9/332 (2.7)	95.8	0/ 27 (0.0)	1/ 54 (1.9)	4.2	0.96 (0.40, 2.32)	0.0	0.5949
Age									
<65 years	1/121 (0.8)	3/139 (2.2)	74.2	0/ 9 (0.0)	1/ 25 (4.0)	25.8	2.60 (0.35,19.22)	0.0	0.9752
>=65 years	9/210 (4.3)	6/193 (3.1)	94.7	0/ 18 (0.0)	0/ 29 (0.0)	5.3	0.73 (0.26, 2.02)	0.0	0.8766
Sex									
Male	6/177 (3.4)	2/179 (1.1)	93.6	0/ 11 (0.0)	0/ 26 (0.0)	6.4	0.37 (0.08, 1.60)	0.0	0.6318
Female	4/154 (2.6)	7/153 (4.6)	89.7	0/ 16 (0.0)	1/ 28 (3.6)	10.3	1.89 (0.58, 6.13)	0.0	0.8414
Baseline FVC percent predicted									
<=70%	8/193 (4.1)	6/196 (3.1)	94.6	0/ 10 (0.0)	0/ 17 (0.0)	5.4	0.74 (0.26, 2.11)	0.0	0.8852
>70%	2/138 (1.4)	3/136 (2.2)	82.5	0/ 17 (0.0)	1/ 37 (2.7)	17.5	1.71 (0.34, 8.64)	0.0	0.8180
Baseline HRCT pattern									
UIP-like	8/206 (3.9)	5/206 (2.4)	94.8	0/ 23 (0.0)	1/ 45 (2.2)	5.2	0.72 (0.25, 2.06)	0.0	0.4730
Other fibrotic patterns	2/125 (1.6)	4/126 (3.2)	83.0	0/ 4 (0.0)	0/ 9 (0.0)	17.0	1.84 (0.37, 9.12)	0.0	0.7708
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	4/ 76 (5.3)	1/ 79 (1.3)	90.3	0/ 27 (0.0)	1/ 54 (1.9)	9.7	0.45 (0.09, 2.29)	14.5	0.2796
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Musculoskeletal and connective tissue disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	14/331 (4.2)	9/332 (2.7)	96.9	0/ 27 (0.0)	0/ 54 (0.0)	3.1	0.65 (0.29, 1.46)	0.2987	0.0	0.8361
Age										
<65 years	5/121 (4.1)	4/139 (2.9)	93.2	0/ 9 (0.0)	0/ 25 (0.0)	6.8	0.72 (0.21, 2.47)	0.5983	0.0	0.8766
>=65 years	9/210 (4.3)	5/193 (2.6)	94.8	0/ 18 (0.0)	0/ 29 (0.0)	5.2	0.63 (0.22, 1.76)	0.3742	0.0	0.8113
Sex										
Male	4/177 (2.3)	6/179 (3.4)	90.6	0/ 11 (0.0)	0/ 26 (0.0)	9.4	1.44 (0.44, 4.75)	0.5516	0.0	0.8610
Female	10/154 (6.5)	3/153 (2.0)	95.6	0/ 16 (0.0)	0/ 28 (0.0)	4.4	0.33 (0.10, 1.10)	0.0718	0.0	0.5786
Baseline FVC percent predicted										
<=70%	7/193 (3.6)	5/196 (2.6)	93.8	0/ 10 (0.0)	0/ 17 (0.0)	6.2	0.72 (0.24, 2.14)	0.5563	0.0	0.8679
>70%	7/138 (5.1)	4/136 (2.9)	94.2	0/ 17 (0.0)	0/ 37 (0.0)	5.8	0.60 (0.19, 1.92)	0.3930	0.0	0.8061
Baseline HRCT pattern										
UIP-like	9/206 (4.4)	6/206 (2.9)	95.3	0/ 23 (0.0)	0/ 45 (0.0)	4.7	0.68 (0.26, 1.83)	0.4467	0.0	0.8512
Other fibrotic patterns	5/125 (4.0)	3/126 (2.4)	92.2	0/ 4 (0.0)	0/ 9 (0.0)	7.8	0.63 (0.17, 2.37)	0.4912	0.0	0.8147
Underlying ILD diagnosis										
iNSIP	0/ 61 (0.0)	1/ 64 (1.6)	51.3	0/ 7 (0.0)	0/ 11 (0.0)	48.7	2.00 (0.18,22.30)	0.5728	0.0	0.6752
Unclassifiable IIP	1/ 50 (2.0)	2/ 64 (3.1)	70.1	0/ 3 (0.0)	0/ 2 (0.0)	29.9	1.39 (0.19,10.24)	0.7440	0.0	0.8424
HP	4/ 89 (4.5)	2/ 84 (2.4)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	7/ 88 (8.0)	3/ 82 (3.7)	94.6	0/ 12 (0.0)	0/ 34 (0.0)	5.4	0.49 (0.14, 1.72)	0.2647	0.0	0.7412
Other ILD	2/ 43 (4.7)	1/ 38 (2.6)	79.1	0/ 5 (0.0)	0/ 6 (0.0)	20.9	0.66 (0.09, 4.80)	0.6784	0.0	0.8023
Region										
Europe										
Asia	2/ 76 (2.6)	4/ 79 (5.1)	82.1	0/ 27 (0.0)	0/ 54 (0.0)	17.9	1.76 (0.38, 8.18)	0.4716	0.0	0.7735
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Musculoskeletal and connective tissue disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	14/331 (4.2)	9/332 (2.7)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	-1.37 (-3.92, 1.19)	0.0	0.6018
Age									
<65 years	5/121 (4.1)	4/139 (2.9)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	-1.13 (-5.37, 3.10)	0.0	0.8497
>=65 years	9/210 (4.3)	5/193 (2.6)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	-1.52 (-4.80, 1.76)	0.0	0.7083
Sex									
Male	4/177 (2.3)	6/179 (3.4)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	1.00 (-2.27, 4.27)	0.0	0.8508
Female	10/154 (6.5)	3/153 (2.0)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	-3.98 (-8.05, 0.09)	0.0	0.3663
Baseline FVC percent predicted									
<=70%	7/193 (3.6)	5/196 (2.6)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-1.01 (-4.34, 2.33)	0.0	0.8817
>70%	7/138 (5.1)	4/136 (2.9)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	-1.81 (-5.91, 2.28)	0.0	0.6346
Baseline HRCT pattern									
UIP-like	9/206 (4.4)	6/206 (2.9)	86.8	0/ 23 (0.0)	0/ 45 (0.0)	13.2	-1.26 (-4.50, 1.97)	0.0	0.6790
Other fibrotic patterns	5/125 (4.0)	3/126 (2.4)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-1.54 (-5.88, 2.80)	0.0	0.9088
Underlying ILD diagnosis									
iNSIP	0/ 61 (0.0)	1/ 64 (1.6)	87.0	0/ 7 (0.0)	0/ 11 (0.0)	13.0	1.34 (-3.17, 5.85)	0.0	0.8805
Unclassifiable IIP	1/ 50 (2.0)	2/ 64 (3.1)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	1.06 (-5.14, 7.27)	0.0	0.9670
HP	4/ 89 (4.5)	2/ 84 (2.4)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	7/ 88 (8.0)	3/ 82 (3.7)	82.1	0/ 12 (0.0)	0/ 34 (0.0)	17.9	-3.53 (-9.48, 2.42)	0.0	0.4656
Other ILD	2/ 43 (4.7)	1/ 38 (2.6)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	-1.74 (-9.79, 6.31)	0.0	0.8957
Region									
Europe									
Asia	2/ 76 (2.6)	4/ 79 (5.1)	67.7	0/ 27 (0.0)	0/ 54 (0.0)	32.3	1.65 (-2.74, 6.03)	0.0	0.5421
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Musculoskeletal and connective tissue disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	14/331 (4.2)	9/332 (2.7)	96.9	0/ 27 (0.0)	0/ 54 (0.0)	3.1	0.64 (0.28, 1.48)	0.0	0.8325
Age									
<65 years	5/121 (4.1)	4/139 (2.9)	93.2	0/ 9 (0.0)	0/ 25 (0.0)	6.8	0.71 (0.20, 2.54)	0.0	0.8758
>=65 years	9/210 (4.3)	5/193 (2.6)	94.8	0/ 18 (0.0)	0/ 29 (0.0)	5.2	0.62 (0.21, 1.79)	0.0	0.8089
Sex									
Male	4/177 (2.3)	6/179 (3.4)	90.5	0/ 11 (0.0)	0/ 26 (0.0)	9.5	1.45 (0.42, 4.98)	0.0	0.8607
Female	10/154 (6.5)	3/153 (2.0)	95.6	0/ 16 (0.0)	0/ 28 (0.0)	4.4	0.32 (0.09, 1.09)	0.0	0.5725
Baseline FVC percent predicted									
<=70%	7/193 (3.6)	5/196 (2.6)	93.9	0/ 10 (0.0)	0/ 17 (0.0)	6.1	0.71 (0.23, 2.19)	0.0	0.8683
>70%	7/138 (5.1)	4/136 (2.9)	94.1	0/ 17 (0.0)	0/ 37 (0.0)	5.9	0.59 (0.18, 1.96)	0.0	0.8022
Baseline HRCT pattern									
UIP-like	9/206 (4.4)	6/206 (2.9)	95.2	0/ 23 (0.0)	0/ 45 (0.0)	4.8	0.67 (0.24, 1.86)	0.0	0.8481
Other fibrotic patterns	5/125 (4.0)	3/126 (2.4)	92.5	0/ 4 (0.0)	0/ 9 (0.0)	7.5	0.62 (0.16, 2.43)	0.0	0.8206
Underlying ILD diagnosis									
iNSIP	0/ 61 (0.0)	1/ 64 (1.6)	51.9	0/ 7 (0.0)	0/ 11 (0.0)	48.1	2.04 (0.17,24.85)	0.0	0.6817
Unclassifiable IIP	1/ 50 (2.0)	2/ 64 (3.1)	72.6	0/ 3 (0.0)	0/ 2 (0.0)	27.4	1.42 (0.17,11.58)	0.0	0.8564
HP	4/ 89 (4.5)	2/ 84 (2.4)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	7/ 88 (8.0)	3/ 82 (3.7)	94.5	0/ 12 (0.0)	0/ 34 (0.0)	5.5	0.47 (0.13, 1.74)	0.0	0.7327
Other ILD	2/ 43 (4.7)	1/ 38 (2.6)	80.0	0/ 5 (0.0)	0/ 6 (0.0)	20.0	0.64 (0.08, 5.12)	0.0	0.8083
Region									
Europe									
Asia	2/ 76 (2.6)	4/ 79 (5.1)	81.5	0/ 27 (0.0)	0/ 54 (0.0)	18.5	1.79 (0.36, 8.85)	0.0	0.7685
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup / Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo: Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	11/331 (3.3)	11/332 (3.3)	86.1	1/ 27 (3.7)	0/ 54 (0.0)	13.9	0.89 (0.41, 1.94)	0.7758	0.0	0.3691
Age										
<65 years	2/121 (1.7)	3/139 (2.2)	84.6	0/ 9 (0.0)	0/ 25 (0.0)	15.4	1.26 (0.24, 6.50)	0.7835	0.0	0.9119
>=65 years	9/210 (4.3)	8/193 (4.1)	83.5	1/ 18 (5.6)	0/ 29 (0.0)	16.5	0.85 (0.36, 2.04)	0.7215	0.0	0.4274
Sex										
Male	8/177 (4.5)	9/179 (5.0)	95.1	0/ 11 (0.0)	0/ 26 (0.0)	4.9	1.11 (0.45, 2.74)	0.8265	0.0	0.9616
Female	3/154 (1.9)	2/153 (1.3)	63.3	1/ 16 (6.3)	0/ 28 (0.0)	36.7	0.52 (0.12, 2.31)	0.3916	0.0	0.5961
Baseline FVC percent predicted										
<=70%	5/193 (2.6)	4/196 (2.0)	91.5	0/ 10 (0.0)	0/ 17 (0.0)	8.5	0.81 (0.23, 2.77)	0.7318	0.0	0.9112
>70%	6/138 (4.3)	7/136 (5.1)	76.8	1/ 17 (5.9)	0/ 37 (0.0)	23.2	0.96 (0.37, 2.53)	0.9414	4.8	0.3055
Baseline HRCT pattern										
UIP-like	8/206 (3.9)	10/206 (4.9)	81.9	1/ 23 (4.3)	0/ 45 (0.0)	18.1	1.07 (0.46, 2.49)	0.8766	5.7	0.3031
Other fibrotic patterns	3/125 (2.4)	1/126 (0.8)	87.6	0/ 4 (0.0)	0/ 9 (0.0)	12.4	0.41 (0.06, 2.85)	0.3703	0.0	0.6430
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup / Category	Trial 1199_0247: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247: Wt	Trial 1199_0434: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434: Wt	Fixed effects: Nin 150bid vs Placebo: Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	11/331 (3.3)	11/332 (3.3)	90.0	1/ 27 (3.7)	0/ 54 (0.0)	10.0	-0.37 (-2.97, 2.23)	0.0	0.4278
Age									
<65 years	2/121 (1.7)	3/139 (2.2)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	0.46 (-2.76, 3.68)	0.0	0.9374
>=65 years	9/210 (4.3)	8/193 (4.1)	89.7	1/ 18 (5.6)	0/ 29 (0.0)	10.3	-0.68 (-4.44, 3.09)	0.0	0.4492
Sex									
Male	8/177 (4.5)	9/179 (5.0)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	0.47 (-3.69, 4.62)	0.0	0.9323
Female	3/154 (1.9)	2/153 (1.3)	87.8	1/ 16 (6.3)	0/ 28 (0.0)	12.2	-1.29 (-4.31, 1.73)	0.0	0.4681
Baseline FVC percent predicted									
<=70%	5/193 (2.6)	4/196 (2.0)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-0.51 (-3.45, 2.42)	0.0	0.9390
>70%	6/138 (4.3)	7/136 (5.1)	85.0	1/ 17 (5.9)	0/ 37 (0.0)	15.0	-0.17 (-4.87, 4.53)	0.0	0.3616
Baseline HRCT pattern									
UIP-like	8/206 (3.9)	10/206 (4.9)	86.8	1/ 23 (4.3)	0/ 45 (0.0)	13.2	0.29 (-3.38, 3.95)	0.0	0.3398
Other fibrotic patterns	3/125 (2.4)	1/126 (0.8)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-1.53 (-4.76, 1.70)	0.0	0.9089
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup / Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo: Odds ratio (95% CI)	Heterogeneity I²	Heterogeneity p-value
Overall	11/331 (3.3)	11/332 (3.3)	85.8	1/ 27 (3.7)	0/ 54 (0.0)	14.2	0.89 (0.40, 2.00)	0.0	0.3684
Age									
<65 years	2/121 (1.7)	3/139 (2.2)	84.7	0/ 9 (0.0)	0/ 25 (0.0)	15.3	1.26 (0.24, 6.78)	0.0	0.9126
>=65 years	9/210 (4.3)	8/193 (4.1)	83.2	1/ 18 (5.6)	0/ 29 (0.0)	16.8	0.85 (0.34, 2.12)	0.0	0.4255
Sex									
Male	8/177 (4.5)	9/179 (5.0)	94.9	0/ 11 (0.0)	0/ 26 (0.0)	5.1	1.11 (0.43, 2.88)	0.0	0.9607
Female	3/154 (1.9)	2/153 (1.3)	63.5	1/ 16 (6.3)	0/ 28 (0.0)	36.5	0.51 (0.11, 2.40)	0.0	0.5870
Baseline FVC percent predicted									
<=70%	5/193 (2.6)	4/196 (2.0)	91.6	0/ 10 (0.0)	0/ 17 (0.0)	8.4	0.80 (0.23, 2.84)	0.0	0.9122
>70%	6/138 (4.3)	7/136 (5.1)	76.1	1/ 17 (5.9)	0/ 37 (0.0)	23.9	0.96 (0.34, 2.69)	5.2	0.3045
Baseline HRCT pattern									
UIP-like	8/206 (3.9)	10/206 (4.9)	81.3	1/ 23 (4.3)	0/ 45 (0.0)	18.7	1.07 (0.44, 2.61)	6.2	0.3017
Other fibrotic patterns	3/125 (2.4)	1/126 (0.8)	88.3	0/ 4 (0.0)	0/ 9 (0.0)	11.7	0.40 (0.06, 2.84)	0.0	0.6566
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	93/331 (28.1)	65/332 (19.6)	90.9	7/ 27 (25.9)	5/ 54 (9.3)	9.1	0.67 (0.51, 0.87)	0.0029	31.2	0.2280
Age										
<65 years	27/121 (22.3)	19/139 (13.7)	93.9	1/ 9 (11.1)	0/ 25 (0.0)	6.1	0.59 (0.35, 0.99)	0.0461	0.0	0.4567
>=65 years	66/210 (31.4)	46/193 (23.8)	89.5	6/ 18 (33.3)	5/ 29 (17.2)	10.5	0.73 (0.54, 1.00)	0.0472	0.0	0.4874
Sex										
Male	54/177 (30.5)	45/179 (25.1)	95.1	2/ 11 (18.2)	5/ 26 (19.2)	4.9	0.84 (0.60, 1.16)	0.2833	0.0	0.7473
Female	39/154 (25.3)	20/153 (13.1)	85.1	5/ 16 (31.3)	0/ 28 (0.0)	14.9	0.45 (0.28, 0.72)	0.0009	58.1	0.1224
Baseline FVC percent predicted										
<=70%	69/193 (35.8)	45/196 (23.0)	94.2	3/ 10 (30.0)	0/ 17 (0.0)	5.8	0.61 (0.45, 0.84)	0.0022	43.4	0.1837
>70%	24/138 (17.4)	20/136 (14.7)	81.3	4/ 17 (23.5)	5/ 37 (13.5)	18.7	0.79 (0.49, 1.30)	0.3618	0.0	0.5603
Baseline HRCT pattern										
UIP-like	66/206 (32.0)	43/206 (20.9)	89.3	6/ 23 (26.1)	4/ 45 (8.9)	10.7	0.62 (0.45, 0.85)	0.0030	9.6	0.2928
Other fibrotic patterns	27/125 (21.6)	22/126 (17.5)	95.1	1/ 4 (25.0)	1/ 9 (11.1)	4.9	0.79 (0.48, 1.30)	0.3523	0.0	0.6469
Underlying ILD diagnosis										
iNSIP	15/ 61 (24.6)	9/ 64 (14.1)	86.3	2/ 7 (28.6)	1/ 11 (9.1)	13.7	0.54 (0.27, 1.09)	0.0843	0.0	0.6217
Unclassifiable IIP	23/ 50 (46.0)	21/ 64 (32.8)	95.3	1/ 3 (33.3)	0/ 2 (0.0)	4.7	0.70 (0.44, 1.10)	0.1227	0.0	0.6892
HP	24/ 89 (27.0)	17/ 84 (20.2)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	20/ 88 (22.7)	9/ 82 (11.0)	86.7	2/ 12 (16.7)	3/ 34 (8.8)	13.3	0.49 (0.25, 0.95)	0.0357	0.0	0.9210
Other ILD	11/ 43 (25.6)	9/ 38 (23.7)	82.5	2/ 5 (40.0)	1/ 6 (16.7)	17.5	0.84 (0.41, 1.71)	0.6244	0.0	0.4814
Region										
Europe										
Asia	32/ 76 (42.1)	18/ 79 (22.8)	77.8	7/ 27 (25.9)	5/ 54 (9.3)	22.2	0.50 (0.32, 0.78)	0.0020	0.0	0.4814
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	93/331 (28.1)	65/332 (19.6)	90.2	7/ 27 (25.9)	5/ 54 (9.3)	9.8	-9.32 (-15.41, -3.23)	0.0	0.4093
Age									
<65 years	27/121 (22.3)	19/139 (13.7)	90.2	1/ 9 (11.1)	0/ 25 (0.0)	9.8	-8.83 (-17.55, -0.10)	0.0	0.8815
>=65 years	66/210 (31.4)	46/193 (23.8)	90.1	6/ 18 (33.3)	5/ 29 (17.2)	9.9	-8.44 (-16.68, -0.20)	0.0	0.5401
Sex									
Male	54/177 (30.5)	45/179 (25.1)	92.0	2/ 11 (18.2)	5/ 26 (19.2)	8.0	-4.86 (-13.68, 3.97)	0.0	0.6634
Female	39/154 (25.3)	20/153 (13.1)	87.8	5/ 16 (31.3)	0/ 28 (0.0)	12.2	-14.40 (-22.54, -6.26)	49.5	0.1595
Baseline FVC percent predicted									
<=70%	69/193 (35.8)	45/196 (23.0)	93.5	3/ 10 (30.0)	0/ 17 (0.0)	6.5	-13.78 (-22.37, -5.18)	0.0	0.3281
>70%	24/138 (17.4)	20/136 (14.7)	85.5	4/ 17 (23.5)	5/ 37 (13.5)	14.5	-3.75 (-11.89, 4.39)	0.0	0.5586
Baseline HRCT pattern									
UIP-like	66/206 (32.0)	43/206 (20.9)	87.1	6/ 23 (26.1)	4/ 45 (8.9)	12.9	-11.94 (-19.73, -4.15)	0.0	0.5825
Other fibrotic patterns	27/125 (21.6)	22/126 (17.5)	95.8	1/ 4 (25.0)	1/ 9 (11.1)	4.2	-4.55 (-14.14, 5.04)	0.0	0.6915
Underlying ILD diagnosis									
iNSIP	15/ 61 (24.6)	9/ 64 (14.1)	88.0	2/ 7 (28.6)	1/ 11 (9.1)	12.0	-11.61 (-24.52, 1.31)	0.0	0.6607
Unclassifiable IIP	23/ 50 (46.0)	21/ 64 (32.8)	94.4	1/ 3 (33.3)	0/ 2 (0.0)	5.6	-13.79 (-31.11, 3.53)	0.0	0.7469
HP	24/ 89 (27.0)	17/ 84 (20.2)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	20/ 88 (22.7)	9/ 82 (11.0)	82.7	2/ 12 (16.7)	3/ 34 (8.8)	17.3	-11.08 (-21.06, -1.09)	0.0	0.7652
Other ILD	11/ 43 (25.6)	9/ 38 (23.7)	88.1	2/ 5 (40.0)	1/ 6 (16.7)	11.9	-4.45 (-22.13, 13.23)	0.0	0.4495
Region									
Europe									
Asia	32/ 76 (42.1)	18/ 79 (22.8)	68.3	7/ 27 (25.9)	5/ 54 (9.3)	31.7	-18.48 (-29.92, -7.04)	0.0	0.8232
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
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Table M.2.2.1.3: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	93/331 (28.1)	65/332 (19.6)	89.8	7/ 27 (25.9)	5/ 54 (9.3)	10.2	0.59 (0.42, 0.83)	22.4	0.2562
Age									
<65 years	27/121 (22.3)	19/139 (13.7)	93.2	1/ 9 (11.1)	0/ 25 (0.0)	6.8	0.53 (0.28, 0.99)	0.0	0.4864
>=65 years	66/210 (31.4)	46/193 (23.8)	88.7	6/ 18 (33.3)	5/ 29 (17.2)	11.3	0.65 (0.43, 0.99)	0.0	0.5025
Sex									
Male	54/177 (30.5)	45/179 (25.1)	94.7	2/ 11 (18.2)	5/ 26 (19.2)	5.3	0.78 (0.50, 1.22)	0.0	0.7246
Female	39/154 (25.3)	20/153 (13.1)	83.5	5/ 16 (31.3)	0/ 28 (0.0)	16.5	0.38 (0.21, 0.67)	60.8	0.1103
Baseline FVC percent predicted									
<=70%	69/193 (35.8)	45/196 (23.0)	92.9	3/ 10 (30.0)	0/ 17 (0.0)	7.1	0.50 (0.33, 0.78)	42.6	0.1870
>70%	24/138 (17.4)	20/136 (14.7)	81.1	4/ 17 (23.5)	5/ 37 (13.5)	18.9	0.76 (0.42, 1.38)	0.0	0.5585
Baseline HRCT pattern									
UIP-like	66/206 (32.0)	43/206 (20.9)	87.8	6/ 23 (26.1)	4/ 45 (8.9)	12.2	0.53 (0.34, 0.80)	0.0	0.3423
Other fibrotic patterns	27/125 (21.6)	22/126 (17.5)	94.8	1/ 4 (25.0)	1/ 9 (11.1)	5.2	0.75 (0.40, 1.38)	0.0	0.6543
Underlying ILD diagnosis									
iNSIP	15/ 61 (24.6)	9/ 64 (14.1)	85.6	2/ 7 (28.6)	1/ 11 (9.1)	14.4	0.47 (0.20, 1.10)	0.0	0.6238
Unclassifiable IIP	23/ 50 (46.0)	21/ 64 (32.8)	94.1	1/ 3 (33.3)	0/ 2 (0.0)	5.9	0.56 (0.26, 1.17)	0.0	0.7104
HP	24/ 89 (27.0)	17/ 84 (20.2)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	20/ 88 (22.7)	9/ 82 (11.0)	86.4	2/ 12 (16.7)	3/ 34 (8.8)	13.6	0.43 (0.20, 0.93)	0.0	0.8938
Other ILD	11/ 43 (25.6)	9/ 38 (23.7)	81.2	2/ 5 (40.0)	1/ 6 (16.7)	18.8	0.79 (0.31, 2.03)	0.0	0.4677
Region									
Europe									
Asia	32/ 76 (42.1)	18/ 79 (22.8)	74.8	7/ 27 (25.9)	5/ 54 (9.3)	25.2	0.38 (0.20, 0.69)	0.0	0.6526
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
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Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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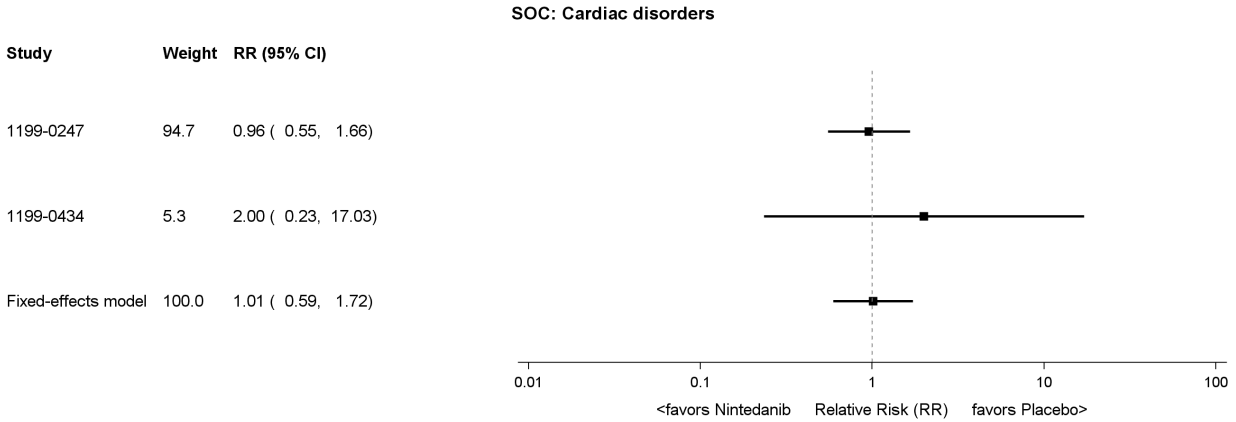

Figure M.2.2.1.3: 2 Forest Plot comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

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Boehringer Ingelheim
BI Trial No.: x1305p3.hta

Figure M.2.2.1.3: 2

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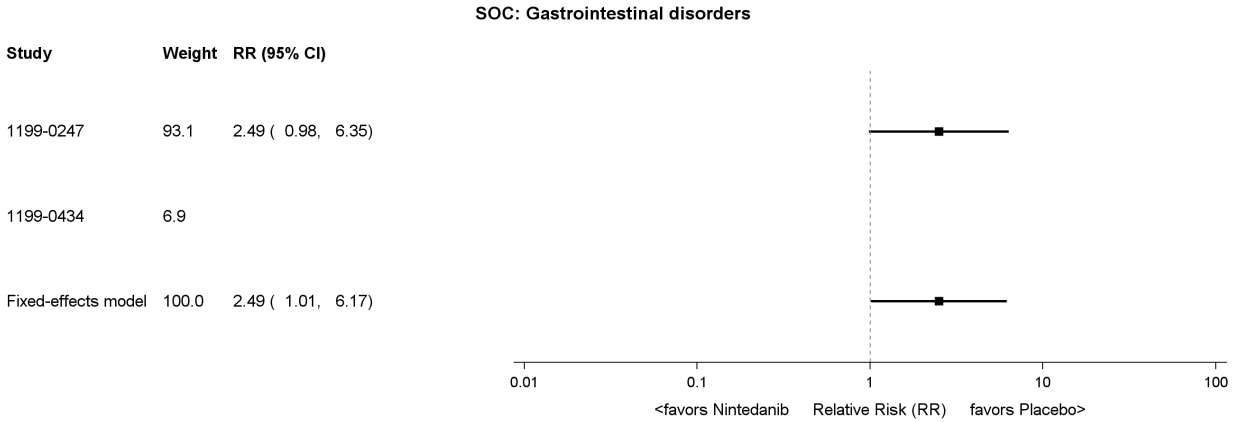

Figure M.2.2.1.3: 2 Forest Plot comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

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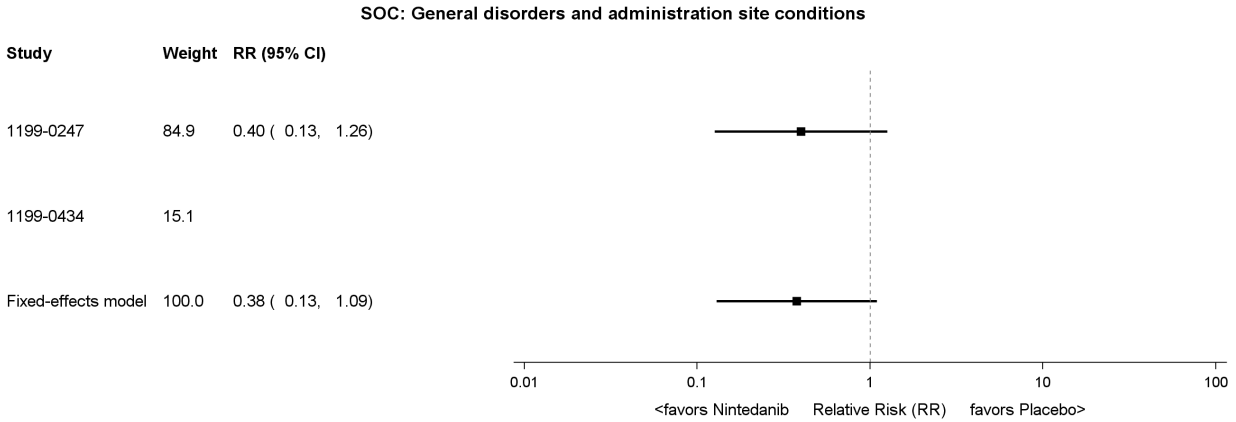

Figure M.2.2.1.3: 2 Forest Plot comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

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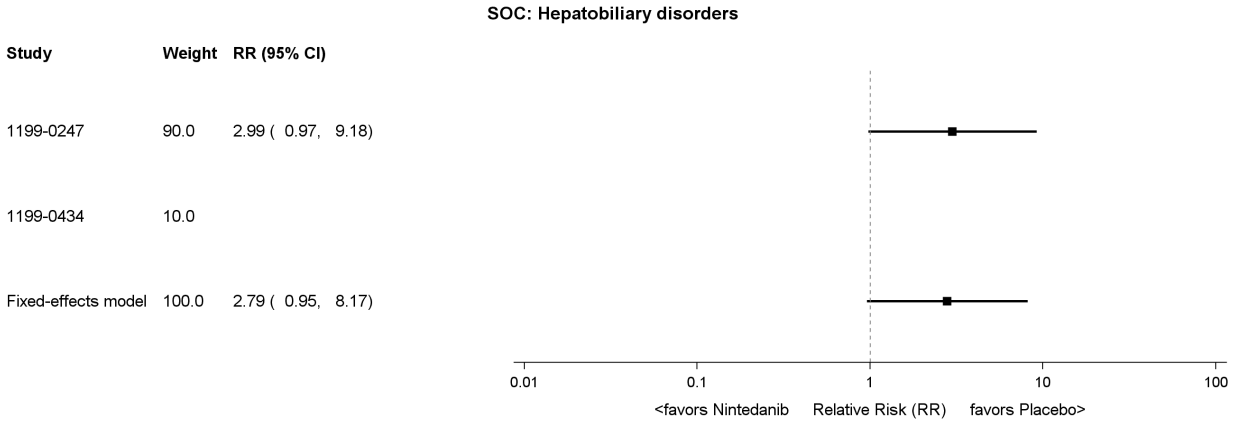

Figure M.2.2.1.3: 2 Forest Plot comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

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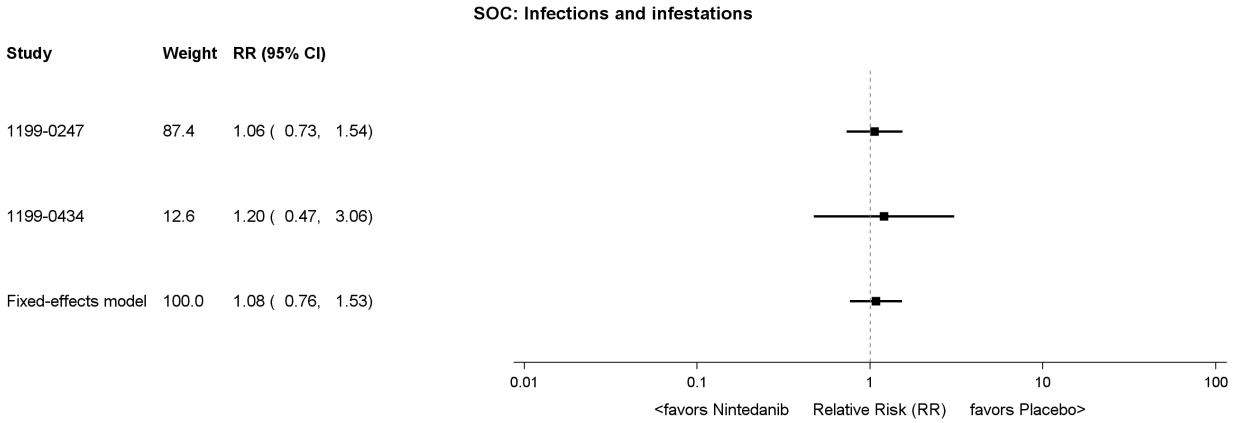

Figure M.2.2.1.3: 2 Forest Plot comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

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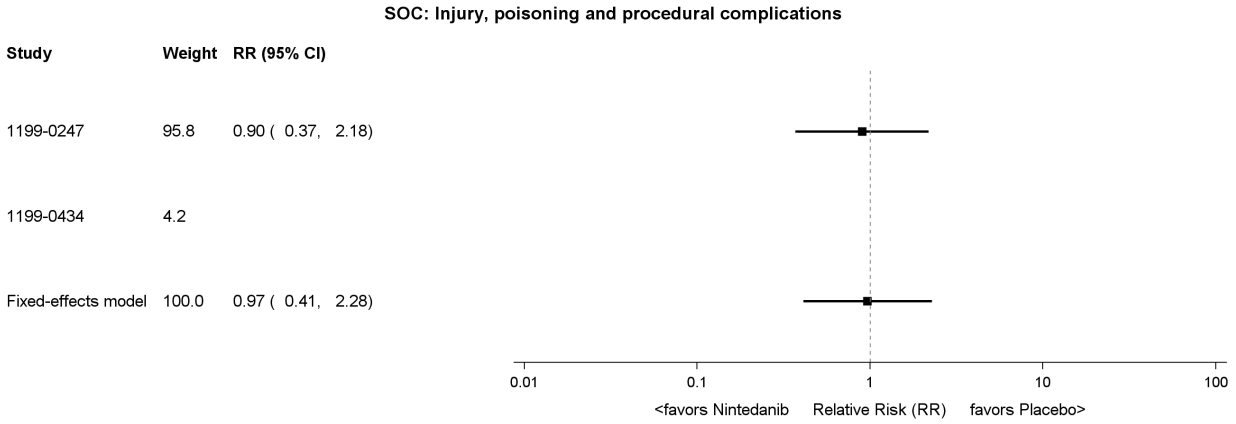

Figure M.2.2.1.3: 2 Forest Plot comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

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Boehringer Ingelheim
BI Trial No.: x1305p3.hta
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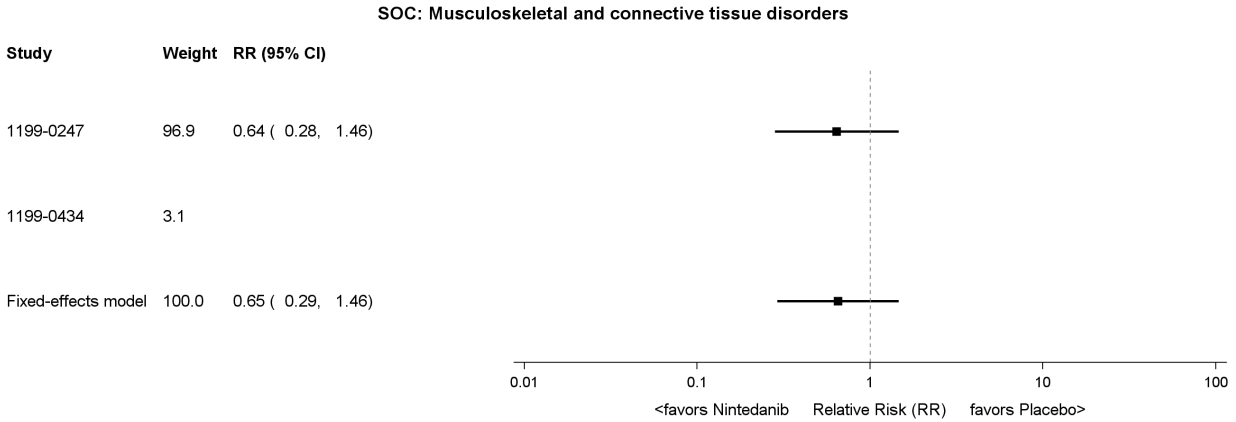

Figure M.2.2.1.3: 2 Forest Plot comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

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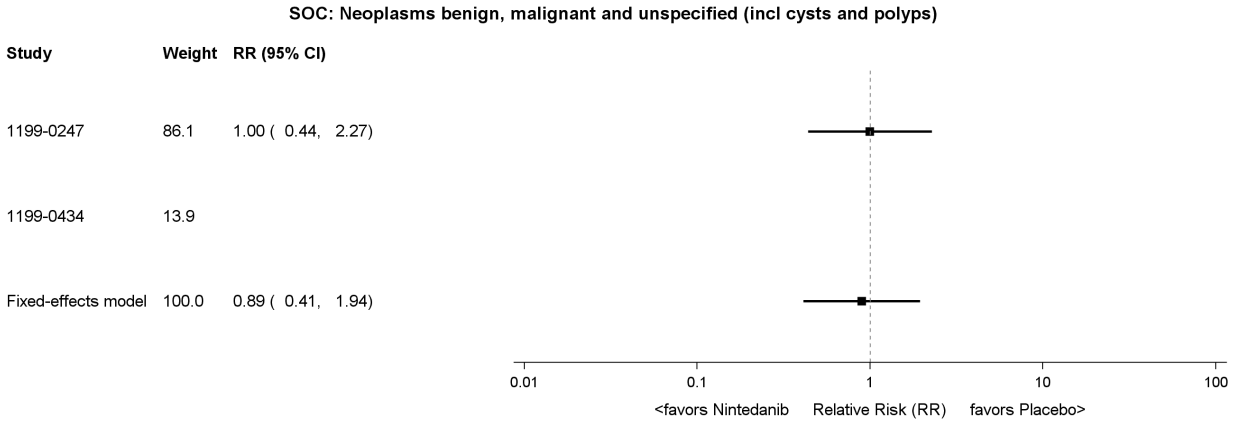

Figure M.2.2.1.3: 2 Forest Plot comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

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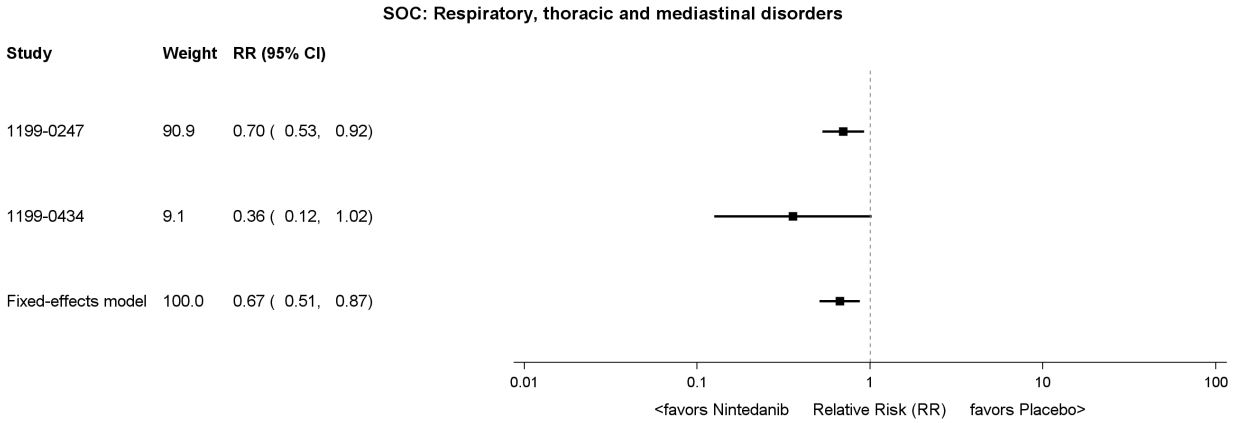

Figure M.2.2.1.3: 2 Forest Plot comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC over the whole trial

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M.2.2.1.4 Adverse events on PT level over the whole trial

Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Eye disorders
PT: Cataract

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	10/331 (3.0)	5/332 (1.5)	95.8	0/ 27 (0.0)	0/ 54 (0.0)	4.2	0.52 (0.19, 1.45)	0.2112	0.0	0.7491
Age										
<65 years	0/121 (0.0)	1/139 (0.7)	56.1	0/ 9 (0.0)	0/ 25 (0.0)	43.9	2.05 (0.16,26.34)	0.5818	0.0	0.7054
>=65 years	10/210 (4.8)	4/193 (2.1)	95.3	0/ 18 (0.0)	0/ 29 (0.0)	4.7	0.46 (0.15, 1.38)	0.1658	0.0	0.6945
Sex										
Male	7/177 (4.0)	3/179 (1.7)	94.4	0/ 11 (0.0)	0/ 26 (0.0)	5.6	0.46 (0.13, 1.62)	0.2241	0.0	0.7046
Female	3/154 (1.9)	2/153 (1.3)	86.6	0/ 16 (0.0)	0/ 28 (0.0)	13.4	0.72 (0.14, 3.61)	0.6850	0.0	0.8591
Baseline FVC percent predicted										
<=70%										
>70%										
Baseline HRCT pattern										
UIP-like	7/206 (3.4)	4/206 (1.9)	94.0	0/ 23 (0.0)	0/ 45 (0.0)	6.0	0.60 (0.19, 1.91)	0.3839	0.0	0.7981
Other fibrotic patterns	3/125 (2.4)	1/126 (0.8)	87.6	0/ 4 (0.0)	0/ 9 (0.0)	12.4	0.41 (0.06, 2.85)	0.3703	0.0	0.6430
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Eye disorders
PT: Cataract

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	10/331 (3.0)	5/332 (1.5)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	-1.36 (-3.46, 0.73)	0.0	0.5871
Age									
<65 years	0/121 (0.0)	1/139 (0.7)	90.3	0/ 9 (0.0)	0/ 25 (0.0)	9.7	0.64 (-1.54, 2.83)	0.0	0.9097
>=65 years	10/210 (4.8)	4/193 (2.1)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	-2.41 (-5.67, 0.85)	0.0	0.5523
Sex									
Male	7/177 (4.0)	3/179 (1.7)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-2.09 (-5.36, 1.19)	0.0	0.6948
Female	3/154 (1.9)	2/153 (1.3)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	-0.56 (-3.27, 2.14)	0.0	0.8915
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like	7/206 (3.4)	4/206 (1.9)	86.8	0/ 23 (0.0)	0/ 45 (0.0)	13.2	-1.26 (-4.07, 1.54)	0.0	0.6677
Other fibrotic patterns	3/125 (2.4)	1/126 (0.8)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-1.53 (-4.76, 1.70)	0.0	0.9089
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Eye disorders
PT: Cataract

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2 p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid			
Overall	10/331 (3.0)	5/332 (1.5)	95.7	0/ 27 (0.0)	0/ 54 (0.0)	4.3	0.51 (0.18, 1.45)	0.0 0.7469
Age								
<65 years	0/121 (0.0)	1/139 (0.7)	56.5	0/ 9 (0.0)	0/ 25 (0.0)	43.5	2.07 (0.15,28.97)	0.0 0.7091
>=65 years	10/210 (4.8)	4/193 (2.1)	95.3	0/ 18 (0.0)	0/ 29 (0.0)	4.7	0.45 (0.15, 1.38)	0.0 0.6911
Sex								
Male	7/177 (4.0)	3/179 (1.7)	94.4	0/ 11 (0.0)	0/ 26 (0.0)	5.6	0.45 (0.12, 1.62)	0.0 0.7043
Female	3/154 (1.9)	2/153 (1.3)	86.7	0/ 16 (0.0)	0/ 28 (0.0)	13.3	0.71 (0.14, 3.67)	0.0 0.8597
Baseline FVC percent predicted								
<=70%								
>70%								
Baseline HRCT pattern								
UIP-like	7/206 (3.4)	4/206 (1.9)	94.0	0/ 23 (0.0)	0/ 45 (0.0)	6.0	0.59 (0.18, 1.93)	0.0 0.7959
Other fibrotic patterns	3/125 (2.4)	1/126 (0.8)	88.3	0/ 4 (0.0)	0/ 9 (0.0)	11.7	0.40 (0.06, 2.84)	0.0 0.6566
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia								
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal discomfort

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Fixed effects Nin 150bid vs Placebo		Heterogeneity	
	Placebo	Nin 150bid Wt	Placebo	Nin 150bid Wt	Risk ratio (95% CI)	p-value	I^2	p-value
Overall	5/331 (1.5)	10/332 (3.0) 79.0	1/ 27 (3.7)	7/ 54 (13.0) 21.0	2.31 (0.90, 5.93)	0.0814	0.0	0.6321
Age								
<65 years	0/121 (0.0)	4/139 (2.9) 25.3	1/ 9 (11.1)	4/ 25 (16.0) 74.7	3.22 (0.65,16.03)	0.1533	0.0	0.3399
>=65 years	5/210 (2.4)	6/193 (3.1) 91.0	0/ 18 (0.0)	3/ 29 (10.3) 9.0	1.71 (0.58, 5.04)	0.3265	0.0	0.3981
Sex								
Male								
Female								
Baseline FVC percent predicted								
<=70%								
>70%								
Baseline HRCT pattern								
UIP-like	2/206 (1.0)	9/206 (4.4) 60.2	1/ 23 (4.3)	7/ 45 (15.6) 39.8	4.13 (1.22,13.94)	0.0222	0.0	0.8595
Other fibrotic patterns	3/125 (2.4)	1/126 (0.8) 87.6	0/ 4 (0.0)	0/ 9 (0.0) 12.4	0.41 (0.06, 2.85)	0.3703	0.0	0.6430
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia								
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal discomfort

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	5/331 (1.5)	10/332 (3.0)	90.2	1/ 27 (3.7)	7/ 54 (13.0)	9.8	2.26 (-0.07, 4.59)	41.1	0.1925
Age									
<65 years	0/121 (0.0)	4/139 (2.9)	90.8	1/ 9 (11.1)	4/ 25 (16.0)	9.2	3.04 (-0.62, 6.70)	0.0	0.8746
>=65 years	5/210 (2.4)	6/193 (3.1)	89.7	0/ 18 (0.0)	3/ 29 (10.3)	10.3	1.68 (-1.50, 4.86)	43.0	0.1852
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like	2/206 (1.0)	9/206 (4.4)	87.1	1/ 23 (4.3)	7/ 45 (15.6)	12.9	4.40 (1.20, 7.61)	18.4	0.2683
Other fibrotic patterns	3/125 (2.4)	1/126 (0.8)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-1.53 (-4.76, 1.70)	0.0	0.9089
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal discomfort

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	5/331 (1.5)	10/332 (3.0)	80.7	1/ 27 (3.7)	7/ 54 (13.0)	19.3	2.38 (0.91, 6.21)	0.0	0.5976
Age									
<65 years	0/121 (0.0)	4/139 (2.9)	28.0	1/ 9 (11.1)	4/ 25 (16.0)	72.0	3.55 (0.60,20.87)	0.0	0.3709
>=65 years	5/210 (2.4)	6/193 (3.1)	91.8	0/ 18 (0.0)	3/ 29 (10.3)	8.2	1.74 (0.59, 5.19)	0.0	0.3822
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like	2/206 (1.0)	9/206 (4.4)	63.1	1/ 23 (4.3)	7/ 45 (15.6)	36.9	4.44 (1.26,15.61)	0.0	0.9179
Other fibrotic patterns	3/125 (2.4)	1/126 (0.8)	88.3	0/ 4 (0.0)	0/ 9 (0.0)	11.7	0.40 (0.06, 2.84)	0.0	0.6566
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal distension

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid					
Overall	7/331 (2.1)	12/332 (3.6)	94.0	0/ 27 (0.0)	0/ 54 (0.0)	6.0	1.67 (0.68, 4.08)	0.2639	0.0	0.8040
Age										
<65 years	2/121 (1.7)	4/139 (2.9)	84.6	0/ 9 (0.0)	0/ 25 (0.0)	15.4	1.63 (0.34, 7.76)	0.5415	0.0	0.8168
>=65 years	5/210 (2.4)	8/193 (4.1)	91.0	0/ 18 (0.0)	0/ 29 (0.0)	9.0	1.67 (0.58, 4.82)	0.3396	0.0	0.7929
Sex										
Male	3/177 (1.7)	9/179 (5.0)	87.8	0/ 11 (0.0)	0/ 26 (0.0)	12.2	2.73 (0.80, 9.26)	0.1076	0.0	0.6301
Female	4/154 (2.6)	3/153 (2.0)	89.6	0/ 16 (0.0)	0/ 28 (0.0)	10.4	0.78 (0.19, 3.13)	0.7262	0.0	0.8979
Baseline FVC percent predicted										
<=70%	2/193 (1.0)	8/196 (4.1)	81.2	0/ 10 (0.0)	0/ 17 (0.0)	18.8	3.39 (0.83,13.82)	0.0891	0.0	0.5296
>70%	5/138 (3.6)	4/136 (2.9)	92.0	0/ 17 (0.0)	0/ 37 (0.0)	8.0	0.83 (0.24, 2.84)	0.7628	0.0	0.9256
Baseline HRCT pattern										
UIP-like	3/206 (1.5)	9/206 (4.4)	87.0	0/ 23 (0.0)	0/ 45 (0.0)	13.0	2.74 (0.81, 9.28)	0.1053	0.0	0.6175
Other fibrotic patterns	4/125 (3.2)	3/126 (2.4)	90.4	0/ 4 (0.0)	0/ 9 (0.0)	9.6	0.77 (0.19, 3.08)	0.7101	0.0	0.8943
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	3/ 76 (3.9)	1/ 79 (1.3)	87.3	0/ 27 (0.0)	0/ 54 (0.0)	12.7	0.41 (0.06, 2.78)	0.3591	0.0	0.6354
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal distension

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Fixed effects Nin 150bid vs Placebo Wt	Risk difference (95% CI)	Heterogeneity I^2 p-value
	Placebo	Nin 150bid	Placebo	Nin 150bid			
Overall	7/331 (2.1)	12/332 (3.6)	0/ 27 (0.0)	0/ 54 (0.0)	10.0	1.35 (-0.99, 3.69)	0.0 0.5989
Age							
<65 years	2/121 (1.7)	4/139 (2.9)	0/ 9 (0.0)	0/ 25 (0.0)	9.8	1.11 (-2.35, 4.56)	0.0 0.8499
>=65 years	5/210 (2.4)	8/193 (4.1)	0/ 18 (0.0)	0/ 29 (0.0)	10.3	1.58 (-1.66, 4.82)	0.0 0.6963
Sex							
Male	3/177 (1.7)	9/179 (5.0)	0/ 11 (0.0)	0/ 26 (0.0)	8.4	3.05 (-0.48, 6.58)	0.0 0.5691
Female	4/154 (2.6)	3/153 (2.0)	0/ 16 (0.0)	0/ 28 (0.0)	12.2	-0.56 (-3.68, 2.56)	0.0 0.8941
Baseline FVC percent predicted							
<=70%	2/193 (1.0)	8/196 (4.1)	0/ 10 (0.0)	0/ 17 (0.0)	6.5	2.85 (-0.20, 5.90)	0.0 0.6721
>70%	5/138 (3.6)	4/136 (2.9)	0/ 17 (0.0)	0/ 37 (0.0)	15.0	-0.58 (-4.34, 3.18)	0.0 0.8761
Baseline HRCT pattern							
UIP-like	3/206 (1.5)	9/206 (4.4)	0/ 23 (0.0)	0/ 45 (0.0)	13.2	2.53 (-0.39, 5.44)	0.0 0.3947
Other fibrotic patterns	4/125 (3.2)	3/126 (2.4)	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-0.78 (-4.88, 3.32)	0.0 0.9537
Underlying ILD diagnosis							
iNSIP							
Unclassifiable IIP							
HP							
Autoimmune ILD							
Other ILD							
Region							
Europe							
Asia	3/ 76 (3.9)	1/ 79 (1.3)	0/ 27 (0.0)	0/ 54 (0.0)	32.3	-1.82 (-5.58, 1.95)	0.0 0.4575
Canada and USA							
Rest of the World							

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal distension

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2 p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid			
Overall	7/331 (2.1)	12/332 (3.6)	93.9	0/ 27 (0.0)	0/ 54 (0.0)	6.1	1.69 (0.67, 4.25)	0.0 0.8010
Age								
<65 years	2/121 (1.7)	4/139 (2.9)	84.6	0/ 9 (0.0)	0/ 25 (0.0)	15.4	1.65 (0.33, 8.20)	0.0 0.8177
>=65 years	5/210 (2.4)	8/193 (4.1)	90.8	0/ 18 (0.0)	0/ 29 (0.0)	9.2	1.70 (0.57, 5.08)	0.0 0.7907
Sex								
Male	3/177 (1.7)	9/179 (5.0)	87.6	0/ 11 (0.0)	0/ 26 (0.0)	12.4	2.81 (0.80, 9.95)	0.0 0.6283
Female	4/154 (2.6)	3/153 (2.0)	89.6	0/ 16 (0.0)	0/ 28 (0.0)	10.4	0.78 (0.19, 3.20)	0.0 0.8978
Baseline FVC percent predicted								
<=70%	2/193 (1.0)	8/196 (4.1)	81.1	0/ 10 (0.0)	0/ 17 (0.0)	18.9	3.48 (0.82,14.76)	0.0 0.5338
>70%	5/138 (3.6)	4/136 (2.9)	91.9	0/ 17 (0.0)	0/ 37 (0.0)	8.1	0.82 (0.23, 2.93)	0.0 0.9246
Baseline HRCT pattern								
UIP-like	3/206 (1.5)	9/206 (4.4)	86.7	0/ 23 (0.0)	0/ 45 (0.0)	13.3	2.81 (0.80, 9.86)	0.0 0.6133
Other fibrotic patterns	4/125 (3.2)	3/126 (2.4)	90.8	0/ 4 (0.0)	0/ 9 (0.0)	9.2	0.76 (0.18, 3.18)	0.0 0.8980
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia	3/ 76 (3.9)	1/ 79 (1.3)	87.3	0/ 27 (0.0)	0/ 54 (0.0)	12.7	0.40 (0.06, 2.74)	0.0 0.6320
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	10/331 (3.0)	34/332 (10.2)	95.8	0/ 27 (0.0)	4/ 54 (7.4)	4.2	3.54 (1.80, 6.98)	0.0003	0.0	0.6890
Age										
<65 years	3/121 (2.5)	14/139 (10.1)	89.2	0/ 9 (0.0)	2/ 25 (8.0)	10.8	4.03 (1.25,12.96)	0.0196	0.0	0.9665
>=65 years	7/210 (3.3)	20/193 (10.4)	93.4	0/ 18 (0.0)	2/ 29 (6.9)	6.6	3.18 (1.41, 7.19)	0.0053	0.0	0.8597
Sex										
Male	4/177 (2.3)	19/179 (10.6)	90.6	0/ 11 (0.0)	2/ 26 (7.7)	9.4	4.62 (1.67,12.78)	0.0032	0.0	0.9194
Female	6/154 (3.9)	15/153 (9.8)	92.8	0/ 16 (0.0)	2/ 28 (7.1)	7.2	2.63 (1.08, 6.41)	0.0329	0.0	0.7823
Baseline FVC percent predicted										
<=70%	5/193 (2.6)	19/196 (9.7)	91.5	0/ 10 (0.0)	0/ 17 (0.0)	8.5	3.51 (1.39, 8.89)	0.0081	0.0	0.5285
>70%	5/138 (3.6)	15/136 (11.0)	92.0	0/ 17 (0.0)	4/ 37 (10.8)	8.0	3.35 (1.29, 8.70)	0.0131	0.0	0.6680
Baseline HRCT pattern										
UIP-like	3/206 (1.5)	20/206 (9.7)	87.0	0/ 23 (0.0)	3/ 45 (6.7)	13.0	6.52 (2.10,20.26)	0.0012	0.0	0.9211
Other fibrotic patterns	7/125 (5.6)	14/126 (11.1)	94.3	0/ 4 (0.0)	1/ 9 (11.1)	5.7	2.01 (0.86, 4.70)	0.1073	0.0	0.9139
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	2/ 64 (3.1)	68.3	0/ 7 (0.0)	3/ 11 (27.3)	31.7	3.18 (0.49,20.48)	0.2244	0.0	0.5766
Unclassifiable IIP	0/ 50 (0.0)	9/ 64 (14.1)	50.6	0/ 3 (0.0)	0/ 2 (0.0)	49.4	9.12 (1.05,79.51)	0.0455	26.3	0.2440
HP	2/ 89 (2.2)	14/ 84 (16.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	4/ 88 (4.5)	7/ 82 (8.5)	90.9	0/ 12 (0.0)	1/ 34 (2.9)	9.1	1.92 (0.61, 6.04)	0.2641	0.0	0.9169
Other ILD	3/ 43 (7.0)	2/ 38 (5.3)	85.0	0/ 5 (0.0)	0/ 6 (0.0)	15.0	0.79 (0.16, 3.82)	0.7707	0.0	0.8944
Region										
Europe										
Asia	1/ 76 (1.3)	3/ 79 (3.8)	69.6	0/ 27 (0.0)	4/ 54 (7.4)	30.4	4.14 (0.62,27.53)	0.1422	0.0	0.6751
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	10/331 (3.0)	34/332 (10.2)	90.0	0/ 27 (0.0)	4/ 54 (7.4)	10.0	7.22 (3.75, 10.69)	0.0	0.9984
Age									
<65 years	3/121 (2.5)	14/139 (10.1)	90.2	0/ 9 (0.0)	2/ 25 (8.0)	9.8	7.59 (2.21, 12.97)	0.0	0.9965
>=65 years	7/210 (3.3)	20/193 (10.4)	89.7	0/ 18 (0.0)	2/ 29 (6.9)	10.3	6.99 (2.39, 11.58)	0.0	0.9497
Sex									
Male	4/177 (2.3)	19/179 (10.6)	91.6	0/ 11 (0.0)	2/ 26 (7.7)	8.4	8.27 (3.52, 13.02)	0.0	0.8920
Female	6/154 (3.9)	15/153 (9.8)	87.8	0/ 16 (0.0)	2/ 28 (7.1)	12.2	6.02 (0.86, 11.18)	0.0	0.8948
Baseline FVC percent predicted									
<=70%	5/193 (2.6)	19/196 (9.7)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	6.64 (2.15, 11.13)	0.0	0.3382
>70%	5/138 (3.6)	15/136 (11.0)	85.0	0/ 17 (0.0)	4/ 37 (10.8)	15.0	7.86 (2.35, 13.37)	0.0	0.6618
Baseline HRCT pattern									
UIP-like	3/206 (1.5)	20/206 (9.7)	86.8	0/ 23 (0.0)	3/ 45 (6.7)	13.2	8.02 (4.05, 11.99)	0.0	0.7306
Other fibrotic patterns	7/125 (5.6)	14/126 (11.1)	95.2	0/ 4 (0.0)	1/ 9 (11.1)	4.8	5.71 (-0.95, 12.37)	0.0	0.8050
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	2/ 64 (3.1)	86.8	0/ 7 (0.0)	3/ 11 (27.3)	13.2	4.53 (-1.54, 10.60)	55.1	0.1356
Unclassifiable IIP	0/ 50 (0.0)	9/ 64 (14.1)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	13.05 (4.09, 22.01)	0.0	0.6138
HP	2/ 89 (2.2)	14/ 84 (16.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	7/ 82 (8.5)	82.1	0/ 12 (0.0)	1/ 34 (2.9)	17.9	3.78 (-2.63, 10.19)	0.0	0.8595
Other ILD	3/ 43 (7.0)	2/ 38 (5.3)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	-1.48 (-11.31, 8.35)	0.0	0.9134
Region									
Europe									
Asia	1/ 76 (1.3)	3/ 79 (3.8)	67.7	0/ 27 (0.0)	4/ 54 (7.4)	32.3	4.01 (-0.28, 8.31)	0.0	0.3384
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	10/331 (3.0)	34/332 (10.2)	95.7	0/ 27 (0.0)	4/ 54 (7.4)	4.3	3.83 (1.89, 7.77)	0.0	0.6949
Age									
<65 years	3/121 (2.5)	14/139 (10.1)	89.2	0/ 9 (0.0)	2/ 25 (8.0)	10.8	4.37 (1.29,14.73)	0.0	0.9676
>=65 years	7/210 (3.3)	20/193 (10.4)	93.3	0/ 18 (0.0)	2/ 29 (6.9)	6.7	3.43 (1.46, 8.08)	0.0	0.8664
Sex									
Male	4/177 (2.3)	19/179 (10.6)	90.5	0/ 11 (0.0)	2/ 26 (7.7)	9.5	5.04 (1.75,14.55)	0.0	0.9176
Female	6/154 (3.9)	15/153 (9.8)	92.8	0/ 16 (0.0)	2/ 28 (7.1)	7.2	2.81 (1.10, 7.17)	0.0	0.7854
Baseline FVC percent predicted									
<=70%	5/193 (2.6)	19/196 (9.7)	91.0	0/ 10 (0.0)	0/ 17 (0.0)	9.0	3.76 (1.42, 9.95)	0.0	0.5201
>70%	5/138 (3.6)	15/136 (11.0)	92.1	0/ 17 (0.0)	4/ 37 (10.8)	7.9	3.64 (1.34, 9.88)	0.0	0.6643
Baseline HRCT pattern									
UIP-like	3/206 (1.5)	20/206 (9.7)	86.8	0/ 23 (0.0)	3/ 45 (6.7)	13.2	7.10 (2.21,22.75)	0.0	0.9147
Other fibrotic patterns	7/125 (5.6)	14/126 (11.1)	94.6	0/ 4 (0.0)	1/ 9 (11.1)	5.4	2.14 (0.85, 5.36)	0.0	0.9026
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	2/ 64 (3.1)	74.8	0/ 7 (0.0)	3/ 11 (27.3)	25.2	3.46 (0.51,23.40)	0.0	0.5109
Unclassifiable IIP	0/ 50 (0.0)	9/ 64 (14.1)	50.5	0/ 3 (0.0)	0/ 2 (0.0)	49.5	10.49 (1.18,93.69)	18.3	0.2687
HP	2/ 89 (2.2)	14/ 84 (16.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	7/ 82 (8.5)	90.6	0/ 12 (0.0)	1/ 34 (2.9)	9.4	2.00 (0.60, 6.73)	0.0	0.9240
Other ILD	3/ 43 (7.0)	2/ 38 (5.3)	85.3	0/ 5 (0.0)	0/ 6 (0.0)	14.7	0.78 (0.15, 4.17)	0.0	0.8958
Region									
Europe									
Asia	1/ 76 (1.3)	3/ 79 (3.8)	70.7	0/ 27 (0.0)	4/ 54 (7.4)	29.3	4.31 (0.65,28.72)	0.0	0.6634
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain upper

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Fixed effects Nin 150bid vs Placebo Wt	Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
	Placebo	Nin 150bid	Placebo	Nin 150bid					
Overall	7/331 (2.1)	33/332 (9.9)	0/ 27 (0.0)	5/ 54 (9.3)	6.0	4.93 (2.25,10.79)	<.0001	0.0	0.7439
Age									
<65 years	4/121 (3.3)	10/139 (7.2)	0/ 9 (0.0)	3/ 25 (12.0)	8.3	2.42 (0.81, 7.20)	0.1127	0.0	0.6805
>=65 years	3/210 (1.4)	23/193 (11.9)	0/ 18 (0.0)	2/ 29 (6.9)	14.1	7.76 (2.55,23.62)	0.0003	0.0	0.7085
Sex									
Male	3/177 (1.7)	13/179 (7.3)	0/ 11 (0.0)	1/ 26 (3.8)	12.2	4.06 (1.25,13.13)	0.0194	0.0	0.7816
Female	4/154 (2.6)	20/153 (13.1)	0/ 16 (0.0)	4/ 28 (14.3)	10.4	5.27 (1.93,14.39)	0.0012	0.0	0.8351
Baseline FVC percent predicted									
<=70%	3/193 (1.6)	25/196 (12.8)	0/ 10 (0.0)	0/ 17 (0.0)	13.4	7.24 (2.39,21.91)	0.0005	0.0	0.3213
>70%	4/138 (2.9)	8/136 (5.9)	0/ 17 (0.0)	5/ 37 (13.5)	9.8	2.64 (0.87, 8.06)	0.0875	0.0	0.4598
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	18/206 (8.7)	0/ 23 (0.0)	3/ 45 (6.7)	8.2	3.76 (1.47, 9.62)	0.0057	0.0	0.8160
Other fibrotic patterns	2/125 (1.6)	15/126 (11.9)	0/ 4 (0.0)	2/ 9 (22.2)	17.5	6.82 (1.79,26.02)	0.0050	0.0	0.7412
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	8/ 64 (12.5)	0/ 7 (0.0)	1/ 11 (9.1)	31.7	6.04 (1.08,33.90)	0.0409	0.0	0.5988
Unclassifiable IIP	2/ 50 (4.0)	5/ 64 (7.8)	0/ 3 (0.0)	0/ 2 (0.0)	17.6	1.79 (0.41, 7.69)	0.4368	0.0	0.7450
HP	1/ 89 (1.1)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	2/ 88 (2.3)	10/ 82 (12.2)	83.3	0/ 12 (0.0)	3/ 34 (8.8)	16.7	5.31 (1.31,21.54)	0.0193	0.0	0.9780
Other ILD	1/ 43 (2.3)	3/ 38 (7.9)	65.4	0/ 5 (0.0)	1/ 6 (16.7)	34.6	3.20 (0.52,19.53)	0.2074	0.0	0.9263
Region									
Europe									
Asia	3/ 76 (3.9)	9/ 79 (11.4)	87.3	0/ 27 (0.0)	5/ 54 (9.3)	12.7	3.60 (1.08,11.94)	0.0364	0.0	0.5659
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain upper

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	7/331 (2.1)	33/332 (9.9)	90.0	0/ 27 (0.0)	5/ 54 (9.3)	10.0	7.95 (4.61, 11.28)	0.0	0.8057
Age									
<65 years	4/121 (3.3)	10/139 (7.2)	90.2	0/ 9 (0.0)	3/ 25 (12.0)	9.8	4.62 (-0.48, 9.72)	0.0	0.4098
>=65 years	3/210 (1.4)	23/193 (11.9)	89.7	0/ 18 (0.0)	2/ 29 (6.9)	10.3	10.09 (5.57, 14.60)	0.0	0.5543
Sex									
Male	3/177 (1.7)	13/179 (7.3)	91.6	0/ 11 (0.0)	1/ 26 (3.8)	8.4	5.41 (1.37, 9.45)	0.0	0.7807
Female	4/154 (2.6)	20/153 (13.1)	87.8	0/ 16 (0.0)	4/ 28 (14.3)	12.2	10.86 (5.37, 16.36)	0.0	0.6974
Baseline FVC percent predicted									
<=70%	3/193 (1.6)	25/196 (12.8)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	10.47 (5.73, 15.22)	55.6	0.1334
>70%	4/138 (2.9)	8/136 (5.9)	85.0	0/ 17 (0.0)	5/ 37 (13.5)	15.0	4.49 (-0.06, 9.04)	51.5	0.1510
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	18/206 (8.7)	86.8	0/ 23 (0.0)	3/ 45 (6.7)	13.2	6.33 (2.33, 10.33)	0.0	0.9744
Other fibrotic patterns	2/125 (1.6)	15/126 (11.9)	95.2	0/ 4 (0.0)	2/ 9 (22.2)	4.8	10.74 (4.72, 16.76)	0.0	0.6217
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	8/ 64 (12.5)	86.8	0/ 7 (0.0)	1/ 11 (9.1)	13.2	10.51 (2.29, 18.72)	0.0	0.8393
Unclassifiable IIP	2/ 50 (4.0)	5/ 64 (7.8)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	3.60 (-4.99, 12.18)	0.0	0.8891
HP	1/ 89 (1.1)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	2/ 88 (2.3)	10/ 82 (12.2)	82.1	0/ 12 (0.0)	3/ 34 (8.8)	17.9	9.66 (2.91, 16.41)	0.0	0.8479
Other ILD	1/ 43 (2.3)	3/ 38 (7.9)	86.2	0/ 5 (0.0)	1/ 6 (16.7)	13.8	6.74 (-3.05, 16.54)	0.0	0.6636
Region									
Europe									
Asia	3/ 76 (3.9)	9/ 79 (11.4)	67.7	0/ 27 (0.0)	5/ 54 (9.3)	32.3	7.96 (1.66, 14.26)	0.0	0.7981
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain upper

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo: Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	7/331 (2.1)	33/332 (9.9)	94.1	0/ 27 (0.0)	5/ 54 (9.3)	5.9	5.36 (2.39,12.03)	0.0	0.7433
Age									
<65 years	4/121 (3.3)	10/139 (7.2)	92.2	0/ 9 (0.0)	3/ 25 (12.0)	7.8	2.54 (0.82, 7.85)	0.0	0.6631
>=65 years	3/210 (1.4)	23/193 (11.9)	85.4	0/ 18 (0.0)	2/ 29 (6.9)	14.6	8.64 (2.74,27.26)	0.0	0.6996
Sex									
Male	3/177 (1.7)	13/179 (7.3)	87.7	0/ 11 (0.0)	1/ 26 (3.8)	12.3	4.29 (1.28,14.45)	0.0	0.7809
Female	4/154 (2.6)	20/153 (13.1)	89.9	0/ 16 (0.0)	4/ 28 (14.3)	10.1	5.92 (2.08,16.87)	0.0	0.8250
Baseline FVC percent predicted									
<=70%	3/193 (1.6)	25/196 (12.8)	85.4	0/ 10 (0.0)	0/ 17 (0.0)	14.6	8.05 (2.56,25.35)	2.6	0.3110
>70%	4/138 (2.9)	8/136 (5.9)	91.0	0/ 17 (0.0)	5/ 37 (13.5)	9.0	2.76 (0.89, 8.56)	0.0	0.4376
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	18/206 (8.7)	91.7	0/ 23 (0.0)	3/ 45 (6.7)	8.3	4.02 (1.52,10.63)	0.0	0.8194
Other fibrotic patterns	2/125 (1.6)	15/126 (11.9)	84.9	0/ 4 (0.0)	2/ 9 (22.2)	15.1	7.79 (1.93,31.52)	0.0	0.8047
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	8/ 64 (12.5)	68.5	0/ 7 (0.0)	1/ 11 (9.1)	31.5	6.78 (1.12,41.17)	0.0	0.6109
Unclassifiable IIP	2/ 50 (4.0)	5/ 64 (7.8)	83.4	0/ 3 (0.0)	0/ 2 (0.0)	16.6	1.86 (0.39, 8.80)	0.0	0.7641
HP	1/ 89 (1.1)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	2/ 88 (2.3)	10/ 82 (12.2)	83.1	0/ 12 (0.0)	3/ 34 (8.8)	16.9	5.90 (1.38,25.29)	0.0	0.9726
Other ILD	1/ 43 (2.3)	3/ 38 (7.9)	69.0	0/ 5 (0.0)	1/ 6 (16.7)	31.0	3.52 (0.51,24.22)	0.0	0.9726
Region									
Europe									
Asia	3/ 76 (3.9)	9/ 79 (11.4)	87.2	0/ 27 (0.0)	5/ 54 (9.3)	12.8	3.93 (1.13,13.64)	0.0	0.5693
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Constipation

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	32/331 (9.7)	26/332 (7.8)	92.3	2/ 27 (7.4)	3/ 54 (5.6)	7.7	0.81 (0.50, 1.30)	0.3725	0.0	0.9331
Age										
<65 years	7/121 (5.8)	10/139 (7.2)	71.8	2/ 9 (22.2)	1/ 25 (4.0)	28.2	0.94 (0.42, 2.14)	0.8895	57.8	0.1237
>=65 years	25/210 (11.9)	16/193 (8.3)	98.1	0/ 18 (0.0)	2/ 29 (6.9)	1.9	0.76 (0.43, 1.36)	0.3639	8.1	0.2968
Sex										
Male	17/177 (9.6)	16/179 (8.9)	97.6	0/ 11 (0.0)	0/ 26 (0.0)	2.4	0.93 (0.49, 1.77)	0.8308	0.0	0.9738
Female	15/154 (9.7)	10/153 (6.5)	85.5	2/ 16 (12.5)	3/ 28 (10.7)	14.5	0.70 (0.35, 1.40)	0.3131	0.0	0.7951
Baseline FVC percent predicted										
<=70%	23/193 (11.9)	21/196 (10.7)	94.8	1/ 10 (10.0)	1/ 17 (5.9)	5.2	0.88 (0.51, 1.52)	0.6546	0.0	0.7596
>70%	9/138 (6.5)	5/136 (3.7)	86.7	1/ 17 (5.9)	2/ 37 (5.4)	13.3	0.61 (0.23, 1.61)	0.3178	0.0	0.7087
Baseline HRCT pattern										
UIP-like	23/206 (11.2)	19/206 (9.2)	89.7	2/ 23 (8.7)	3/ 45 (6.7)	10.3	0.82 (0.47, 1.42)	0.4762	0.0	0.9356
Other fibrotic patterns	9/125 (7.2)	7/126 (5.6)	95.5	0/ 4 (0.0)	0/ 9 (0.0)	4.5	0.78 (0.31, 1.98)	0.6044	0.0	0.9040
Underlying ILD diagnosis										
iNSIP	4/ 61 (6.6)	4/ 64 (6.3)	58.4	2/ 7 (28.6)	0/ 11 (0.0)	41.6	0.62 (0.20, 1.91)	0.4098	26.0	0.2452
Unclassifiable IIP	9/ 50 (18.0)	4/ 64 (6.3)	95.5	0/ 3 (0.0)	0/ 2 (0.0)	4.5	0.38 (0.13, 1.09)	0.0713	0.0	0.5921
HP	9/ 89 (10.1)	6/ 84 (7.1)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	6/ 88 (6.8)	10/ 82 (12.2)	93.8	0/ 12 (0.0)	2/ 34 (5.9)	6.2	1.91 (0.74, 4.90)	0.1790	0.0	0.7264
Other ILD	4/ 43 (9.3)	2/ 38 (5.3)	88.3	0/ 5 (0.0)	0/ 6 (0.0)	11.7	0.62 (0.14, 2.76)	0.5267	0.0	0.7866
Region										
Europe										
Asia	17/ 76 (22.4)	10/ 79 (12.7)	86.7	2/ 27 (7.4)	3/ 54 (5.6)	13.3	0.59 (0.31, 1.14)	0.1175	0.0	0.7679
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Constipation

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	32/331 (9.7)	26/332 (7.8)	90.2	2/ 27 (7.4)	3/ 54 (5.6)	9.8	-1.84 (-5.88, 2.20)	0.0	0.9980
Age									
<65 years	7/121 (5.8)	10/139 (7.2)	90.7	2/ 9 (22.2)	1/ 25 (4.0)	9.3	-0.41 (-6.44, 5.61)	43.8	0.1824
>=65 years	25/210 (11.9)	16/193 (8.3)	89.7	0/ 18 (0.0)	2/ 29 (6.9)	10.3	-2.56 (-7.95, 2.84)	56.3	0.1304
Sex									
Male	17/177 (9.6)	16/179 (8.9)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-0.61 (-6.21, 4.98)	0.0	0.9163
Female	15/154 (9.7)	10/153 (6.5)	88.3	2/ 16 (12.5)	3/ 28 (10.7)	11.7	-3.04 (-8.91, 2.83)	0.0	0.8935
Baseline FVC percent predicted									
<=70%	23/193 (11.9)	21/196 (10.7)	93.9	1/ 10 (10.0)	1/ 17 (5.9)	6.1	-1.38 (-7.44, 4.68)	0.0	0.8004
>70%	9/138 (6.5)	5/136 (3.7)	85.5	1/ 17 (5.9)	2/ 37 (5.4)	14.5	-2.50 (-7.35, 2.34)	0.0	0.7459
Baseline HRCT pattern									
UIP-like	23/206 (11.2)	19/206 (9.2)	87.1	2/ 23 (8.7)	3/ 45 (6.7)	12.9	-1.95 (-7.34, 3.43)	0.0	0.9908
Other fibrotic patterns	9/125 (7.2)	7/126 (5.6)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-1.56 (-7.47, 4.34)	0.0	0.9084
Underlying ILD diagnosis									
iNSIP	4/ 61 (6.6)	4/ 64 (6.3)	86.8	2/ 7 (28.6)	0/ 11 (0.0)	13.2	-3.66 (-12.41, 5.08)	48.6	0.1630
Unclassifiable IIP	9/ 50 (18.0)	4/ 64 (6.3)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	-11.09 (-22.97, 0.80)	0.0	0.6715
HP	9/ 89 (10.1)	6/ 84 (7.1)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	6/ 88 (6.8)	10/ 82 (12.2)	82.1	0/ 12 (0.0)	2/ 34 (5.9)	17.9	5.42 (-2.13, 12.97)	0.0	0.9724
Other ILD	4/ 43 (9.3)	2/ 38 (5.3)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	-3.48 (-13.95, 6.98)	0.0	0.7996
Region									
Europe									
Asia	17/ 76 (22.4)	10/ 79 (12.7)	68.3	2/ 27 (7.4)	3/ 54 (5.6)	31.7	-7.22 (-16.14, 1.70)	0.0	0.3543
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Constipation

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	32/331 (9.7)	26/332 (7.8)	92.1	2/ 27 (7.4)	3/ 54 (5.6)	7.9	0.79 (0.47, 1.33)	0.0	0.9379
Age									
<65 years	7/121 (5.8)	10/139 (7.2)	71.1	2/ 9 (22.2)	1/ 25 (4.0)	28.9	0.94 (0.38, 2.31)	58.3	0.1216
>=65 years	25/210 (11.9)	16/193 (8.3)	98.1	0/ 18 (0.0)	2/ 29 (6.9)	1.9	0.74 (0.39, 1.40)	13.0	0.2837
Sex									
Male	17/177 (9.6)	16/179 (8.9)	97.5	0/ 11 (0.0)	0/ 26 (0.0)	2.5	0.93 (0.46, 1.88)	0.0	0.9719
Female	15/154 (9.7)	10/153 (6.5)	86.0	2/ 16 (12.5)	3/ 28 (10.7)	14.0	0.67 (0.32, 1.45)	0.0	0.8068
Baseline FVC percent predicted									
<=70%	23/193 (11.9)	21/196 (10.7)	94.6	1/ 10 (10.0)	1/ 17 (5.9)	5.4	0.87 (0.47, 1.61)	0.0	0.7628
>70%	9/138 (6.5)	5/136 (3.7)	86.9	1/ 17 (5.9)	2/ 37 (5.4)	13.1	0.60 (0.22, 1.63)	0.0	0.7107
Baseline HRCT pattern									
UIP-like	23/206 (11.2)	19/206 (9.2)	89.4	2/ 23 (8.7)	3/ 45 (6.7)	10.6	0.80 (0.44, 1.47)	0.0	0.9406
Other fibrotic patterns	9/125 (7.2)	7/126 (5.6)	95.5	0/ 4 (0.0)	0/ 9 (0.0)	4.5	0.77 (0.29, 2.07)	0.0	0.9043
Underlying ILD diagnosis									
iNSIP	4/ 61 (6.6)	4/ 64 (6.3)	58.1	2/ 7 (28.6)	0/ 11 (0.0)	41.9	0.60 (0.18, 2.05)	33.9	0.2189
Unclassifiable IIP	9/ 50 (18.0)	4/ 64 (6.3)	95.8	0/ 3 (0.0)	0/ 2 (0.0)	4.2	0.33 (0.10, 1.09)	0.0	0.6035
HP	9/ 89 (10.1)	6/ 84 (7.1)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	6/ 88 (6.8)	10/ 82 (12.2)	93.5	0/ 12 (0.0)	2/ 34 (5.9)	6.5	2.03 (0.73, 5.63)	0.0	0.7343
Other ILD	4/ 43 (9.3)	2/ 38 (5.3)	88.6	0/ 5 (0.0)	0/ 6 (0.0)	11.4	0.59 (0.12, 2.95)	0.0	0.7875
Region									
Europe									
Asia	17/ 76 (22.4)	10/ 79 (12.7)	85.7	2/ 27 (7.4)	3/ 54 (5.6)	14.3	0.54 (0.25, 1.16)	0.0	0.7152
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	85/331 (25.7)	240/332 (72.3)	94.1	4/ 27 (14.8)	19/ 54 (35.2)	5.9	2.79 (2.30, 3.38)	<.0001	0.0	0.7374
Age										
<65 years	25/121 (20.7)	99/139 (71.2)	94.8	1/ 9 (11.1)	5/ 25 (20.0)	5.2	3.36 (2.35, 4.81)	<.0001	0.0	0.5325
>=65 years	60/210 (28.6)	141/193 (73.1)	93.9	3/ 18 (16.7)	14/ 29 (48.3)	6.1	2.58 (2.05, 3.23)	<.0001	0.0	0.8278
Sex										
Male	47/177 (26.6)	132/179 (73.7)	99.1	0/ 11 (0.0)	8/ 26 (30.8)	0.9	2.86 (2.20, 3.72)	<.0001	0.0	0.4157
Female	38/154 (24.7)	108/153 (70.6)	88.2	4/ 16 (25.0)	11/ 28 (39.3)	11.8	2.71 (2.05, 3.58)	<.0001	26.1	0.2447
Baseline FVC percent predicted										
<=70%	50/193 (25.9)	140/196 (71.4)	97.6	1/ 10 (10.0)	6/ 17 (35.3)	2.4	2.78 (2.15, 3.58)	<.0001	0.0	0.8073
>70%	35/138 (25.4)	100/136 (73.5)	89.4	3/ 17 (17.6)	13/ 37 (35.1)	10.6	2.80 (2.09, 3.76)	<.0001	0.0	0.5243
Baseline HRCT pattern										
UIP-like	56/206 (27.2)	154/206 (74.8)	93.4	3/ 23 (13.0)	17/ 45 (37.8)	6.6	2.76 (2.18, 3.49)	<.0001	0.0	0.9293
Other fibrotic patterns	29/125 (23.2)	86/126 (68.3)	95.5	1/ 4 (25.0)	2/ 9 (22.2)	4.5	2.85 (2.04, 3.98)	<.0001	18.4	0.2683
Underlying ILD diagnosis										
iNSIP	13/ 61 (21.3)	43/ 64 (67.2)	91.6	1/ 7 (14.3)	7/ 11 (63.6)	8.4	3.26 (1.99, 5.36)	<.0001	0.0	0.7266
Unclassifiable IIP	9/ 50 (18.0)	48/ 64 (75.0)	95.5	0/ 3 (0.0)	1/ 2 (50.0)	4.5	4.14 (2.29, 7.48)	<.0001	0.0	0.8989
HP	27/ 89 (30.3)	66/ 84 (78.6)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	25/ 88 (28.4)	56/ 82 (68.3)	94.2	1/ 12 (8.3)	10/ 34 (29.4)	5.8	2.47 (1.72, 3.55)	<.0001	0.0	0.7040
Other ILD	11/ 43 (25.6)	27/ 38 (71.1)	82.5	2/ 5 (40.0)	1/ 6 (16.7)	17.5	2.37 (1.41, 3.96)	0.0010	66.3	0.0848
Region										
Europe										
Asia	21/ 76 (27.6)	62/ 79 (78.5)	80.1	4/ 27 (14.8)	19/ 54 (35.2)	19.9	2.75 (1.92, 3.94)	<.0001	0.0	0.7375
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo: Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	85/331 (25.7)	240/332 (72.3)	90.2	4/ 27 (14.8)	19/ 54 (35.2)	9.8	44.04 (37.70, 50.38)	85.4	0.0090
Age									
<65 years	25/121 (20.7)	99/139 (71.2)	90.7	1/ 9 (11.1)	5/ 25 (20.0)	9.3	46.69 (36.94, 56.45)	88.4	0.0034
>=65 years	60/210 (28.6)	141/193 (73.1)	90.1	3/ 18 (16.7)	14/ 29 (48.3)	9.9	43.21 (34.94, 51.47)	0.0	0.3414
Sex									
Male	47/177 (26.6)	132/179 (73.7)	91.6	0/ 11 (0.0)	8/ 26 (30.8)	8.4	45.68 (37.13, 54.23)	62.2	0.1039
Female	38/154 (24.7)	108/153 (70.6)	88.3	4/ 16 (25.0)	11/ 28 (39.3)	11.7	42.21 (32.86, 51.56)	77.2	0.0362
Baseline FVC percent predicted									
<=70%	50/193 (25.9)	140/196 (71.4)	93.9	1/ 10 (10.0)	6/ 17 (35.3)	6.1	44.29 (35.80, 52.79)	40.2	0.1960
>70%	35/138 (25.4)	100/136 (73.5)	85.5	3/ 17 (17.6)	13/ 37 (35.1)	14.5	43.71 (34.19, 53.23)	81.4	0.0204
Baseline HRCT pattern									
UIP-like	56/206 (27.2)	154/206 (74.8)	87.1	3/ 23 (13.0)	17/ 45 (37.8)	12.9	44.63 (36.81, 52.46)	76.9	0.0373
Other fibrotic patterns	29/125 (23.2)	86/126 (68.3)	95.8	1/ 4 (25.0)	2/ 9 (22.2)	4.2	43.03 (32.29, 53.77)	69.7	0.0691
Underlying ILD diagnosis									
iNSIP	13/ 61 (21.3)	43/ 64 (67.2)	88.0	1/ 7 (14.3)	7/ 11 (63.6)	12.0	46.29 (31.96, 60.63)	0.0	0.8695
Unclassifiable IIP	9/ 50 (18.0)	48/ 64 (75.0)	94.4	0/ 3 (0.0)	1/ 2 (50.0)	5.6	55.80 (41.11, 70.48)	0.0	0.5460
HP	27/ 89 (30.3)	66/ 84 (78.6)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	25/ 88 (28.4)	56/ 82 (68.3)	82.7	1/ 12 (8.3)	10/ 34 (29.4)	17.3	36.63 (24.61, 48.65)	50.7	0.1543
Other ILD	11/ 43 (25.6)	27/ 38 (71.1)	88.1	2/ 5 (40.0)	1/ 6 (16.7)	11.9	37.28 (19.05, 55.50)	82.9	0.0156
Region									
Europe									
Asia	21/ 76 (27.6)	62/ 79 (78.5)	68.3	4/ 27 (14.8)	19/ 54 (35.2)	31.7	41.18 (30.23, 52.12)	85.3	0.0091
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid				
Overall	85/331 (25.7)	240/332 (72.3)	87.2	4/ 27 (14.8)	19/ 54 (35.2)	12.8	6.98 (5.01, 9.74)	48.0	0.1655
Age									
<65 years	25/121 (20.7)	99/139 (71.2)	86.7	1/ 9 (11.1)	5/ 25 (20.0)	13.3	8.51 (4.85,14.93)	39.9	0.1972
>=65 years	60/210 (28.6)	141/193 (73.1)	89.0	3/ 18 (16.7)	14/ 29 (48.3)	11.0	6.55 (4.31, 9.95)	0.0	0.6263
Sex									
Male	47/177 (26.6)	132/179 (73.7)	97.8	0/ 11 (0.0)	8/ 26 (30.8)	2.2	7.99 (5.00,12.77)	0.0	0.6680
Female	38/154 (24.7)	108/153 (70.6)	78.3	4/ 16 (25.0)	11/ 28 (39.3)	21.7	6.16 (3.84, 9.88)	68.9	0.0732
Baseline FVC percent predicted									
<=70%	50/193 (25.9)	140/196 (71.4)	94.6	1/ 10 (10.0)	6/ 17 (35.3)	5.4	7.03 (4.53,10.91)	0.0	0.7524
>70%	35/138 (25.4)	100/136 (73.5)	77.5	3/ 17 (17.6)	13/ 37 (35.1)	22.5	6.91 (4.16,11.47)	56.5	0.1295
Baseline HRCT pattern									
UIP-like	56/206 (27.2)	154/206 (74.8)	85.1	3/ 23 (13.0)	17/ 45 (37.8)	14.9	7.35 (4.83,11.20)	0.0	0.3545
Other fibrotic patterns	29/125 (23.2)	86/126 (68.3)	89.6	1/ 4 (25.0)	2/ 9 (22.2)	10.4	6.46 (3.74,11.19)	54.1	0.1401
Underlying ILD diagnosis									
iNSIP	13/ 61 (21.3)	43/ 64 (67.2)	90.8	1/ 7 (14.3)	7/ 11 (63.6)	9.2	7.83 (3.65,16.81)	0.0	0.8027
Unclassifiable IIP	9/ 50 (18.0)	48/ 64 (75.0)	91.3	0/ 3 (0.0)	1/ 2 (50.0)	8.7	13.00 (5.36,31.56)	0.0	0.6640
HP	27/ 89 (30.3)	66/ 84 (78.6)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	25/ 88 (28.4)	56/ 82 (68.3)	88.0	1/ 12 (8.3)	10/ 34 (29.4)	12.0	5.33 (2.83,10.03)	0.0	0.8841
Other ILD	11/ 43 (25.6)	27/ 38 (71.1)	62.2	2/ 5 (40.0)	1/ 6 (16.7)	37.8	4.55 (1.88,11.02)	77.3	0.0359
Region									
Europe									
Asia	21/ 76 (27.6)	62/ 79 (78.5)	57.1	4/ 27 (14.8)	19/ 54 (35.2)	42.9	6.80 (3.61,12.78)	58.8	0.1193
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Dyspepsia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo: Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	12/331 (3.6)	15/332 (4.5)	96.4	0/ 27 (0.0)	0/ 54 (0.0)	3.6	1.24 (0.60, 2.57)	0.5682	0.0	0.9182
Age										
<65 years	5/121 (4.1)	7/139 (5.0)	93.2	0/ 9 (0.0)	0/ 25 (0.0)	6.8	1.20 (0.41, 3.57)	0.7378	0.0	0.9317
>=65 years	7/210 (3.3)	8/193 (4.1)	93.4	0/ 18 (0.0)	0/ 29 (0.0)	6.6	1.23 (0.47, 3.22)	0.6773	0.0	0.9173
Sex										
Male	5/177 (2.8)	7/179 (3.9)	92.3	0/ 11 (0.0)	0/ 26 (0.0)	7.7	1.35 (0.46, 4.03)	0.5849	0.0	0.8843
Female	7/154 (4.5)	8/153 (5.2)	93.8	0/ 16 (0.0)	0/ 28 (0.0)	6.2	1.14 (0.44, 2.98)	0.7879	0.0	0.9473
Baseline FVC percent predicted										
<=70%	9/193 (4.7)	9/196 (4.6)	95.1	0/ 10 (0.0)	0/ 17 (0.0)	4.9	0.99 (0.41, 2.38)	0.9739	0.0	0.9941
>70%	3/138 (2.2)	6/136 (4.4)	87.3	0/ 17 (0.0)	0/ 37 (0.0)	12.7	1.90 (0.52, 6.91)	0.3303	0.0	0.7525
Baseline HRCT pattern										
UIP-like	5/206 (2.4)	9/206 (4.4)	91.8	0/ 23 (0.0)	0/ 45 (0.0)	8.2	1.73 (0.61, 4.90)	0.2987	0.0	0.7864
Other fibrotic patterns	7/125 (5.6)	6/126 (4.8)	94.3	0/ 4 (0.0)	0/ 9 (0.0)	5.7	0.86 (0.31, 2.40)	0.7718	0.0	0.9402
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	1/ 64 (1.6)	68.3	0/ 7 (0.0)	0/ 11 (0.0)	31.7	0.97 (0.10, 9.19)	0.9774	0.0	0.9843
Unclassifiable IIP	3/ 50 (6.0)	4/ 64 (6.3)	87.5	0/ 3 (0.0)	0/ 2 (0.0)	12.5	1.04 (0.27, 4.00)	0.9586	0.0	0.9840
HP	6/ 89 (6.7)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	1/ 88 (1.1)	3/ 82 (3.7)	71.4	0/ 12 (0.0)	0/ 34 (0.0)	28.6	2.59 (0.37,18.22)	0.3403	0.0	0.6436
Other ILD	1/ 43 (2.3)	2/ 38 (5.3)	65.4	0/ 5 (0.0)	0/ 6 (0.0)	34.6	1.83 (0.25,13.13)	0.5495	0.0	0.7195
Region										
Europe										
Asia	2/ 76 (2.6)	4/ 79 (5.1)	82.1	0/ 27 (0.0)	0/ 54 (0.0)	17.9	1.76 (0.38, 8.18)	0.4716	0.0	0.7735
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Dyspepsia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	12/331 (3.6)	15/332 (4.5)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	0.80 (-1.95, 3.56)	0.0	0.7636
Age									
<65 years	5/121 (4.1)	7/139 (5.0)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	0.82 (-3.92, 5.55)	0.0	0.8931
>=65 years	7/210 (3.3)	8/193 (4.1)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	0.73 (-2.71, 4.16)	0.0	0.8589
Sex									
Male	5/177 (2.8)	7/179 (3.9)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	0.99 (-2.55, 4.54)	0.0	0.8530
Female	7/154 (4.5)	8/153 (5.2)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	0.60 (-3.77, 4.97)	0.0	0.8935
Baseline FVC percent predicted									
<=70%	9/193 (4.7)	9/196 (4.6)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-0.07 (-4.07, 3.94)	0.0	0.9922
>70%	3/138 (2.2)	6/136 (4.4)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	1.90 (-1.86, 5.66)	0.0	0.6092
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	9/206 (4.4)	86.8	0/ 23 (0.0)	0/ 45 (0.0)	13.2	1.69 (-1.44, 4.82)	0.0	0.5777
Other fibrotic patterns	7/125 (5.6)	6/126 (4.8)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-0.80 (-6.18, 4.59)	0.0	0.9530
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	1/ 64 (1.6)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	-0.07 (-4.68, 4.55)	0.0	0.9940
Unclassifiable IIP	3/ 50 (6.0)	4/ 64 (6.3)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	0.24 (-8.64, 9.11)	0.0	0.9927
HP	6/ 89 (6.7)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	1/ 88 (1.1)	3/ 82 (3.7)	82.1	0/ 12 (0.0)	0/ 34 (0.0)	17.9	2.07 (-2.07, 6.21)	0.0	0.6313
Other ILD	1/ 43 (2.3)	2/ 38 (5.3)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	2.53 (-5.75, 10.82)	0.0	0.8492
Region									
Europe									
Asia	2/ 76 (2.6)	4/ 79 (5.1)	67.7	0/ 27 (0.0)	0/ 54 (0.0)	32.3	1.65 (-2.74, 6.03)	0.0	0.5421
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Dyspepsia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	12/331 (3.6)	15/332 (4.5)	96.3	0/ 27 (0.0)	0/ 54 (0.0)	3.7	1.25 (0.58, 2.68)	0.0	0.9158
Age									
<65 years	5/121 (4.1)	7/139 (5.0)	93.1	0/ 9 (0.0)	0/ 25 (0.0)	6.9	1.21 (0.39, 3.79)	0.0	0.9305
>=65 years	7/210 (3.3)	8/193 (4.1)	93.3	0/ 18 (0.0)	0/ 29 (0.0)	6.7	1.24 (0.45, 3.37)	0.0	0.9159
Sex									
Male	5/177 (2.8)	7/179 (3.9)	92.2	0/ 11 (0.0)	0/ 26 (0.0)	7.8	1.37 (0.44, 4.23)	0.0	0.8834
Female	7/154 (4.5)	8/153 (5.2)	93.6	0/ 16 (0.0)	0/ 28 (0.0)	6.4	1.15 (0.42, 3.15)	0.0	0.9458
Baseline FVC percent predicted									
<=70%	9/193 (4.7)	9/196 (4.6)	95.1	0/ 10 (0.0)	0/ 17 (0.0)	4.9	0.98 (0.39, 2.48)	0.0	0.9940
>70%	3/138 (2.2)	6/136 (4.4)	87.0	0/ 17 (0.0)	0/ 37 (0.0)	13.0	1.94 (0.51, 7.37)	0.0	0.7494
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	9/206 (4.4)	91.6	0/ 23 (0.0)	0/ 45 (0.0)	8.4	1.77 (0.60, 5.17)	0.0	0.7826
Other fibrotic patterns	7/125 (5.6)	6/126 (4.8)	94.4	0/ 4 (0.0)	0/ 9 (0.0)	5.6	0.85 (0.29, 2.52)	0.0	0.9411
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	1/ 64 (1.6)	69.1	0/ 7 (0.0)	0/ 11 (0.0)	30.9	0.97 (0.10, 9.76)	0.0	0.9847
Unclassifiable IIP	3/ 50 (6.0)	4/ 64 (6.3)	88.5	0/ 3 (0.0)	0/ 2 (0.0)	11.5	1.04 (0.24, 4.45)	0.0	0.9852
HP	6/ 89 (6.7)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	1/ 88 (1.1)	3/ 82 (3.7)	71.1	0/ 12 (0.0)	0/ 34 (0.0)	28.9	2.64 (0.35,20.15)	0.0	0.6432
Other ILD	1/ 43 (2.3)	2/ 38 (5.3)	66.0	0/ 5 (0.0)	0/ 6 (0.0)	34.0	1.88 (0.24,14.99)	0.0	0.7277
Region									
Europe									
Asia	2/ 76 (2.6)	4/ 79 (5.1)	81.5	0/ 27 (0.0)	0/ 54 (0.0)	18.5	1.79 (0.36, 8.85)	0.0	0.7685
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Gastrooesophageal reflux disease

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	9/331 (2.7)	17/332 (5.1)	95.3	0/ 27 (0.0)	0/ 54 (0.0)	4.7	1.84 (0.85, 4.01)	0.1239	0.0	0.7681
Age										
<65 years	3/121 (2.5)	11/139 (7.9)	89.2	0/ 9 (0.0)	0/ 25 (0.0)	10.8	2.95 (0.90, 9.75)	0.0753	0.0	0.6176
>=65 years	6/210 (2.9)	6/193 (3.1)	92.4	0/ 18 (0.0)	0/ 29 (0.0)	7.6	1.08 (0.37, 3.16)	0.8864	0.0	0.9681
Sex										
Male	4/177 (2.3)	8/179 (4.5)	90.6	0/ 11 (0.0)	0/ 26 (0.0)	9.4	1.89 (0.61, 5.86)	0.2731	0.0	0.7610
Female	5/154 (3.2)	9/153 (5.9)	91.5	0/ 16 (0.0)	0/ 28 (0.0)	8.5	1.74 (0.62, 4.89)	0.2912	0.0	0.7800
Baseline FVC percent predicted										
<=70%	7/193 (3.6)	7/196 (3.6)	93.8	0/ 10 (0.0)	0/ 17 (0.0)	6.2	0.99 (0.36, 2.67)	0.9773	0.0	0.9941
>70%	2/138 (1.4)	10/136 (7.4)	82.1	0/ 17 (0.0)	0/ 37 (0.0)	17.9	4.35 (1.10,17.25)	0.0367	0.0	0.4737
Baseline HRCT pattern										
UIP-like	5/206 (2.4)	9/206 (4.4)	91.8	0/ 23 (0.0)	0/ 45 (0.0)	8.2	1.73 (0.61, 4.90)	0.2987	0.0	0.7864
Other fibrotic patterns	4/125 (3.2)	8/126 (6.3)	90.4	0/ 4 (0.0)	0/ 9 (0.0)	9.6	1.89 (0.61, 5.82)	0.2675	0.0	0.7530
Underlying ILD diagnosis										
iNSIP	0/ 61 (0.0)	2/ 64 (3.1)	51.3	0/ 7 (0.0)	0/ 11 (0.0)	48.7	3.00 (0.31,29.36)	0.3447	0.0	0.5300
Unclassifiable IIP	2/ 50 (4.0)	3/ 64 (4.7)	82.4	0/ 3 (0.0)	0/ 2 (0.0)	17.6	1.14 (0.23, 5.56)	0.8698	0.0	0.9395
HP	1/ 89 (1.1)	3/ 84 (3.6)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	3/ 88 (3.4)	7/ 82 (8.5)	88.2	0/ 12 (0.0)	0/ 34 (0.0)	11.8	2.33 (0.66, 8.16)	0.1868	0.0	0.6963
Other ILD	3/ 43 (7.0)	2/ 38 (5.3)	85.0	0/ 5 (0.0)	0/ 6 (0.0)	15.0	0.79 (0.16, 3.82)	0.7707	0.0	0.8944
Region										
Europe										
Asia	2/ 76 (2.6)	4/ 79 (5.1)	82.1	0/ 27 (0.0)	0/ 54 (0.0)	17.9	1.76 (0.38, 8.18)	0.4716	0.0	0.7735
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Gastrooesophageal reflux disease

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	9/331 (2.7)	17/332 (5.1)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	2.16 (-0.54, 4.86)	0.0	0.4160
Age									
<65 years	3/121 (2.5)	11/139 (7.9)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	4.90 (-0.00, 9.81)	0.0	0.4219
>=65 years	6/210 (2.9)	6/193 (3.1)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	0.23 (-2.87, 3.33)	0.0	0.9553
Sex									
Male	4/177 (2.3)	8/179 (4.5)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	2.02 (-1.52, 5.57)	0.0	0.7060
Female	5/154 (3.2)	9/153 (5.9)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	2.31 (-1.92, 6.55)	0.0	0.6027
Baseline FVC percent predicted									
<=70%	7/193 (3.6)	7/196 (3.6)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-0.05 (-3.63, 3.52)	0.0	0.9939
>70%	2/138 (1.4)	10/136 (7.4)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	5.02 (0.77, 9.26)	41.0	0.1929
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	9/206 (4.4)	86.8	0/ 23 (0.0)	0/ 45 (0.0)	13.2	1.69 (-1.44, 4.82)	0.0	0.5777
Other fibrotic patterns	4/125 (3.2)	8/126 (6.3)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	3.00 (-2.18, 8.17)	0.0	0.8246
Underlying ILD diagnosis									
iNSIP	0/ 61 (0.0)	2/ 64 (3.1)	87.0	0/ 7 (0.0)	0/ 11 (0.0)	13.0	2.68 (-2.50, 7.85)	0.0	0.7661
Unclassifiable IIP	2/ 50 (4.0)	3/ 64 (4.7)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	0.65 (-7.04, 8.33)	0.0	0.9799
HP	1/ 89 (1.1)	3/ 84 (3.6)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	3/ 88 (3.4)	7/ 82 (8.5)	82.1	0/ 12 (0.0)	0/ 34 (0.0)	17.9	4.21 (-1.88, 10.30)	0.0	0.3882
Other ILD	3/ 43 (7.0)	2/ 38 (5.3)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	-1.48 (-11.31, 8.35)	0.0	0.9134
Region									
Europe									
Asia	2/ 76 (2.6)	4/ 79 (5.1)	67.7	0/ 27 (0.0)	0/ 54 (0.0)	32.3	1.65 (-2.74, 6.03)	0.0	0.5421
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Gastrooesophageal reflux disease

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo: Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	9/331 (2.7)	17/332 (5.1)	95.1	0/ 27 (0.0)	0/ 54 (0.0)	4.9	1.89 (0.84, 4.23)	0.0	0.7623
Age									
<65 years	3/121 (2.5)	11/139 (7.9)	88.6	0/ 9 (0.0)	0/ 25 (0.0)	11.4	3.11 (0.89,10.82)	0.0	0.6107
>=65 years	6/210 (2.9)	6/193 (3.1)	92.3	0/ 18 (0.0)	0/ 29 (0.0)	7.7	1.08 (0.36, 3.28)	0.0	0.9679
Sex									
Male	4/177 (2.3)	8/179 (4.5)	90.4	0/ 11 (0.0)	0/ 26 (0.0)	9.6	1.93 (0.60, 6.23)	0.0	0.7595
Female	5/154 (3.2)	9/153 (5.9)	91.2	0/ 16 (0.0)	0/ 28 (0.0)	8.8	1.79 (0.61, 5.25)	0.0	0.7752
Baseline FVC percent predicted									
<=70%	7/193 (3.6)	7/196 (3.6)	93.8	0/ 10 (0.0)	0/ 17 (0.0)	6.2	0.99 (0.35, 2.77)	0.0	0.9941
>70%	2/138 (1.4)	10/136 (7.4)	81.3	0/ 17 (0.0)	0/ 37 (0.0)	18.7	4.57 (1.09,19.12)	0.0	0.4655
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	9/206 (4.4)	91.6	0/ 23 (0.0)	0/ 45 (0.0)	8.4	1.77 (0.60, 5.17)	0.0	0.7826
Other fibrotic patterns	4/125 (3.2)	8/126 (6.3)	90.4	0/ 4 (0.0)	0/ 9 (0.0)	9.6	1.95 (0.60, 6.36)	0.0	0.7577
Underlying ILD diagnosis									
iNSIP	0/ 61 (0.0)	2/ 64 (3.1)	51.5	0/ 7 (0.0)	0/ 11 (0.0)	48.5	3.09 (0.29,33.11)	0.0	0.5372
Unclassifiable IIP	2/ 50 (4.0)	3/ 64 (4.7)	83.9	0/ 3 (0.0)	0/ 2 (0.0)	16.1	1.15 (0.21, 6.18)	0.0	0.9448
HP	1/ 89 (1.1)	3/ 84 (3.6)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	3/ 88 (3.4)	7/ 82 (8.5)	87.5	0/ 12 (0.0)	0/ 34 (0.0)	12.5	2.44 (0.65, 9.21)	0.0	0.6863
Other ILD	3/ 43 (7.0)	2/ 38 (5.3)	85.3	0/ 5 (0.0)	0/ 6 (0.0)	14.7	0.78 (0.15, 4.17)	0.0	0.8958
Region									
Europe									
Asia	2/ 76 (2.6)	4/ 79 (5.1)	81.5	0/ 27 (0.0)	0/ 54 (0.0)	18.5	1.79 (0.36, 8.85)	0.0	0.7685
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	33/331 (10.0)	100/332 (30.1)	96.1	1/ 27 (3.7)	4/ 54 (7.4)	3.9	2.98 (2.09, 4.26)	<.0001	0.0	0.7098
Age										
<65 years	11/121 (9.1)	42/139 (30.2)	96.8	0/ 9 (0.0)	2/ 25 (8.0)	3.2	3.34 (1.81, 6.15)	0.0001	0.0	0.9556
>=65 years	22/210 (10.5)	58/193 (30.1)	94.5	1/ 18 (5.6)	2/ 29 (6.9)	5.5	2.78 (1.79, 4.32)	<.0001	0.0	0.4886
Sex										
Male	14/177 (7.9)	39/179 (21.8)	97.1	0/ 11 (0.0)	1/ 26 (3.8)	2.9	2.75 (1.56, 4.85)	0.0005	0.0	0.9483
Female	19/154 (12.3)	61/153 (39.9)	93.7	1/ 16 (6.3)	3/ 28 (10.7)	6.3	3.14 (1.99, 4.93)	<.0001	0.0	0.5769
Baseline FVC percent predicted										
<=70%	22/193 (11.4)	61/196 (31.1)	94.6	1/ 10 (10.0)	4/ 17 (23.5)	5.4	2.71 (1.75, 4.19)	<.0001	0.0	0.8893
>70%	11/138 (8.0)	39/136 (28.7)	96.2	0/ 17 (0.0)	0/ 37 (0.0)	3.8	3.50 (1.89, 6.48)	<.0001	0.0	0.5529
Baseline HRCT pattern										
UIP-like	17/206 (8.3)	59/206 (28.6)	97.4	0/ 23 (0.0)	3/ 45 (6.7)	2.6	3.52 (2.14, 5.81)	<.0001	0.0	0.7953
Other fibrotic patterns	16/125 (12.8)	41/126 (32.5)	92.1	1/ 4 (25.0)	1/ 9 (11.1)	7.9	2.38 (1.43, 3.93)	0.0008	43.8	0.1823
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	18/ 64 (28.1)	68.3	0/ 7 (0.0)	1/ 11 (9.1)	31.7	12.55 (2.39,65.88)	0.0028	0.0	0.3493
Unclassifiable IIP	3/ 50 (6.0)	26/ 64 (40.6)	87.5	0/ 3 (0.0)	0/ 2 (0.0)	12.5	6.05 (2.08,17.62)	0.0010	0.0	0.3333
HP	13/ 89 (14.6)	25/ 84 (29.8)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	11/ 88 (12.5)	22/ 82 (26.8)	96.5	0/ 12 (0.0)	2/ 34 (5.9)	3.5	2.20 (1.15, 4.23)	0.0178	0.0	0.7899
Other ILD	5/ 43 (11.6)	9/ 38 (23.7)	74.7	1/ 5 (20.0)	0/ 6 (0.0)	25.3	1.60 (0.65, 3.96)	0.3082	29.6	0.2332
Region										
Europe										
Asia	2/ 76 (2.6)	28/ 79 (35.4)	60.5	1/ 27 (3.7)	4/ 54 (7.4)	39.5	8.93 (2.93,27.20)	0.0001	53.1	0.1440
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo: Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	33/331 (10.0)	100/332 (30.1)	90.2	1/ 27 (3.7)	4/ 54 (7.4)	9.8	18.54 (13.13, 23.95)	87.1	0.0054
Age									
<65 years	11/121 (9.1)	42/139 (30.2)	90.2	0/ 9 (0.0)	2/ 25 (8.0)	9.8	19.80 (11.37, 28.23)	53.7	0.1419
>=65 years	22/210 (10.5)	58/193 (30.1)	90.1	1/ 18 (5.6)	2/ 29 (6.9)	9.9	17.76 (10.71, 24.82)	80.0	0.0255
Sex									
Male	14/177 (7.9)	39/179 (21.8)	91.6	0/ 11 (0.0)	1/ 26 (3.8)	8.4	13.02 (6.30, 19.74)	46.1	0.1733
Female	19/154 (12.3)	61/153 (39.9)	88.3	1/ 16 (6.3)	3/ 28 (10.7)	11.7	24.83 (16.36, 33.30)	82.4	0.0170
Baseline FVC percent predicted									
<=70%	22/193 (11.4)	61/196 (31.1)	93.9	1/ 10 (10.0)	4/ 17 (23.5)	6.1	19.35 (11.76, 26.93)	0.0	0.6705
>70%	11/138 (8.0)	39/136 (28.7)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	17.60 (10.00, 25.20)	91.9	0.0005
Baseline HRCT pattern									
UIP-like	17/206 (8.3)	59/206 (28.6)	86.8	0/ 23 (0.0)	3/ 45 (6.7)	13.2	18.55 (12.16, 24.94)	81.8	0.0191
Other fibrotic patterns	16/125 (12.8)	41/126 (32.5)	95.8	1/ 4 (25.0)	1/ 9 (11.1)	4.2	18.32 (8.48, 28.16)	46.5	0.1715
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	18/ 64 (28.1)	86.8	0/ 7 (0.0)	1/ 11 (9.1)	13.2	24.07 (13.61, 34.53)	43.6	0.1830
Unclassifiable IIP	3/ 50 (6.0)	26/ 64 (40.6)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	32.67 (19.39, 45.95)	35.1	0.2144
HP	13/ 89 (14.6)	25/ 84 (29.8)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	11/ 88 (12.5)	22/ 82 (26.8)	82.1	0/ 12 (0.0)	2/ 34 (5.9)	17.9	12.77 (2.84, 22.71)	3.7	0.3081
Other ILD	5/ 43 (11.6)	9/ 38 (23.7)	86.2	1/ 5 (20.0)	0/ 6 (0.0)	13.8	8.06 (-7.24, 23.37)	42.2	0.1885
Region									
Europe									
Asia	2/ 76 (2.6)	28/ 79 (35.4)	68.3	1/ 27 (3.7)	4/ 54 (7.4)	31.7	23.58 (15.34, 31.82)	93.1	0.0001
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo	Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	I^2	p-value
Overall	33/331 (10.0)	100/332 (30.1)	94.9	1/ 27 (3.7)	4/ 54 (7.4)	5.1	3.80 (2.49, 5.80)	0.0	0.5905
Age									
<65 years	11/121 (9.1)	42/139 (30.2)	95.9	0/ 9 (0.0)	2/ 25 (8.0)	4.1	4.32 (2.13, 8.77)	0.0	0.9731
>=65 years	22/210 (10.5)	58/193 (30.1)	92.8	1/ 18 (5.6)	2/ 29 (6.9)	7.2	3.50 (2.07, 5.92)	0.0	0.4078
Sex									
Male	14/177 (7.9)	39/179 (21.8)	96.6	0/ 11 (0.0)	1/ 26 (3.8)	3.4	3.22 (1.69, 6.12)	0.0	0.9015
Female	19/154 (12.3)	61/153 (39.9)	90.9	1/ 16 (6.3)	3/ 28 (10.7)	9.1	4.45 (2.53, 7.81)	0.0	0.4363
Baseline FVC percent predicted									
<=70%	22/193 (11.4)	61/196 (31.1)	94.1	1/ 10 (10.0)	4/ 17 (23.5)	5.9	3.47 (2.05, 5.86)	0.0	0.8468
>70%	11/138 (8.0)	39/136 (28.7)	94.8	0/ 17 (0.0)	0/ 37 (0.0)	5.2	4.45 (2.19, 9.05)	0.0	0.4860
Baseline HRCT pattern									
UIP-like	17/206 (8.3)	59/206 (28.6)	96.7	0/ 23 (0.0)	3/ 45 (6.7)	3.3	4.51 (2.54, 8.01)	0.0	0.8777
Other fibrotic patterns	16/125 (12.8)	41/126 (32.5)	89.8	1/ 4 (25.0)	1/ 9 (11.1)	10.2	2.99 (1.60, 5.58)	45.5	0.1754
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	18/ 64 (28.1)	64.1	0/ 7 (0.0)	1/ 11 (9.1)	35.9	16.08 (2.84,91.04)	0.0	0.3238
Unclassifiable IIP	3/ 50 (6.0)	26/ 64 (40.6)	82.9	0/ 3 (0.0)	0/ 2 (0.0)	17.1	9.06 (2.79,29.45)	6.2	0.3020
HP	13/ 89 (14.6)	25/ 84 (29.8)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	11/ 88 (12.5)	22/ 82 (26.8)	95.6	0/ 12 (0.0)	2/ 34 (5.9)	4.4	2.63 (1.20, 5.75)	0.0	0.8402
Other ILD	5/ 43 (11.6)	9/ 38 (23.7)	71.0	1/ 5 (20.0)	0/ 6 (0.0)	29.0	1.75 (0.59, 5.15)	33.9	0.2188
Region									
Europe									
Asia	2/ 76 (2.6)	28/ 79 (35.4)	51.6	1/ 27 (3.7)	4/ 54 (7.4)	48.4	11.49 (3.48,37.96)	63.9	0.0963
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Vomiting

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	16/331 (4.8)	64/332 (19.3)	92.3	1/ 27 (3.7)	7/ 54 (13.0)	7.7	3.95 (2.37, 6.58)	<.0001	0.0	0.9035
Age										
<65 years	5/121 (4.1)	24/139 (17.3)	93.2	0/ 9 (0.0)	3/ 25 (12.0)	6.8	4.24 (1.71,10.53)	0.0018	0.0	0.9234
>=65 years	11/210 (5.2)	40/193 (20.7)	89.5	1/ 18 (5.6)	4/ 29 (13.8)	10.5	3.80 (2.07, 6.99)	<.0001	0.0	0.6787
Sex										
Male	8/177 (4.5)	20/179 (11.2)	95.1	0/ 11 (0.0)	0/ 26 (0.0)	4.9	2.40 (1.10, 5.22)	0.0273	0.0	0.6804
Female	8/154 (5.2)	44/153 (28.8)	86.2	1/ 16 (6.3)	7/ 28 (25.0)	13.8	5.32 (2.71,10.47)	<.0001	0.0	0.7648
Baseline FVC percent predicted										
<=70%	9/193 (4.7)	43/196 (21.9)	87.8	1/ 10 (10.0)	3/ 17 (17.6)	12.2	4.35 (2.26, 8.34)	<.0001	0.0	0.3895
>70%	7/138 (5.1)	21/136 (15.4)	94.2	0/ 17 (0.0)	4/ 37 (10.8)	5.8	3.27 (1.46, 7.31)	0.0040	0.0	0.6646
Baseline HRCT pattern										
UIP-like	13/206 (6.3)	37/206 (18.0)	96.7	0/ 23 (0.0)	6/ 45 (13.3)	3.3	3.09 (1.70, 5.60)	0.0002	0.0	0.4757
Other fibrotic patterns	3/125 (2.4)	27/126 (21.4)	68.5	1/ 4 (25.0)	1/ 9 (11.1)	31.5	6.26 (2.35,16.64)	0.0002	77.9	0.0336
Underlying ILD diagnosis										
iNSIP	2/ 61 (3.3)	12/ 64 (18.8)	81.2	0/ 7 (0.0)	1/ 11 (9.1)	18.8	5.14 (1.36,19.37)	0.0156	0.0	0.6804
Unclassifiable IIP	0/ 50 (0.0)	12/ 64 (18.8)	50.6	0/ 3 (0.0)	0/ 2 (0.0)	49.4	11.82 (1.38, >99)	0.0242	39.0	0.2006
HP	6/ 89 (6.7)	21/ 84 (25.0)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	6/ 88 (6.8)	15/ 82 (18.3)	93.8	0/ 12 (0.0)	5/ 34 (14.7)	6.2	3.00 (1.24, 7.28)	0.0151	0.0	0.6001
Other ILD	2/ 43 (4.7)	4/ 38 (10.5)	54.2	1/ 5 (20.0)	0/ 6 (0.0)	45.8	1.37 (0.37, 5.07)	0.6377	25.7	0.2459
Region										
Europe										
Asia	1/ 76 (1.3)	12/ 79 (15.2)	43.3	1/ 27 (3.7)	7/ 54 (13.0)	56.7	6.99 (1.74,28.05)	0.0061	0.0	0.4151
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Vomiting

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo: Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	16/331 (4.8)	64/332 (19.3)	90.2	1/ 27 (3.7)	7/ 54 (13.0)	9.8	13.94 (9.44, 18.44)	0.0	0.4135
Age									
<65 years	5/121 (4.1)	24/139 (17.3)	90.2	0/ 9 (0.0)	3/ 25 (12.0)	9.8	12.96 (6.24, 19.67)	0.0	0.8475
>=65 years	11/210 (5.2)	40/193 (20.7)	90.1	1/ 18 (5.6)	4/ 29 (13.8)	9.9	14.77 (8.72, 20.81)	0.0	0.4206
Sex									
Male	8/177 (4.5)	20/179 (11.2)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	6.10 (0.94, 11.25)	12.7	0.2845
Female	8/154 (5.2)	44/153 (28.8)	88.3	1/ 16 (6.3)	7/ 28 (25.0)	11.7	23.00 (15.57, 30.42)	0.0	0.6606
Baseline FVC percent predicted									
<=70%	9/193 (4.7)	43/196 (21.9)	93.9	1/ 10 (10.0)	3/ 17 (17.6)	6.1	16.69 (10.37, 23.01)	0.0	0.4808
>70%	7/138 (5.1)	21/136 (15.4)	85.0	0/ 17 (0.0)	4/ 37 (10.8)	15.0	10.38 (4.08, 16.67)	0.0	0.9937
Baseline HRCT pattern									
UIP-like	13/206 (6.3)	37/206 (18.0)	86.8	0/ 23 (0.0)	6/ 45 (13.3)	13.2	11.82 (6.24, 17.41)	0.0	0.8418
Other fibrotic patterns	3/125 (2.4)	27/126 (21.4)	95.8	1/ 4 (25.0)	1/ 9 (11.1)	4.2	17.64 (10.04, 25.23)	45.2	0.1767
Underlying ILD diagnosis									
iNSIP	2/ 61 (3.3)	12/ 64 (18.8)	86.8	0/ 7 (0.0)	1/ 11 (9.1)	13.2	14.51 (4.80, 24.22)	0.0	0.5907
Unclassifiable IIP	0/ 50 (0.0)	12/ 64 (18.8)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	17.40 (7.59, 27.22)	0.0	0.5023
HP	6/ 89 (6.7)	21/ 84 (25.0)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	6/ 88 (6.8)	15/ 82 (18.3)	82.1	0/ 12 (0.0)	5/ 34 (14.7)	17.9	11.94 (3.42, 20.46)	0.0	0.7696
Other ILD	2/ 43 (4.7)	4/ 38 (10.5)	86.2	1/ 5 (20.0)	0/ 6 (0.0)	13.8	2.73 (-8.69, 14.16)	13.6	0.2821
Region									
Europe									
Asia	1/ 76 (1.3)	12/ 79 (15.2)	68.3	1/ 27 (3.7)	7/ 54 (13.0)	31.7	12.41 (5.67, 19.15)	0.0	0.5227
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Gastrointestinal disorders
PT: Vomiting

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		Heterogeneity
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)		I^2 p-value
Overall	16/331 (4.8)	64/332 (19.3)	91.8	1/ 27 (3.7)	7/ 54 (13.0)	8.2	4.63 (2.66, 8.06)		0.0 0.8642
Age									
<65 years	5/121 (4.1)	24/139 (17.3)	93.0	0/ 9 (0.0)	3/ 25 (12.0)	7.0	4.91 (1.86,12.93)		0.0 0.9351
>=65 years	11/210 (5.2)	40/193 (20.7)	88.7	1/ 18 (5.6)	4/ 29 (13.8)	11.3	4.50 (2.31, 8.79)		0.0 0.6489
Sex									
Male	8/177 (4.5)	20/179 (11.2)	94.6	0/ 11 (0.0)	0/ 26 (0.0)	5.4	2.57 (1.12, 5.90)		0.0 0.6652
Female	8/154 (5.2)	44/153 (28.8)	85.6	1/ 16 (6.3)	7/ 28 (25.0)	14.4	7.03 (3.33,14.83)		0.0 0.7451
Baseline FVC percent predicted									
<=70%	9/193 (4.7)	43/196 (21.9)	87.2	1/ 10 (10.0)	3/ 17 (17.6)	12.8	5.26 (2.58,10.73)		0.0 0.3971
>70%	7/138 (5.1)	21/136 (15.4)	93.9	0/ 17 (0.0)	4/ 37 (10.8)	6.1	3.67 (1.55, 8.71)		0.0 0.6746
Baseline HRCT pattern									
UIP-like	13/206 (6.3)	37/206 (18.0)	96.5	0/ 23 (0.0)	6/ 45 (13.3)	3.5	3.54 (1.85, 6.78)		0.0 0.4833
Other fibrotic patterns	3/125 (2.4)	27/126 (21.4)	65.8	1/ 4 (25.0)	1/ 9 (11.1)	34.2	7.42 (2.56,21.53)		75.2 0.0447
Underlying ILD diagnosis									
iNSIP	2/ 61 (3.3)	12/ 64 (18.8)	80.1	0/ 7 (0.0)	1/ 11 (9.1)	19.9	6.03 (1.47,24.80)		0.0 0.6693
Unclassifiable IIP	0/ 50 (0.0)	12/ 64 (18.8)	49.1	0/ 3 (0.0)	0/ 2 (0.0)	50.9	14.01 (1.63, >99)		33.9 0.2188
HP	6/ 89 (6.7)	21/ 84 (25.0)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)		NC NC
Autoimmune ILD	6/ 88 (6.8)	15/ 82 (18.3)	93.6	0/ 12 (0.0)	5/ 34 (14.7)	6.4	3.44 (1.31, 9.03)		0.0 0.6037
Other ILD	2/ 43 (4.7)	4/ 38 (10.5)	53.4	1/ 5 (20.0)	0/ 6 (0.0)	46.6	1.41 (0.33, 5.96)		26.6 0.2431
Region									
Europe									
Asia	1/ 76 (1.3)	12/ 79 (15.2)	42.7	1/ 27 (3.7)	7/ 54 (13.0)	57.3	7.95 (1.84,34.46)		0.0 0.4136
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Asthenia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	14/331 (4.2)	19/332 (5.7)	96.9	0/ 27 (0.0)	0/ 54 (0.0)	3.1	1.34 (0.69, 2.61)	0.3853	0.0	0.8874
Age										
<65 years	4/121 (3.3)	10/139 (7.2)	91.7	0/ 9 (0.0)	0/ 25 (0.0)	8.3	2.08 (0.70, 6.20)	0.1897	0.0	0.7362
>=65 years	10/210 (4.8)	9/193 (4.7)	95.3	0/ 18 (0.0)	0/ 29 (0.0)	4.7	0.98 (0.42, 2.31)	0.9637	0.0	0.9920
Sex										
Male	7/177 (4.0)	14/179 (7.8)	94.4	0/ 11 (0.0)	0/ 26 (0.0)	5.6	1.92 (0.81, 4.56)	0.1374	0.0	0.7572
Female	7/154 (4.5)	5/153 (3.3)	93.8	0/ 16 (0.0)	0/ 28 (0.0)	6.2	0.74 (0.25, 2.18)	0.5799	0.0	0.8772
Baseline FVC percent predicted										
<=70%	9/193 (4.7)	14/196 (7.1)	95.1	0/ 10 (0.0)	0/ 17 (0.0)	4.9	1.51 (0.68, 3.34)	0.3138	0.0	0.8373
>70%	5/138 (3.6)	5/136 (3.7)	92.0	0/ 17 (0.0)	0/ 37 (0.0)	8.0	1.01 (0.32, 3.26)	0.9820	0.0	0.9948
Baseline HRCT pattern										
UIP-like	5/206 (2.4)	13/206 (6.3)	91.8	0/ 23 (0.0)	0/ 45 (0.0)	8.2	2.47 (0.93, 6.57)	0.0702	0.0	0.6584
Other fibrotic patterns	9/125 (7.2)	6/126 (4.8)	95.5	0/ 4 (0.0)	0/ 9 (0.0)	4.5	0.68 (0.26, 1.79)	0.4314	0.0	0.8478
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	0/ 76 (0.0)	4/ 79 (5.1)	52.9	0/ 27 (0.0)	0/ 54 (0.0)	47.1	5.15 (0.57,46.78)	0.1451	0.0	0.3990
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Asthenia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	14/331 (4.2)	19/332 (5.7)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	1.34 (-1.67, 4.36)	0.0	0.6244
Age									
<65 years	4/121 (3.3)	10/139 (7.2)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	3.51 (-1.46, 8.48)	0.0	0.5664
>=65 years	10/210 (4.8)	9/193 (4.7)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	-0.09 (-3.90, 3.72)	0.0	0.9831
Sex									
Male	7/177 (4.0)	14/179 (7.8)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	3.54 (-1.01, 8.10)	0.0	0.5241
Female	7/154 (4.5)	5/153 (3.3)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	-1.12 (-5.07, 2.83)	0.0	0.7978
Baseline FVC percent predicted									
<=70%	9/193 (4.7)	14/196 (7.1)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	2.32 (-2.14, 6.78)	0.0	0.7379
>70%	5/138 (3.6)	5/136 (3.7)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	0.05 (-3.89, 3.98)	0.0	0.9904
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	13/206 (6.3)	86.8	0/ 23 (0.0)	0/ 45 (0.0)	13.2	3.37 (-0.13, 6.87)	13.8	0.2816
Other fibrotic patterns	9/125 (7.2)	6/126 (4.8)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-2.32 (-8.05, 3.41)	0.0	0.8644
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	0/ 76 (0.0)	4/ 79 (5.1)	68.0	0/ 27 (0.0)	0/ 54 (0.0)	32.0	3.40 (-0.58, 7.38)	44.3	0.1803
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Asthenia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2 p-value
Overall	14/331 (4.2)	19/332 (5.7)	96.8	0/ 27 (0.0)	0/ 54 (0.0)	3.2	1.36 (0.68, 2.74)	0.0 0.8832
Age								
<65 years	4/121 (3.3)	10/139 (7.2)	91.3	0/ 9 (0.0)	0/ 25 (0.0)	8.7	2.16 (0.68, 6.80)	0.0 0.7306
>=65 years	10/210 (4.8)	9/193 (4.7)	95.2	0/ 18 (0.0)	0/ 29 (0.0)	4.8	0.98 (0.40, 2.41)	0.0 0.9918
Sex								
Male	7/177 (4.0)	14/179 (7.8)	94.1	0/ 11 (0.0)	0/ 26 (0.0)	5.9	2.00 (0.80, 4.97)	0.0 0.7498
Female	7/154 (4.5)	5/153 (3.3)	93.7	0/ 16 (0.0)	0/ 28 (0.0)	6.3	0.73 (0.24, 2.24)	0.0 0.8752
Baseline FVC percent predicted								
<=70%	9/193 (4.7)	14/196 (7.1)	94.9	0/ 10 (0.0)	0/ 17 (0.0)	5.1	1.54 (0.66, 3.59)	0.0 0.8334
>70%	5/138 (3.6)	5/136 (3.7)	91.9	0/ 17 (0.0)	0/ 37 (0.0)	8.1	1.01 (0.30, 3.40)	0.0 0.9947
Baseline HRCT pattern								
UIP-like	5/206 (2.4)	13/206 (6.3)	91.4	0/ 23 (0.0)	0/ 45 (0.0)	8.6	2.56 (0.93, 7.08)	0.0 0.6500
Other fibrotic patterns	9/125 (7.2)	6/126 (4.8)	95.6	0/ 4 (0.0)	0/ 9 (0.0)	4.4	0.66 (0.24, 1.85)	0.0 0.8490
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia	0/ 76 (0.0)	4/ 79 (5.1)	51.8	0/ 27 (0.0)	0/ 54 (0.0)	48.2	5.31 (0.54,52.52)	0.0 0.3935
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Chest pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	15/331 (4.5)	17/332 (5.1)	84.9	2/ 27 (7.4)	3/ 54 (5.6)	15.1	1.07 (0.57, 2.01)	0.8271	0.0	0.6653
Age										
<65 years	3/121 (2.5)	8/139 (5.8)	68.6	1/ 9 (11.1)	2/ 25 (8.0)	31.4	1.82 (0.60, 5.50)	0.2897	0.0	0.3818
>=65 years	12/210 (5.7)	9/193 (4.7)	90.3	1/ 18 (5.6)	1/ 29 (3.4)	9.7	0.80 (0.36, 1.78)	0.5801	0.0	0.8500
Sex										
Male	8/177 (4.5)	10/179 (5.6)	85.1	1/ 11 (9.1)	1/ 26 (3.8)	14.9	1.12 (0.48, 2.61)	0.8012	0.0	0.4577
Female	7/154 (4.5)	7/153 (4.6)	84.6	1/ 16 (6.3)	2/ 28 (7.1)	15.4	1.03 (0.40, 2.62)	0.9546	0.0	0.9218
Baseline FVC percent predicted										
<=70%	8/193 (4.1)	10/196 (5.1)	86.5	1/ 10 (10.0)	1/ 17 (5.9)	13.5	1.14 (0.49, 2.69)	0.7576	0.0	0.6066
>70%	7/138 (5.1)	7/136 (5.1)	83.5	1/ 17 (5.9)	2/ 37 (5.4)	16.5	1.00 (0.39, 2.54)	0.9982	0.0	0.9391
Baseline HRCT pattern										
UIP-like	10/206 (4.9)	13/206 (6.3)	79.1	2/ 23 (8.7)	1/ 45 (2.2)	20.9	1.08 (0.52, 2.25)	0.8346	39.5	0.1987
Other fibrotic patterns	5/125 (4.0)	4/126 (3.2)	92.2	0/ 4 (0.0)	2/ 9 (22.2)	7.8	1.04 (0.32, 3.35)	0.9532	0.0	0.4114
Underlying ILD diagnosis										
iNSIP	0/ 61 (0.0)	2/ 64 (3.1)	51.3	0/ 7 (0.0)	1/ 11 (9.1)	48.7	3.80 (0.40,35.84)	0.2437	0.0	0.7892
Unclassifiable IIP	1/ 50 (2.0)	7/ 64 (10.9)	70.1	0/ 3 (0.0)	0/ 2 (0.0)	29.9	4.13 (0.72,23.76)	0.1121	0.0	0.4322
HP	6/ 89 (6.7)	4/ 84 (4.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	4/ 88 (4.5)	1/ 82 (1.2)	72.3	1/ 12 (8.3)	2/ 34 (5.9)	27.7	0.39 (0.08, 1.86)	0.2365	0.0	0.5496
Other ILD	4/ 43 (9.3)	3/ 38 (7.9)	70.3	1/ 5 (20.0)	0/ 6 (0.0)	29.7	0.69 (0.20, 2.43)	0.5627	0.0	0.5464
Region										
Europe										
Asia	2/ 76 (2.6)	2/ 79 (2.5)	43.3	2/ 27 (7.4)	3/ 54 (5.6)	56.7	0.84 (0.23, 3.05)	0.7933	0.0	0.8508
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Chest pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	15/331 (4.5)	17/332 (5.1)	90.2	2/ 27 (7.4)	3/ 54 (5.6)	9.8	0.35 (-2.81, 3.50)	0.0	0.6917
Age									
<65 years	3/121 (2.5)	8/139 (5.8)	90.7	1/ 9 (11.1)	2/ 25 (8.0)	9.3	2.68 (-2.14, 7.51)	0.0	0.5959
>=65 years	12/210 (5.7)	9/193 (4.7)	90.1	1/ 18 (5.6)	1/ 29 (3.4)	9.9	-1.16 (-5.24, 2.93)	0.0	0.8756
Sex									
Male	8/177 (4.5)	10/179 (5.6)	92.0	1/ 11 (9.1)	1/ 26 (3.8)	8.0	0.56 (-3.88, 5.00)	0.0	0.5167
Female	7/154 (4.5)	7/153 (4.6)	88.3	1/ 16 (6.3)	2/ 28 (7.1)	11.7	0.13 (-4.36, 4.62)	0.0	0.9154
Baseline FVC percent predicted									
<=70%	8/193 (4.1)	10/196 (5.1)	93.9	1/ 10 (10.0)	1/ 17 (5.9)	6.1	0.65 (-3.49, 4.78)	0.0	0.6526
>70%	7/138 (5.1)	7/136 (5.1)	85.5	1/ 17 (5.9)	2/ 37 (5.4)	14.5	-0.01 (-4.87, 4.86)	0.0	0.9399
Baseline HRCT pattern									
UIP-like	10/206 (4.9)	13/206 (6.3)	87.1	2/ 23 (8.7)	1/ 45 (2.2)	12.9	0.44 (-3.74, 4.61)	29.3	0.2343
Other fibrotic patterns	5/125 (4.0)	4/126 (3.2)	95.2	0/ 4 (0.0)	2/ 9 (22.2)	4.8	0.15 (-4.55, 4.84)	19.4	0.2654
Underlying ILD diagnosis									
iNSIP	0/ 61 (0.0)	2/ 64 (3.1)	87.0	0/ 7 (0.0)	1/ 11 (9.1)	13.0	3.74 (-1.77, 9.25)	0.0	0.6880
Unclassifiable IIP	1/ 50 (2.0)	7/ 64 (10.9)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	8.43 (-0.19, 17.06)	0.0	0.7438
HP	6/ 89 (6.7)	4/ 84 (4.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	1/ 82 (1.2)	82.7	1/ 12 (8.3)	2/ 34 (5.9)	17.3	-3.17 (-8.27, 1.92)	0.0	0.9250
Other ILD	4/ 43 (9.3)	3/ 38 (7.9)	86.2	1/ 5 (20.0)	0/ 6 (0.0)	13.8	-3.55 (-15.41, 8.32)	0.0	0.4660
Region									
Europe									
Asia	2/ 76 (2.6)	2/ 79 (2.5)	68.3	2/ 27 (7.4)	3/ 54 (5.6)	31.7	-0.66 (-5.68, 4.37)	0.0	0.7859
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Chest pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo	Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	I^2	p-value
Overall	15/331 (4.5)	17/332 (5.1)	85.0	2/ 27 (7.4)	3/ 54 (5.6)	15.0	1.08 (0.55, 2.09)	0.0	0.6668
Age									
<65 years	3/121 (2.5)	8/139 (5.8)	69.1	1/ 9 (11.1)	2/ 25 (8.0)	30.9	1.87 (0.58, 6.10)	0.0	0.3973
>=65 years	12/210 (5.7)	9/193 (4.7)	90.2	1/ 18 (5.6)	1/ 29 (3.4)	9.8	0.79 (0.34, 1.84)	0.0	0.8511
Sex									
Male	8/177 (4.5)	10/179 (5.6)	84.9	1/ 11 (9.1)	1/ 26 (3.8)	15.1	1.12 (0.46, 2.76)	0.0	0.4599
Female	7/154 (4.5)	7/153 (4.6)	84.9	1/ 16 (6.3)	2/ 28 (7.1)	15.1	1.03 (0.38, 2.75)	0.0	0.9213
Baseline FVC percent predicted									
<=70%	8/193 (4.1)	10/196 (5.1)	86.6	1/ 10 (10.0)	1/ 17 (5.9)	13.4	1.15 (0.47, 2.84)	0.0	0.6094
>70%	7/138 (5.1)	7/136 (5.1)	83.6	1/ 17 (5.9)	2/ 37 (5.4)	16.4	1.00 (0.37, 2.68)	0.0	0.9392
Baseline HRCT pattern									
UIP-like	10/206 (4.9)	13/206 (6.3)	78.4	2/ 23 (8.7)	1/ 45 (2.2)	21.6	1.09 (0.49, 2.38)	39.9	0.1969
Other fibrotic patterns	5/125 (4.0)	4/126 (3.2)	93.9	0/ 4 (0.0)	2/ 9 (22.2)	6.1	1.04 (0.31, 3.47)	0.0	0.3860
Underlying ILD diagnosis									
iNSIP	0/ 61 (0.0)	2/ 64 (3.1)	53.8	0/ 7 (0.0)	1/ 11 (9.1)	46.2	4.06 (0.39,42.10)	0.0	0.8169
Unclassifiable IIP	1/ 50 (2.0)	7/ 64 (10.9)	70.9	0/ 3 (0.0)	0/ 2 (0.0)	29.1	4.55 (0.74,27.99)	0.0	0.4653
HP	6/ 89 (6.7)	4/ 84 (4.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	1/ 82 (1.2)	73.3	1/ 12 (8.3)	2/ 34 (5.9)	26.7	0.37 (0.08, 1.82)	0.0	0.5666
Other ILD	4/ 43 (9.3)	3/ 38 (7.9)	70.2	1/ 5 (20.0)	0/ 6 (0.0)	29.8	0.66 (0.16, 2.68)	0.0	0.5281
Region									
Europe									
Asia	2/ 76 (2.6)	2/ 79 (2.5)	44.1	2/ 27 (7.4)	3/ 54 (5.6)	55.9	0.83 (0.21, 3.25)	0.0	0.8468
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Disease progression

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	15/331 (4.5)	7/332 (2.1)	97.1	0/ 27 (0.0)	0/ 54 (0.0)	2.9	0.48 (0.20, 1.14)	0.0958	0.0	0.7227
Age										
<65 years	7/121 (5.8)	1/139 (0.7)	95.1	0/ 9 (0.0)	0/ 25 (0.0)	4.9	0.17 (0.03, 1.00)	0.0498	0.0	0.3995
>=65 years	8/210 (3.8)	6/193 (3.1)	94.2	0/ 18 (0.0)	0/ 29 (0.0)	5.8	0.83 (0.30, 2.26)	0.7110	0.0	0.9230
Sex										
Male	8/177 (4.5)	5/179 (2.8)	95.1	0/ 11 (0.0)	0/ 26 (0.0)	4.9	0.64 (0.22, 1.84)	0.4046	0.0	0.8292
Female	7/154 (4.5)	2/153 (1.3)	93.8	0/ 16 (0.0)	0/ 28 (0.0)	6.2	0.33 (0.08, 1.38)	0.1295	0.0	0.5718
Baseline FVC percent predicted										
<=70%	12/193 (6.2)	6/196 (3.1)	96.3	0/ 10 (0.0)	0/ 17 (0.0)	3.7	0.51 (0.20, 1.30)	0.1574	0.0	0.7349
>70%	3/138 (2.2)	1/136 (0.7)	87.3	0/ 17 (0.0)	0/ 37 (0.0)	12.7	0.42 (0.06, 2.93)	0.3832	0.0	0.6546
Baseline HRCT pattern										
UIP-like	7/206 (3.4)	3/206 (1.5)	94.0	0/ 23 (0.0)	0/ 45 (0.0)	6.0	0.46 (0.13, 1.64)	0.2324	0.0	0.7010
Other fibrotic patterns	8/125 (6.4)	4/126 (3.2)	95.0	0/ 4 (0.0)	0/ 9 (0.0)	5.0	0.52 (0.17, 1.61)	0.2565	0.0	0.7474
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Disease progression

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Fixed effects Nin 150bid vs Placebo Wt	Risk difference (95% CI)	Heterogeneity I^2 p-value
	Placebo	Nin 150bid	Placebo	Nin 150bid			
Overall	15/331 (4.5)	7/332 (2.1)	0/ 27 (0.0)	0/ 54 (0.0)	10.0	-2.18 (-4.68, 0.32)	0.0 0.4026
Age							
<65 years	7/121 (5.8)	1/139 (0.7)	0/ 9 (0.0)	0/ 25 (0.0)	9.8	-4.57 (-8.71, -0.43)	0.0 0.4428
>=65 years	8/210 (3.8)	6/193 (3.1)	0/ 18 (0.0)	0/ 29 (0.0)	10.3	-0.63 (-3.93, 2.68)	0.0 0.8772
Sex							
Male	8/177 (4.5)	5/179 (2.8)	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-1.58 (-5.27, 2.10)	0.0 0.7692
Female	7/154 (4.5)	2/153 (1.3)	0/ 16 (0.0)	0/ 28 (0.0)	12.2	-2.84 (-6.31, 0.62)	0.0 0.5054
Baseline FVC percent predicted							
<=70%	12/193 (6.2)	6/196 (3.1)	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-2.95 (-6.95, 1.05)	0.0 0.6669
>70%	3/138 (2.2)	1/136 (0.7)	0/ 17 (0.0)	0/ 37 (0.0)	15.0	-1.22 (-3.87, 1.43)	0.0 0.7240
Baseline HRCT pattern							
UIP-like	7/206 (3.4)	3/206 (1.5)	0/ 23 (0.0)	0/ 45 (0.0)	13.2	-1.69 (-4.37, 1.00)	0.0 0.5631
Other fibrotic patterns	8/125 (6.4)	4/126 (3.2)	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-3.07 (-8.26, 2.12)	0.0 0.8205
Underlying ILD diagnosis							
iNSIP							
Unclassifiable IIP							
HP							
Autoimmune ILD							
Other ILD							
Region							
Europe							
Asia							
Canada and USA							
Rest of the World							

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Disease progression

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2 p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid			
Overall	15/331 (4.5)	7/332 (2.1)	97.1	0/ 27 (0.0)	0/ 54 (0.0)	2.9	0.47 (0.19, 1.14)	0.0 0.7175
Age								
<65 years	7/121 (5.8)	1/139 (0.7)	95.2	0/ 9 (0.0)	0/ 25 (0.0)	4.8	0.16 (0.03, 0.94)	0.0 0.3999
>=65 years	8/210 (3.8)	6/193 (3.1)	94.1	0/ 18 (0.0)	0/ 29 (0.0)	5.9	0.82 (0.29, 2.32)	0.0 0.9220
Sex								
Male	8/177 (4.5)	5/179 (2.8)	95.1	0/ 11 (0.0)	0/ 26 (0.0)	4.9	0.63 (0.21, 1.87)	0.0 0.8275
Female	7/154 (4.5)	2/153 (1.3)	93.8	0/ 16 (0.0)	0/ 28 (0.0)	6.2	0.32 (0.08, 1.37)	0.0 0.5700
Baseline FVC percent predicted								
<=70%	12/193 (6.2)	6/196 (3.1)	96.3	0/ 10 (0.0)	0/ 17 (0.0)	3.7	0.50 (0.19, 1.30)	0.0 0.7323
>70%	3/138 (2.2)	1/136 (0.7)	87.5	0/ 17 (0.0)	0/ 37 (0.0)	12.5	0.42 (0.06, 2.88)	0.0 0.6556
Baseline HRCT pattern								
UIP-like	7/206 (3.4)	3/206 (1.5)	94.0	0/ 23 (0.0)	0/ 45 (0.0)	6.0	0.45 (0.13, 1.64)	0.0 0.6987
Other fibrotic patterns	8/125 (6.4)	4/126 (3.2)	95.1	0/ 4 (0.0)	0/ 9 (0.0)	4.9	0.50 (0.16, 1.63)	0.0 0.7523
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia								
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Fatigue

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk ratio (95% CI)	p-value	I^2	p-value
Overall	21/331 (6.3)	34/332 (10.2)	97.9	0/ 27 (0.0)	4/ 54 (7.4)	2.1	1.73 (1.03, 2.89)	0.0381	0.0	0.4144
Age										
<65 years	5/121 (4.1)	16/139 (11.5)	93.2	0/ 9 (0.0)	2/ 25 (8.0)	6.8	2.85 (1.10, 7.35)	0.0304	0.0	0.8884
>=65 years	16/210 (7.6)	18/193 (9.3)	97.0	0/ 18 (0.0)	2/ 29 (6.9)	3.0	1.31 (0.70, 2.47)	0.3947	0.0	0.4742
Sex										
Male	6/177 (3.4)	19/179 (10.6)	93.5	0/ 11 (0.0)	3/ 26 (11.5)	6.5	3.27 (1.37, 7.82)	0.0078	0.0	0.7873
Female	15/154 (9.7)	15/153 (9.8)	97.0	0/ 16 (0.0)	1/ 28 (3.6)	3.0	1.05 (0.54, 2.05)	0.8780	0.0	0.6103
Baseline FVC percent predicted										
<=70%	12/193 (6.2)	17/196 (8.7)	96.3	0/ 10 (0.0)	4/ 17 (23.5)	3.7	1.62 (0.81, 3.21)	0.1708	0.0	0.3290
>70%	9/138 (6.5)	17/136 (12.5)	95.4	0/ 17 (0.0)	0/ 37 (0.0)	4.6	1.87 (0.88, 4.00)	0.1044	0.0	0.7643
Baseline HRCT pattern										
UIP-like	12/206 (5.8)	21/206 (10.2)	96.4	0/ 23 (0.0)	3/ 45 (6.7)	3.6	1.89 (0.97, 3.68)	0.0631	0.0	0.5255
Other fibrotic patterns	9/125 (7.2)	13/126 (10.3)	95.5	0/ 4 (0.0)	1/ 9 (11.1)	4.5	1.48 (0.67, 3.27)	0.3341	0.0	0.7813
Underlying ILD diagnosis										
iNSIP	3/ 61 (4.9)	7/ 64 (10.9)	86.6	0/ 7 (0.0)	3/ 11 (27.3)	13.4	2.72 (0.82, 9.03)	0.1028	0.0	0.5778
Unclassifiable IIP	5/ 50 (10.0)	8/ 64 (12.5)	92.1	0/ 3 (0.0)	0/ 2 (0.0)	7.9	1.23 (0.45, 3.39)	0.6886	0.0	0.9096
HP	8/ 89 (9.0)	9/ 84 (10.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	4/ 88 (4.5)	5/ 82 (6.1)	90.9	0/ 12 (0.0)	1/ 34 (2.9)	9.1	1.43 (0.42, 4.86)	0.5633	0.0	0.7961
Other ILD	1/ 43 (2.3)	5/ 38 (13.2)	65.4	0/ 5 (0.0)	0/ 6 (0.0)	34.6	4.05 (0.70,23.32)	0.1176	0.0	0.4324
Region										
Europe										
Asia	0/ 76 (0.0)	1/ 79 (1.3)	52.9	0/ 27 (0.0)	4/ 54 (7.4)	47.1	4.86 (0.45,52.12)	0.1913	0.0	0.7218
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Fatigue

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid				
Overall	21/331 (6.3)	34/332 (10.2)	90.0	0/ 27 (0.0)	4/ 54 (7.4)	10.0	4.23 (0.37, 8.09)	0.0	0.4855
Age									
<65 years	5/121 (4.1)	16/139 (11.5)	90.2	0/ 9 (0.0)	2/ 25 (8.0)	9.8	7.40 (1.44, 13.35)	0.0	0.9836
>=65 years	16/210 (7.6)	18/193 (9.3)	89.7	0/ 18 (0.0)	2/ 29 (6.9)	10.3	2.21 (-2.83, 7.25)	0.0	0.4621
Sex									
Male	6/177 (3.4)	19/179 (10.6)	91.6	0/ 11 (0.0)	3/ 26 (11.5)	8.4	7.54 (2.56, 12.52)	0.0	0.6594
Female	15/154 (9.7)	15/153 (9.8)	87.8	0/ 16 (0.0)	1/ 28 (3.6)	12.2	0.47 (-5.51, 6.45)	0.0	0.6059
Baseline FVC percent predicted									
<=70%	12/193 (6.2)	17/196 (8.7)	93.5	0/ 10 (0.0)	4/ 17 (23.5)	6.5	3.72 (-1.37, 8.81)	62.5	0.1023
>70%	9/138 (6.5)	17/136 (12.5)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	5.08 (-0.90, 11.07)	24.5	0.2497
Baseline HRCT pattern									
UIP-like	12/206 (5.8)	21/206 (10.2)	86.8	0/ 23 (0.0)	3/ 45 (6.7)	13.2	4.65 (-0.05, 9.34)	0.0	0.6944
Other fibrotic patterns	9/125 (7.2)	13/126 (10.3)	95.2	0/ 4 (0.0)	1/ 9 (11.1)	4.8	3.43 (-3.39, 10.25)	0.0	0.6966
Underlying ILD diagnosis									
iNSIP	3/ 61 (4.9)	7/ 64 (10.9)	86.8	0/ 7 (0.0)	3/ 11 (27.3)	13.2	8.47 (-0.57, 17.51)	25.9	0.2453
Unclassifiable IIP	5/ 50 (10.0)	8/ 64 (12.5)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	2.36 (-9.00, 13.71)	0.0	0.9279
HP	8/ 89 (9.0)	9/ 84 (10.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	5/ 82 (6.1)	82.1	0/ 12 (0.0)	1/ 34 (2.9)	17.9	1.78 (-4.09, 7.65)	0.0	0.8438
Other ILD	1/ 43 (2.3)	5/ 38 (13.2)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	9.34 (-1.48, 20.16)	0.0	0.4981
Region									
Europe									
Asia	0/ 76 (0.0)	1/ 79 (1.3)	68.0	0/ 27 (0.0)	4/ 54 (7.4)	32.0	3.16 (-0.41, 6.73)	40.2	0.1961
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Fatigue

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	21/331 (6.3)	34/332 (10.2)	97.9	0/ 27 (0.0)	4/ 54 (7.4)	2.1	1.81 (1.04, 3.15)	0.0	0.4126
Age									
<65 years	5/121 (4.1)	16/139 (11.5)	93.1	0/ 9 (0.0)	2/ 25 (8.0)	6.9	3.09 (1.13, 8.42)	0.0	0.8921
>=65 years	16/210 (7.6)	18/193 (9.3)	97.0	0/ 18 (0.0)	2/ 29 (6.9)	3.0	1.35 (0.68, 2.66)	0.0	0.4704
Sex									
Male	6/177 (3.4)	19/179 (10.6)	93.7	0/ 11 (0.0)	3/ 26 (11.5)	6.3	3.54 (1.42, 8.84)	0.0	0.7786
Female	15/154 (9.7)	15/153 (9.8)	96.9	0/ 16 (0.0)	1/ 28 (3.6)	3.1	1.06 (0.51, 2.20)	0.0	0.6085
Baseline FVC percent predicted									
<=70%	12/193 (6.2)	17/196 (8.7)	96.9	0/ 10 (0.0)	4/ 17 (23.5)	3.1	1.68 (0.81, 3.49)	9.6	0.2929
>70%	9/138 (6.5)	17/136 (12.5)	94.9	0/ 17 (0.0)	0/ 37 (0.0)	5.1	1.99 (0.87, 4.57)	0.0	0.7463
Baseline HRCT pattern									
UIP-like	12/206 (5.8)	21/206 (10.2)	96.3	0/ 23 (0.0)	3/ 45 (6.7)	3.7	1.99 (0.97, 4.06)	0.0	0.5274
Other fibrotic patterns	9/125 (7.2)	13/126 (10.3)	95.8	0/ 4 (0.0)	1/ 9 (11.1)	4.2	1.54 (0.65, 3.64)	0.0	0.7715
Underlying ILD diagnosis									
iNSIP	3/ 61 (4.9)	7/ 64 (10.9)	89.1	0/ 7 (0.0)	3/ 11 (27.3)	10.9	2.98 (0.83,10.68)	0.0	0.5240
Unclassifiable IIP	5/ 50 (10.0)	8/ 64 (12.5)	92.3	0/ 3 (0.0)	0/ 2 (0.0)	7.7	1.26 (0.40, 3.95)	0.0	0.9125
HP	8/ 89 (9.0)	9/ 84 (10.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	5/ 82 (6.1)	90.8	0/ 12 (0.0)	1/ 34 (2.9)	9.2	1.46 (0.41, 5.23)	0.0	0.7971
Other ILD	1/ 43 (2.3)	5/ 38 (13.2)	64.0	0/ 5 (0.0)	0/ 6 (0.0)	36.0	4.43 (0.69,28.39)	0.0	0.4352
Region									
Europe									
Asia	0/ 76 (0.0)	1/ 79 (1.3)	54.6	0/ 27 (0.0)	4/ 54 (7.4)	45.4	5.06 (0.48,53.76)	0.0	0.7062
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
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with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
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(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Malaise

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid					
Overall	4/331 (1.2)	10/332 (3.0)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	2.34 (0.78, 7.04)	0.1294	0.0	0.6765
Age										
<65 years	0/121 (0.0)	3/139 (2.2)	56.1	0/ 9 (0.0)	0/ 25 (0.0)	43.9	4.15 (0.39,43.74)	0.2365	0.0	0.4878
>=65 years	4/210 (1.9)	7/193 (3.6)	89.0	0/ 18 (0.0)	0/ 29 (0.0)	11.0	1.80 (0.57, 5.73)	0.3167	0.0	0.7622
Sex										
Male										
Female										
Baseline FVC percent predicted										
<=70%	1/193 (0.5)	9/196 (4.6)	68.4	0/ 10 (0.0)	0/ 17 (0.0)	31.6	6.37 (1.13,36.00)	0.0360	0.0	0.3406
>70%	3/138 (2.2)	1/136 (0.7)	87.3	0/ 17 (0.0)	0/ 37 (0.0)	12.7	0.42 (0.06, 2.93)	0.3832	0.0	0.6546
Baseline HRCT pattern										
UIP-like	4/206 (1.9)	7/206 (3.4)	89.9	0/ 23 (0.0)	0/ 45 (0.0)	10.1	1.67 (0.52, 5.34)	0.3839	0.0	0.7981
Other fibrotic patterns	0/125 (0.0)	3/126 (2.4)	54.0	0/ 4 (0.0)	0/ 9 (0.0)	46.0	4.23 (0.45,40.02)	0.2088	0.0	0.4516
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Malaise

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	4/331 (1.2)	10/332 (3.0)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	1.62 (-0.40, 3.65)	0.0	0.5156
Age									
<65 years	0/121 (0.0)	3/139 (2.2)	90.3	0/ 9 (0.0)	0/ 25 (0.0)	9.7	1.93 (-0.87, 4.74)	0.0	0.7368
>=65 years	4/210 (1.9)	7/193 (3.6)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	1.54 (-1.46, 4.55)	0.0	0.6999
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%	1/193 (0.5)	9/196 (4.6)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	3.81 (0.78, 6.84)	0.0	0.5711
>70%	3/138 (2.2)	1/136 (0.7)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	-1.22 (-3.87, 1.43)	0.0	0.7240
Baseline HRCT pattern									
UIP-like	4/206 (1.9)	7/206 (3.4)	86.8	0/ 23 (0.0)	0/ 45 (0.0)	13.2	1.26 (-1.54, 4.07)	0.0	0.6677
Other fibrotic patterns	0/125 (0.0)	3/126 (2.4)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	2.25 (-0.94, 5.44)	0.0	0.8664
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Malaise

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2 p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid			
Overall	4/331 (1.2)	10/332 (3.0)	89.8	0/ 27 (0.0)	0/ 54 (0.0)	10.2	2.38 (0.77, 7.34)	0.0 0.6742
Age								
<65 years	0/121 (0.0)	3/139 (2.2)	56.2	0/ 9 (0.0)	0/ 25 (0.0)	43.8	4.23 (0.36,49.26)	0.0 0.4920
>=65 years	4/210 (1.9)	7/193 (3.6)	88.9	0/ 18 (0.0)	0/ 29 (0.0)	11.1	1.83 (0.56, 6.02)	0.0 0.7608
Sex								
Male								
Female								
Baseline FVC percent predicted								
<=70%	1/193 (0.5)	9/196 (4.6)	68.1	0/ 10 (0.0)	0/ 17 (0.0)	31.9	6.61 (1.11,39.25)	0.0 0.3458
>70%	3/138 (2.2)	1/136 (0.7)	87.5	0/ 17 (0.0)	0/ 37 (0.0)	12.5	0.42 (0.06, 2.88)	0.0 0.6556
Baseline HRCT pattern								
UIP-like	4/206 (1.9)	7/206 (3.4)	89.8	0/ 23 (0.0)	0/ 45 (0.0)	10.2	1.70 (0.51, 5.59)	0.0 0.7959
Other fibrotic patterns	0/125 (0.0)	3/126 (2.4)	55.0	0/ 4 (0.0)	0/ 9 (0.0)	45.0	4.38 (0.41,46.69)	0.0 0.4679
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia								
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Oedema peripheral

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk ratio (95% CI)	p-value	I^2	p-value
Overall	22/331 (6.6)	18/332 (5.4)	92.5	1/ 27 (3.7)	0/ 54 (0.0)	7.5	0.77 (0.43, 1.39)	0.3912	0.0	0.4346
Age										
<65 years	5/121 (4.1)	8/139 (5.8)	93.2	0/ 9 (0.0)	0/ 25 (0.0)	6.8	1.37 (0.47, 3.93)	0.5630	0.0	0.8856
>=65 years	17/210 (8.1)	10/193 (5.2)	90.5	1/ 18 (5.6)	0/ 29 (0.0)	9.5	0.61 (0.29, 1.25)	0.1773	0.0	0.5891
Sex										
Male	11/177 (6.2)	8/179 (4.5)	96.4	0/ 11 (0.0)	0/ 26 (0.0)	3.6	0.73 (0.31, 1.74)	0.4758	0.0	0.8812
Female	11/154 (7.1)	10/153 (6.5)	86.3	1/ 16 (6.3)	0/ 28 (0.0)	13.7	0.83 (0.38, 1.81)	0.6338	0.0	0.4250
Baseline FVC percent predicted										
<=70%	16/193 (8.3)	10/196 (5.1)	97.2	0/ 10 (0.0)	0/ 17 (0.0)	2.8	0.63 (0.30, 1.33)	0.2215	0.0	0.8148
>70%	6/138 (4.3)	8/136 (5.9)	76.8	1/ 17 (5.9)	0/ 37 (0.0)	23.2	1.09 (0.43, 2.78)	0.8500	19.5	0.2651
Baseline HRCT pattern										
UIP-like	12/206 (5.8)	9/206 (4.4)	87.1	1/ 23 (4.3)	0/ 45 (0.0)	12.9	0.69 (0.31, 1.53)	0.3561	0.0	0.4807
Other fibrotic patterns	10/125 (8.0)	9/126 (7.1)	95.9	0/ 4 (0.0)	0/ 9 (0.0)	4.1	0.90 (0.38, 2.09)	0.8019	0.0	0.9578
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	3/ 64 (4.7)	68.3	0/ 7 (0.0)	0/ 11 (0.0)	31.7	2.27 (0.34,15.21)	0.3982	0.0	0.6481
Unclassifiable IIP	1/ 50 (2.0)	6/ 64 (9.4)	70.1	0/ 3 (0.0)	0/ 2 (0.0)	29.9	3.58 (0.61,21.04)	0.1576	0.0	0.4762
HP	11/ 89 (12.4)	4/ 84 (4.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	5/ 88 (5.7)	4/ 82 (4.9)	72.1	1/ 12 (8.3)	0/ 34 (0.0)	27.9	0.68 (0.22, 2.09)	0.4968	0.0	0.3647
Other ILD	4/ 43 (9.3)	1/ 38 (2.6)	88.3	0/ 5 (0.0)	0/ 6 (0.0)	11.7	0.37 (0.06, 2.26)	0.2795	0.0	0.5693
Region										
Europe										
Asia	2/ 76 (2.6)	4/ 79 (5.1)	53.4	1/ 27 (3.7)	0/ 54 (0.0)	46.6	1.14 (0.31, 4.27)	0.8411	29.9	0.2324
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Oedema peripheral

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	22/331 (6.6)	18/332 (5.4)	90.0	1/ 27 (3.7)	0/ 54 (0.0)	10.0	-1.46 (-4.83, 1.91)	0.0	0.6116
Age									
<65 years	5/121 (4.1)	8/139 (5.8)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	1.46 (-3.42, 6.35)	0.0	0.8103
>=65 years	17/210 (8.1)	10/193 (5.2)	89.7	1/ 18 (5.6)	0/ 29 (0.0)	10.3	-3.16 (-7.70, 1.37)	0.0	0.7303
Sex									
Male	11/177 (6.2)	8/179 (4.5)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-1.60 (-5.97, 2.78)	0.0	0.7722
Female	11/154 (7.1)	10/153 (6.5)	87.8	1/ 16 (6.3)	0/ 28 (0.0)	12.2	-1.26 (-6.51, 3.99)	0.0	0.4892
Baseline FVC percent predicted									
<=70%	16/193 (8.3)	10/196 (5.1)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-2.98 (-7.71, 1.74)	0.0	0.6691
>70%	6/138 (4.3)	8/136 (5.9)	85.0	1/ 17 (5.9)	0/ 37 (0.0)	15.0	0.45 (-4.39, 5.30)	2.2	0.3120
Baseline HRCT pattern									
UIP-like	12/206 (5.8)	9/206 (4.4)	86.8	1/ 23 (4.3)	0/ 45 (0.0)	13.2	-1.82 (-5.73, 2.09)	0.0	0.6149
Other fibrotic patterns	10/125 (8.0)	9/126 (7.1)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-0.82 (-7.18, 5.55)	0.0	0.9524
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	3/ 64 (4.7)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	2.65 (-3.23, 8.52)	0.0	0.7709
Unclassifiable IIP	1/ 50 (2.0)	6/ 64 (9.4)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	6.96 (-1.27, 15.19)	0.0	0.7872
HP	11/ 89 (12.4)	4/ 84 (4.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	5/ 88 (5.7)	4/ 82 (4.9)	82.1	1/ 12 (8.3)	0/ 34 (0.0)	17.9	-2.09 (-8.42, 4.24)	0.0	0.4485
Other ILD	4/ 43 (9.3)	1/ 38 (2.6)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	-5.75 (-15.31, 3.81)	0.0	0.6710
Region									
Europe									
Asia	2/ 76 (2.6)	4/ 79 (5.1)	67.7	1/ 27 (3.7)	0/ 54 (0.0)	32.3	0.48 (-4.43, 5.40)	22.9	0.2548
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Oedema peripheral

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2 p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid			
Overall	22/331 (6.6)	18/332 (5.4)	92.2	1/ 27 (3.7)	0/ 54 (0.0)	7.8	0.76 (0.41, 1.42)	0.0 0.4373
Age								
<65 years	5/121 (4.1)	8/139 (5.8)	93.0	0/ 9 (0.0)	0/ 25 (0.0)	7.0	1.39 (0.46, 4.21)	0.0 0.8832
>=65 years	17/210 (8.1)	10/193 (5.2)	90.2	1/ 18 (5.6)	0/ 29 (0.0)	9.8	0.59 (0.27, 1.28)	0.0 0.5930
Sex								
Male	11/177 (6.2)	8/179 (4.5)	96.3	0/ 11 (0.0)	0/ 26 (0.0)	3.7	0.72 (0.29, 1.79)	0.0 0.8780
Female	11/154 (7.1)	10/153 (6.5)	85.8	1/ 16 (6.3)	0/ 28 (0.0)	14.2	0.82 (0.35, 1.90)	0.0 0.4247
Baseline FVC percent predicted								
<=70%	16/193 (8.3)	10/196 (5.1)	97.1	0/ 10 (0.0)	0/ 17 (0.0)	2.9	0.61 (0.27, 1.35)	0.0 0.8089
>70%	6/138 (4.3)	8/136 (5.9)	76.0	1/ 17 (5.9)	0/ 37 (0.0)	24.0	1.10 (0.41, 2.98)	20.0 0.2637
Baseline HRCT pattern								
UIP-like	12/206 (5.8)	9/206 (4.4)	86.8	1/ 23 (4.3)	0/ 45 (0.0)	13.2	0.67 (0.29, 1.57)	0.0 0.4828
Other fibrotic patterns	10/125 (8.0)	9/126 (7.1)	95.9	0/ 4 (0.0)	0/ 9 (0.0)	4.1	0.89 (0.36, 2.22)	0.0 0.9574
Underlying ILD diagnosis								
iNSIP	1/ 61 (1.6)	3/ 64 (4.7)	68.4	0/ 7 (0.0)	0/ 11 (0.0)	31.6	2.33 (0.32,16.83)	0.0 0.6531
Unclassifiable IIP	1/ 50 (2.0)	6/ 64 (9.4)	71.2	0/ 3 (0.0)	0/ 2 (0.0)	28.8	3.90 (0.62,24.53)	0.0 0.5099
HP	11/ 89 (12.4)	4/ 84 (4.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC NC
Autoimmune ILD	5/ 88 (5.7)	4/ 82 (4.9)	71.5	1/ 12 (8.3)	0/ 34 (0.0)	28.5	0.66 (0.20, 2.24)	0.0 0.3648
Other ILD	4/ 43 (9.3)	1/ 38 (2.6)	88.9	0/ 5 (0.0)	0/ 6 (0.0)	11.1	0.35 (0.05, 2.30)	0.0 0.5755
Region								
Europe								
Asia	2/ 76 (2.6)	4/ 79 (5.1)	52.4	1/ 27 (3.7)	0/ 54 (0.0)	47.6	1.15 (0.28, 4.66)	30.3 0.2310
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Pyrexia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	19/331 (5.7)	17/332 (5.1)	87.7	2/ 27 (7.4)	4/ 54 (7.4)	12.3	0.91 (0.50, 1.64)	0.7423	0.0	0.8984
Age										
<65 years	7/121 (5.8)	6/139 (4.3)	95.1	0/ 9 (0.0)	1/ 25 (4.0)	4.9	0.83 (0.30, 2.28)	0.7126	0.0	0.5875
>=65 years	12/210 (5.7)	11/193 (5.7)	82.3	2/ 18 (11.1)	3/ 29 (10.3)	17.7	0.99 (0.48, 2.02)	0.9686	0.0	0.9424
Sex										
Male	13/177 (7.3)	12/179 (6.7)	90.3	1/ 11 (9.1)	3/ 26 (11.5)	9.7	0.95 (0.46, 1.93)	0.8818	0.0	0.7768
Female	6/154 (3.9)	5/153 (3.3)	82.5	1/ 16 (6.3)	1/ 28 (3.6)	17.5	0.79 (0.27, 2.30)	0.6685	0.0	0.7983
Baseline FVC percent predicted										
<=70%	12/193 (6.2)	12/196 (6.1)	96.3	0/ 10 (0.0)	0/ 17 (0.0)	3.7	0.99 (0.46, 2.11)	0.9695	0.0	0.9941
>70%	7/138 (5.1)	5/136 (3.7)	71.7	2/ 17 (11.8)	4/ 37 (10.8)	28.3	0.78 (0.31, 1.95)	0.5954	0.0	0.8117
Baseline HRCT pattern										
UIP-like	13/206 (6.3)	13/206 (6.3)	83.1	2/ 23 (8.7)	2/ 45 (4.4)	16.9	0.92 (0.46, 1.83)	0.8058	0.0	0.5181
Other fibrotic patterns	6/125 (4.8)	4/126 (3.2)	93.4	0/ 4 (0.0)	2/ 9 (22.2)	6.6	0.87 (0.28, 2.69)	0.8151	0.0	0.3577
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	2/ 64 (3.1)	68.3	0/ 7 (0.0)	0/ 11 (0.0)	31.7	1.62 (0.22,12.11)	0.6389	0.0	0.7826
Unclassifiable IIP	5/ 50 (10.0)	6/ 64 (9.4)	92.1	0/ 3 (0.0)	0/ 2 (0.0)	7.9	0.94 (0.32, 2.77)	0.9142	0.0	0.9739
HP	3/ 89 (3.4)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	6/ 88 (6.8)	1/ 82 (1.2)	66.2	2/ 12 (16.7)	2/ 34 (5.9)	33.8	0.24 (0.06, 0.99)	0.0479	0.0	0.6334
Other ILD	4/ 43 (9.3)	3/ 38 (7.9)	88.3	0/ 5 (0.0)	2/ 6 (33.3)	11.7	1.29 (0.38, 4.37)	0.6777	3.1	0.3098
Region										
Europe										
Asia	9/ 76 (11.8)	7/ 79 (8.9)	77.5	2/ 27 (7.4)	4/ 54 (7.4)	22.5	0.80 (0.36, 1.81)	0.5998	0.0	0.7627
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Pyrexia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	19/331 (5.7)	17/332 (5.1)	90.2	2/ 27 (7.4)	4/ 54 (7.4)	9.8	-0.56 (-3.89, 2.77)	0.0	0.9231
Age									
<65 years	7/121 (5.8)	6/139 (4.3)	90.2	0/ 9 (0.0)	1/ 25 (4.0)	9.8	-0.96 (-5.98, 4.07)	0.0	0.4944
>=65 years	12/210 (5.7)	11/193 (5.7)	90.1	2/ 18 (11.1)	3/ 29 (10.3)	9.9	-0.09 (-4.56, 4.38)	0.0	0.9376
Sex									
Male	13/177 (7.3)	12/179 (6.7)	92.0	1/ 11 (9.1)	3/ 26 (11.5)	8.0	-0.39 (-5.56, 4.77)	0.0	0.7795
Female	6/154 (3.9)	5/153 (3.3)	88.3	1/ 16 (6.3)	1/ 28 (3.6)	11.7	-0.87 (-4.87, 3.14)	0.0	0.7791
Baseline FVC percent predicted									
<=70%	12/193 (6.2)	12/196 (6.1)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-0.09 (-4.65, 4.47)	0.0	0.9898
>70%	7/138 (5.1)	5/136 (3.7)	85.5	2/ 17 (11.8)	4/ 37 (10.8)	14.5	-1.33 (-6.25, 3.58)	0.0	0.9635
Baseline HRCT pattern									
UIP-like	13/206 (6.3)	13/206 (6.3)	87.1	2/ 23 (8.7)	2/ 45 (4.4)	12.9	-0.55 (-4.97, 3.87)	0.0	0.5465
Other fibrotic patterns	6/125 (4.8)	4/126 (3.2)	95.2	0/ 4 (0.0)	2/ 9 (22.2)	4.8	-0.61 (-5.52, 4.29)	25.3	0.2473
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	2/ 64 (3.1)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	1.29 (-4.01, 6.58)	0.0	0.8860
Unclassifiable IIP	5/ 50 (10.0)	6/ 64 (9.4)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	-0.59 (-11.35, 10.18)	0.0	0.9819
HP	3/ 89 (3.4)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	6/ 88 (6.8)	1/ 82 (1.2)	82.7	2/ 12 (16.7)	2/ 34 (5.9)	17.3	-6.49 (-12.66, -0.33)	0.0	0.6620
Other ILD	4/ 43 (9.3)	3/ 38 (7.9)	86.2	0/ 5 (0.0)	2/ 6 (33.3)	13.8	2.67 (-9.29, 14.63)	44.9	0.1780
Region									
Europe									
Asia	9/ 76 (11.8)	7/ 79 (8.9)	68.3	2/ 27 (7.4)	4/ 54 (7.4)	31.7	-2.04 (-9.63, 5.56)	0.0	0.7051
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: General disorders and administration site conditions
PT: Pyrexia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	19/331 (5.7)	17/332 (5.1)	88.0	2/ 27 (7.4)	4/ 54 (7.4)	12.0	0.90 (0.48, 1.69)	0.0	0.9002
Age									
<65 years	7/121 (5.8)	6/139 (4.3)	95.2	0/ 9 (0.0)	1/ 25 (4.0)	4.8	0.82 (0.28, 2.36)	0.0	0.5829
>=65 years	12/210 (5.7)	11/193 (5.7)	83.0	2/ 18 (11.1)	3/ 29 (10.3)	17.0	0.98 (0.46, 2.13)	0.0	0.9418
Sex									
Male	13/177 (7.3)	12/179 (6.7)	90.7	1/ 11 (9.1)	3/ 26 (11.5)	9.3	0.94 (0.44, 2.03)	0.0	0.7769
Female	6/154 (3.9)	5/153 (3.3)	82.5	1/ 16 (6.3)	1/ 28 (3.6)	17.5	0.78 (0.26, 2.39)	0.0	0.7970
Baseline FVC percent predicted									
<=70%	12/193 (6.2)	12/196 (6.1)	96.2	0/ 10 (0.0)	0/ 17 (0.0)	3.8	0.98 (0.44, 2.21)	0.0	0.9939
>70%	7/138 (5.1)	5/136 (3.7)	73.2	2/ 17 (11.8)	4/ 37 (10.8)	26.8	0.77 (0.29, 2.04)	0.0	0.8261
Baseline HRCT pattern									
UIP-like	13/206 (6.3)	13/206 (6.3)	82.8	2/ 23 (8.7)	2/ 45 (4.4)	17.2	0.91 (0.44, 1.91)	0.0	0.5190
Other fibrotic patterns	6/125 (4.8)	4/126 (3.2)	94.9	0/ 4 (0.0)	2/ 9 (22.2)	5.1	0.87 (0.27, 2.77)	0.0	0.3366
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	2/ 64 (3.1)	68.7	0/ 7 (0.0)	0/ 11 (0.0)	31.3	1.64 (0.20,13.19)	0.0	0.7868
Unclassifiable IIP	5/ 50 (10.0)	6/ 64 (9.4)	92.5	0/ 3 (0.0)	0/ 2 (0.0)	7.5	0.94 (0.28, 3.11)	0.0	0.9752
HP	3/ 89 (3.4)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	6/ 88 (6.8)	1/ 82 (1.2)	67.3	2/ 12 (16.7)	2/ 34 (5.9)	32.7	0.22 (0.05, 0.95)	0.0	0.6859
Other ILD	4/ 43 (9.3)	3/ 38 (7.9)	91.6	0/ 5 (0.0)	2/ 6 (33.3)	8.4	1.33 (0.35, 5.02)	16.4	0.2742
Region									
Europe									
Asia	9/ 76 (11.8)	7/ 79 (8.9)	77.2	2/ 27 (7.4)	4/ 54 (7.4)	22.8	0.79 (0.32, 1.92)	0.0	0.7571
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Hepatobiliary disorders
PT: Hepatic function abnormal

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	3/331 (0.9)	19/332 (5.7)	53.0	2/ 27 (7.4)	12/ 54 (22.2)	47.0	4.76 (1.92,11.81)	0.0008	0.0	0.4347
Age										
<65 years	1/121 (0.8)	8/139 (5.8)	73.3	0/ 9 (0.0)	7/ 25 (28.0)	26.7	7.91 (1.26,49.82)	0.0276	0.0	0.8518
>=65 years	2/210 (1.0)	11/193 (5.7)	43.7	2/ 18 (11.1)	5/ 29 (17.2)	56.3	3.49 (1.25, 9.77)	0.0174	34.6	0.2161
Sex										
Male	2/177 (1.1)	10/179 (5.6)	41.7	2/ 11 (18.2)	5/ 26 (19.2)	58.3	2.68 (0.98, 7.36)	0.0559	51.2	0.1521
Female	1/154 (0.6)	9/153 (5.9)	68.3	0/ 16 (0.0)	7/ 28 (25.0)	31.7	9.99 (1.73,57.73)	0.0101	0.0	0.8866
Baseline FVC percent predicted										
<=70%	1/193 (0.5)	12/196 (6.1)	68.4	0/ 10 (0.0)	6/ 17 (35.3)	31.6	11.41 (2.05,63.64)	0.0055	0.0	0.9527
>70%	2/138 (1.4)	7/136 (5.1)	42.0	2/ 17 (11.8)	6/ 37 (16.2)	58.0	2.29 (0.80, 6.58)	0.1232	0.0	0.3894
Baseline HRCT pattern										
UIP-like	3/206 (1.5)	11/206 (5.3)	53.1	2/ 23 (8.7)	10/ 45 (22.2)	46.9	3.15 (1.22, 8.08)	0.0173	0.0	0.7109
Other fibrotic patterns	0/125 (0.0)	8/126 (6.3)	54.0	0/ 4 (0.0)	2/ 9 (22.2)	46.0	10.93 (1.28,93.74)	0.0291	0.0	0.5273
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	2/ 76 (2.6)	18/ 79 (22.8)	43.3	2/ 27 (7.4)	12/ 54 (22.2)	56.7	5.45 (2.04,14.56)	0.0007	5.9	0.3027
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Hepatobiliary disorders
PT: Hepatic function abnormal

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo: Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	3/331 (0.9)	19/332 (5.7)	90.2	2/ 27 (7.4)	12/ 54 (22.2)	9.8	5.80 (2.96, 8.63)	40.7	0.1942
Age									
<65 years	1/121 (0.8)	8/139 (5.8)	90.2	0/ 9 (0.0)	7/ 25 (28.0)	9.8	7.03 (2.76, 11.30)	76.0	0.0412
>=65 years	2/210 (1.0)	11/193 (5.7)	90.1	2/ 18 (11.1)	5/ 29 (17.2)	9.9	4.88 (1.14, 8.63)	0.0	0.8938
Sex									
Male	2/177 (1.1)	10/179 (5.6)	92.0	2/ 11 (18.2)	5/ 26 (19.2)	8.0	4.18 (0.13, 8.24)	0.0	0.8089
Female	1/154 (0.6)	9/153 (5.9)	87.8	0/ 16 (0.0)	7/ 28 (25.0)	12.2	7.51 (3.45, 11.56)	76.3	0.0399
Baseline FVC percent predicted									
<=70%	1/193 (0.5)	12/196 (6.1)	93.5	0/ 10 (0.0)	6/ 17 (35.3)	6.5	7.38 (3.73, 11.02)	78.3	0.0316
>70%	2/138 (1.4)	7/136 (5.1)	85.5	2/ 17 (11.8)	6/ 37 (16.2)	14.5	3.81 (-0.77, 8.38)	0.0	0.9406
Baseline HRCT pattern									
UIP-like	3/206 (1.5)	11/206 (5.3)	87.1	2/ 23 (8.7)	10/ 45 (22.2)	12.9	5.13 (1.41, 8.84)	18.2	0.2689
Other fibrotic patterns	0/125 (0.0)	8/126 (6.3)	95.2	0/ 4 (0.0)	2/ 9 (22.2)	4.8	6.92 (2.33, 11.51)	0.0	0.4722
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	2/ 76 (2.6)	18/ 79 (22.8)	68.3	2/ 27 (7.4)	12/ 54 (22.2)	31.7	18.46 (10.21, 26.71)	0.0	0.5580
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Hepatobiliary disorders
PT: Hepatic function abnormal

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	3/331 (0.9)	19/332 (5.7)	57.7	2/ 27 (7.4)	12/ 54 (22.2)	42.3	5.34 (2.04,14.01)	0.0	0.5433
Age									
<65 years	1/121 (0.8)	8/139 (5.8)	78.5	0/ 9 (0.0)	7/ 25 (28.0)	21.5	8.86 (1.40,56.03)	0.0	0.7661
>=65 years	2/210 (1.0)	11/193 (5.7)	46.9	2/ 18 (11.1)	5/ 29 (17.2)	53.1	3.83 (1.25,11.72)	20.2	0.2628
Sex									
Male	2/177 (1.1)	10/179 (5.6)	45.5	2/ 11 (18.2)	5/ 26 (19.2)	54.5	2.94 (0.95, 9.10)	40.8	0.1939
Female	1/154 (0.6)	9/153 (5.9)	73.3	0/ 16 (0.0)	7/ 28 (25.0)	26.7	11.25 (1.92,65.93)	0.0	0.8025
Baseline FVC percent predicted									
<=70%	1/193 (0.5)	12/196 (6.1)	76.1	0/ 10 (0.0)	6/ 17 (35.3)	23.9	13.34 (2.30,77.38)	0.0	0.9049
>70%	2/138 (1.4)	7/136 (5.1)	45.1	2/ 17 (11.8)	6/ 37 (16.2)	54.9	2.46 (0.78, 7.80)	0.0	0.4343
Baseline HRCT pattern									
UIP-like	3/206 (1.5)	11/206 (5.3)	58.0	2/ 23 (8.7)	10/ 45 (22.2)	42.0	3.47 (1.27, 9.52)	0.0	0.8192
Other fibrotic patterns	0/125 (0.0)	8/126 (6.3)	59.6	0/ 4 (0.0)	2/ 9 (22.2)	40.4	12.76 (1.31, >99)	0.0	0.5978
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	2/ 76 (2.6)	18/ 79 (22.8)	43.1	2/ 27 (7.4)	12/ 54 (22.2)	56.9	6.74 (2.31,19.68)	1.3	0.3142
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Bronchitis

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid					
Overall	64/331 (19.3)	48/332 (14.5)	99.3	0/ 27 (0.0)	0/ 54 (0.0)	0.7	0.75 (0.53, 1.05)	0.0971	0.0	0.8907
Age										
<65 years	18/121 (14.9)	26/139 (18.7)	98.0	0/ 9 (0.0)	0/ 25 (0.0)	2.0	1.25 (0.73, 2.16)	0.4186	0.0	0.9190
>=65 years	46/210 (21.9)	22/193 (11.4)	98.9	0/ 18 (0.0)	0/ 29 (0.0)	1.1	0.53 (0.33, 0.84)	0.0067	0.0	0.7500
Sex										
Male	31/177 (17.5)	25/179 (14.0)	98.7	0/ 11 (0.0)	0/ 26 (0.0)	1.3	0.80 (0.49, 1.29)	0.3636	0.0	0.9171
Female	33/154 (21.4)	23/153 (15.0)	98.6	0/ 16 (0.0)	0/ 28 (0.0)	1.4	0.71 (0.44, 1.14)	0.1543	0.0	0.8641
Baseline FVC percent predicted										
<=70%	37/193 (19.2)	35/196 (17.9)	98.8	0/ 10 (0.0)	0/ 17 (0.0)	1.2	0.93 (0.62, 1.41)	0.7407	0.0	0.9723
>70%	27/138 (19.6)	13/136 (9.6)	98.4	0/ 17 (0.0)	0/ 37 (0.0)	1.6	0.50 (0.27, 0.91)	0.0246	0.0	0.7398
Baseline HRCT pattern										
UIP-like	43/206 (20.9)	31/206 (15.0)	99.0	0/ 23 (0.0)	0/ 45 (0.0)	1.0	0.72 (0.48, 1.10)	0.1290	0.0	0.8767
Other fibrotic patterns	21/125 (16.8)	17/126 (13.5)	98.0	0/ 4 (0.0)	0/ 9 (0.0)	2.0	0.81 (0.45, 1.45)	0.4714	0.0	0.9174
Underlying ILD diagnosis										
iNSIP	8/ 61 (13.1)	5/ 64 (7.8)	94.5	0/ 7 (0.0)	0/ 11 (0.0)	5.5	0.62 (0.22, 1.72)	0.3557	0.0	0.8025
Unclassifiable IIP	9/ 50 (18.0)	7/ 64 (10.9)	95.5	0/ 3 (0.0)	0/ 2 (0.0)	4.5	0.63 (0.26, 1.52)	0.3000	0.0	0.7980
HP	18/ 89 (20.2)	16/ 84 (19.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	20/ 88 (22.7)	13/ 82 (15.9)	98.0	0/ 12 (0.0)	0/ 34 (0.0)	2.0	0.70 (0.38, 1.31)	0.2691	0.0	0.8743
Other ILD	9/ 43 (20.9)	7/ 38 (18.4)	94.5	0/ 5 (0.0)	0/ 6 (0.0)	5.5	0.89 (0.37, 2.10)	0.7849	0.0	0.9486
Region										
Europe										
Asia	8/ 76 (10.5)	10/ 79 (12.7)	94.8	0/ 27 (0.0)	0/ 54 (0.0)	5.2	1.19 (0.51, 2.81)	0.6874	0.0	0.9318
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Bronchitis

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	64/331 (19.3)	48/332 (14.5)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	-4.39 (-9.54, 0.76)	37.4	0.2062
Age									
<65 years	18/121 (14.9)	26/139 (18.7)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	3.45 (-4.81, 11.72)	0.0	0.6209
>=65 years	46/210 (21.9)	22/193 (11.4)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	-9.42 (-15.90, -2.94)	72.2	0.0577
Sex									
Male	31/177 (17.5)	25/179 (14.0)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-3.25 (-10.23, 3.73)	0.0	0.5991
Female	33/154 (21.4)	23/153 (15.0)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	-5.62 (-13.25, 2.02)	4.0	0.3074
Baseline FVC percent predicted									
<=70%	37/193 (19.2)	35/196 (17.9)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-1.23 (-8.50, 6.04)	0.0	0.8703
>70%	27/138 (19.6)	13/136 (9.6)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	-8.51 (-15.62, -1.40)	67.8	0.0782
Baseline HRCT pattern									
UIP-like	43/206 (20.9)	31/206 (15.0)	86.8	0/ 23 (0.0)	0/ 45 (0.0)	13.2	-5.06 (-11.52, 1.41)	31.6	0.2266
Other fibrotic patterns	21/125 (16.8)	17/126 (13.5)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-3.15 (-11.68, 5.39)	0.0	0.8216
Underlying ILD diagnosis									
iNSIP	8/ 61 (13.1)	5/ 64 (7.8)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	-4.60 (-14.26, 5.06)	0.0	0.6417
Unclassifiable IIP	9/ 50 (18.0)	7/ 64 (10.9)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	-6.66 (-19.39, 6.06)	0.0	0.7996
HP	18/ 89 (20.2)	16/ 84 (19.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	20/ 88 (22.7)	13/ 82 (15.9)	82.1	0/ 12 (0.0)	0/ 34 (0.0)	17.9	-5.64 (-15.47, 4.18)	0.0	0.3679
Other ILD	9/ 43 (20.9)	7/ 38 (18.4)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	-2.16 (-17.62, 13.29)	0.0	0.8845
Region									
Europe									
Asia	8/ 76 (10.5)	10/ 79 (12.7)	67.7	0/ 27 (0.0)	0/ 54 (0.0)	32.3	1.44 (-5.56, 8.45)	0.0	0.7099
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Bronchitis

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo: Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	64/331 (19.3)	48/332 (14.5)	99.2	0/ 27 (0.0)	0/ 54 (0.0)	0.8	0.71 (0.47, 1.06)	0.0	0.8706
Age									
<65 years	18/121 (14.9)	26/139 (18.7)	97.6	0/ 9 (0.0)	0/ 25 (0.0)	2.4	1.31 (0.68, 2.51)	0.0	0.9058
>=65 years	46/210 (21.9)	22/193 (11.4)	98.8	0/ 18 (0.0)	0/ 29 (0.0)	1.2	0.47 (0.27, 0.80)	0.0	0.7102
Sex									
Male	31/177 (17.5)	25/179 (14.0)	98.5	0/ 11 (0.0)	0/ 26 (0.0)	1.5	0.77 (0.44, 1.36)	0.0	0.9044
Female	33/154 (21.4)	23/153 (15.0)	98.4	0/ 16 (0.0)	0/ 28 (0.0)	1.6	0.65 (0.37, 1.17)	0.0	0.8385
Baseline FVC percent predicted									
<=70%	37/193 (19.2)	35/196 (17.9)	98.6	0/ 10 (0.0)	0/ 17 (0.0)	1.4	0.92 (0.55, 1.53)	0.0	0.9673
>70%	27/138 (19.6)	13/136 (9.6)	98.3	0/ 17 (0.0)	0/ 37 (0.0)	1.7	0.44 (0.22, 0.89)	0.0	0.7051
Baseline HRCT pattern									
UIP-like	43/206 (20.9)	31/206 (15.0)	98.8	0/ 23 (0.0)	0/ 45 (0.0)	1.2	0.68 (0.41, 1.12)	0.0	0.8527
Other fibrotic patterns	21/125 (16.8)	17/126 (13.5)	97.9	0/ 4 (0.0)	0/ 9 (0.0)	2.1	0.78 (0.39, 1.54)	0.0	0.9094
Underlying ILD diagnosis									
iNSIP	8/ 61 (13.1)	5/ 64 (7.8)	94.4	0/ 7 (0.0)	0/ 11 (0.0)	5.6	0.59 (0.19, 1.81)	0.0	0.7920
Unclassifiable IIP	9/ 50 (18.0)	7/ 64 (10.9)	95.6	0/ 3 (0.0)	0/ 2 (0.0)	4.4	0.58 (0.21, 1.63)	0.0	0.7981
HP	18/ 89 (20.2)	16/ 84 (19.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	20/ 88 (22.7)	13/ 82 (15.9)	97.7	0/ 12 (0.0)	0/ 34 (0.0)	2.3	0.65 (0.30, 1.39)	0.0	0.8487
Other ILD	9/ 43 (20.9)	7/ 38 (18.4)	93.8	0/ 5 (0.0)	0/ 6 (0.0)	6.2	0.86 (0.30, 2.50)	0.0	0.9415
Region									
Europe									
Asia	8/ 76 (10.5)	10/ 79 (12.7)	94.2	0/ 27 (0.0)	0/ 54 (0.0)	5.8	1.22 (0.47, 3.19)	0.0	0.9242
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Influenza

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	12/331 (3.6)	9/332 (2.7)	90.0	1/ 27 (3.7)	3/ 54 (5.6)	10.0	0.82 (0.37, 1.81)	0.6281	0.0	0.5653
Age										
<65 years	4/121 (3.3)	4/139 (2.9)	74.4	1/ 9 (11.1)	2/ 25 (8.0)	25.6	0.83 (0.26, 2.68)	0.7583	0.0	0.8885
>=65 years	8/210 (3.8)	5/193 (2.6)	94.2	0/ 18 (0.0)	1/ 29 (3.4)	5.8	0.79 (0.28, 2.22)	0.6578	0.0	0.4682
Sex										
Male	5/177 (2.8)	7/179 (3.9)	92.3	0/ 11 (0.0)	1/ 26 (3.8)	7.7	1.46 (0.50, 4.32)	0.4897	0.0	0.7837
Female	7/154 (4.5)	2/153 (1.3)	84.6	1/ 16 (6.3)	2/ 28 (7.1)	15.4	0.42 (0.12, 1.45)	0.1695	0.0	0.3330
Baseline FVC percent predicted										
<=70%	6/193 (3.1)	8/196 (4.1)	77.8	1/ 10 (10.0)	0/ 17 (0.0)	22.2	1.08 (0.42, 2.79)	0.8713	1.9	0.3127
>70%	6/138 (4.3)	1/136 (0.7)	93.2	0/ 17 (0.0)	3/ 37 (8.1)	6.8	0.52 (0.13, 2.04)	0.3484	62.3	0.1036
Baseline HRCT pattern										
UIP-like	7/206 (3.4)	8/206 (3.9)	84.1	1/ 23 (4.3)	3/ 45 (6.7)	15.9	1.20 (0.49, 2.98)	0.6869	0.0	0.8119
Other fibrotic patterns	5/125 (4.0)	1/126 (0.8)	92.2	0/ 4 (0.0)	0/ 9 (0.0)	7.8	0.26 (0.04, 1.62)	0.1493	0.0	0.4930
Underlying ILD diagnosis										
iNSIP	2/ 61 (3.3)	0/ 64 (0.0)	60.0	1/ 7 (14.3)	0/ 11 (0.0)	40.0	0.23 (0.03, 1.85)	0.1670	0.0	0.8663
Unclassifiable IIP	3/ 50 (6.0)	2/ 64 (3.1)	87.5	0/ 3 (0.0)	0/ 2 (0.0)	12.5	0.58 (0.12, 2.80)	0.4981	0.0	0.7550
HP	6/ 89 (6.7)	4/ 84 (4.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	1/ 88 (1.1)	2/ 82 (2.4)	71.4	0/ 12 (0.0)	2/ 34 (5.9)	28.6	2.59 (0.33,20.27)	0.3641	0.0	0.8169
Other ILD	0/ 43 (0.0)	1/ 38 (2.6)	50.1	0/ 5 (0.0)	1/ 6 (16.7)	49.9	2.98 (0.33,26.99)	0.3308	0.0	0.9645
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Influenza

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	12/331 (3.6)	9/332 (2.7)	90.2	1/ 27 (3.7)	3/ 54 (5.6)	9.8	-0.64 (-3.22, 1.93)	0.0	0.5784
Age									
<65 years	4/121 (3.3)	4/139 (2.9)	90.7	1/ 9 (11.1)	2/ 25 (8.0)	9.3	-0.68 (-5.07, 3.72)	0.0	0.8230
>=65 years	8/210 (3.8)	5/193 (2.6)	89.7	0/ 18 (0.0)	1/ 29 (3.4)	10.3	-0.75 (-4.00, 2.50)	0.0	0.4121
Sex									
Male	5/177 (2.8)	7/179 (3.9)	91.6	0/ 11 (0.0)	1/ 26 (3.8)	8.4	1.30 (-2.29, 4.90)	0.0	0.7069
Female	7/154 (4.5)	2/153 (1.3)	88.3	1/ 16 (6.3)	2/ 28 (7.1)	11.7	-2.75 (-6.51, 1.01)	0.0	0.6055
Baseline FVC percent predicted									
<=70%	6/193 (3.1)	8/196 (4.1)	93.5	1/ 10 (10.0)	0/ 17 (0.0)	6.5	0.30 (-3.43, 4.04)	0.0	0.3585
>70%	6/138 (4.3)	1/136 (0.7)	85.0	0/ 17 (0.0)	3/ 37 (8.1)	15.0	-1.90 (-5.46, 1.66)	72.4	0.0572
Baseline HRCT pattern									
UIP-like	7/206 (3.4)	8/206 (3.9)	87.1	1/ 23 (4.3)	3/ 45 (6.7)	12.9	0.72 (-2.74, 4.18)	0.0	0.7577
Other fibrotic patterns	5/125 (4.0)	1/126 (0.8)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-3.05 (-6.87, 0.77)	0.0	0.8199
Underlying ILD diagnosis									
iNSIP	2/ 61 (3.3)	0/ 64 (0.0)	87.0	1/ 7 (14.3)	0/ 11 (0.0)	13.0	-4.48 (-10.51, 1.55)	0.0	0.5298
Unclassifiable IIP	3/ 50 (6.0)	2/ 64 (3.1)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	-2.71 (-10.69, 5.27)	0.0	0.9161
HP	6/ 89 (6.7)	4/ 84 (4.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	1/ 88 (1.1)	2/ 82 (2.4)	82.1	0/ 12 (0.0)	2/ 34 (5.9)	17.9	2.08 (-1.83, 5.99)	0.0	0.4961
Other ILD	0/ 43 (0.0)	1/ 38 (2.6)	86.5	0/ 5 (0.0)	1/ 6 (16.7)	13.5	4.12 (-3.61, 11.86)	0.0	0.5501
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Influenza

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo	Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	I^2	p-value
Overall	12/331 (3.6)	9/332 (2.7)	90.3	1/ 27 (3.7)	3/ 54 (5.6)	9.7	0.82 (0.36, 1.84)	0.0	0.5656
Age									
<65 years	4/121 (3.3)	4/139 (2.9)	75.4	1/ 9 (11.1)	2/ 25 (8.0)	24.6	0.82 (0.24, 2.83)	0.0	0.8818
>=65 years	8/210 (3.8)	5/193 (2.6)	94.3	0/ 18 (0.0)	1/ 29 (3.4)	5.7	0.79 (0.28, 2.25)	0.0	0.4652
Sex									
Male	5/177 (2.8)	7/179 (3.9)	92.5	0/ 11 (0.0)	1/ 26 (3.8)	7.5	1.48 (0.49, 4.51)	0.0	0.7805
Female	7/154 (4.5)	2/153 (1.3)	85.4	1/ 16 (6.3)	2/ 28 (7.1)	14.6	0.41 (0.12, 1.43)	0.0	0.3441
Baseline FVC percent predicted									
<=70%	6/193 (3.1)	8/196 (4.1)	77.7	1/ 10 (10.0)	0/ 17 (0.0)	22.3	1.08 (0.40, 2.93)	2.8	0.3105
>70%	6/138 (4.3)	1/136 (0.7)	93.8	0/ 17 (0.0)	3/ 37 (8.1)	6.2	0.51 (0.14, 1.92)	63.2	0.0993
Baseline HRCT pattern									
UIP-like	7/206 (3.4)	8/206 (3.9)	84.5	1/ 23 (4.3)	3/ 45 (6.7)	15.5	1.21 (0.47, 3.11)	0.0	0.8090
Other fibrotic patterns	5/125 (4.0)	1/126 (0.8)	92.6	0/ 4 (0.0)	0/ 9 (0.0)	7.4	0.25 (0.04, 1.57)	0.0	0.5091
Underlying ILD diagnosis									
iNSIP	2/ 61 (3.3)	0/ 64 (0.0)	61.0	1/ 7 (14.3)	0/ 11 (0.0)	39.0	0.21 (0.02, 1.88)	0.0	0.9131
Unclassifiable IIP	3/ 50 (6.0)	2/ 64 (3.1)	88.8	0/ 3 (0.0)	0/ 2 (0.0)	11.2	0.56 (0.10, 3.02)	0.0	0.7756
HP	6/ 89 (6.7)	4/ 84 (4.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	1/ 88 (1.1)	2/ 82 (2.4)	72.6	0/ 12 (0.0)	2/ 34 (5.9)	27.4	2.66 (0.34,20.90)	0.0	0.8063
Other ILD	0/ 43 (0.0)	1/ 38 (2.6)	55.3	0/ 5 (0.0)	1/ 6 (16.7)	44.7	3.27 (0.31,34.41)	0.0	0.9870
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Nasopharyngitis

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo: Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	48/331 (14.5)	54/332 (16.3)	97.3	1/ 27 (3.7)	1/ 54 (1.9)	2.7	1.10 (0.78, 1.57)	0.5812	0.0	0.5656
Age										
<65 years	20/121 (16.5)	24/139 (17.3)	98.2	0/ 9 (0.0)	1/ 25 (4.0)	1.8	1.07 (0.62, 1.83)	0.8097	0.0	0.6939
>=65 years	28/210 (13.3)	30/193 (15.5)	94.0	1/ 18 (5.6)	0/ 29 (0.0)	6.0	1.11 (0.70, 1.77)	0.6542	0.0	0.3450
Sex										
Male	30/177 (16.9)	27/179 (15.1)	98.6	0/ 11 (0.0)	0/ 26 (0.0)	1.4	0.89 (0.56, 1.43)	0.6345	0.0	0.9572
Female	18/154 (11.7)	27/153 (17.6)	93.4	1/ 16 (6.3)	1/ 28 (3.6)	6.6	1.45 (0.84, 2.48)	0.1786	0.0	0.4900
Baseline FVC percent predicted										
<=70%	24/193 (12.4)	31/196 (15.8)	98.1	0/ 10 (0.0)	0/ 17 (0.0)	1.9	1.27 (0.78, 2.07)	0.3449	0.0	0.9066
>70%	24/138 (17.4)	23/136 (16.9)	94.6	1/ 17 (5.9)	1/ 37 (2.7)	5.4	0.94 (0.57, 1.57)	0.8264	0.0	0.5946
Baseline HRCT pattern										
UIP-like	33/206 (16.0)	40/206 (19.4)	96.1	1/ 23 (4.3)	1/ 45 (2.2)	3.9	1.19 (0.78, 1.79)	0.4200	0.0	0.5394
Other fibrotic patterns	15/125 (12.0)	14/126 (11.1)	97.2	0/ 4 (0.0)	0/ 9 (0.0)	2.8	0.93 (0.47, 1.82)	0.8283	0.0	0.9711
Underlying ILD diagnosis										
iNSIP	9/ 61 (14.8)	12/ 64 (18.8)	88.3	1/ 7 (14.3)	1/ 11 (9.1)	11.7	1.20 (0.56, 2.54)	0.6402	0.0	0.6185
Unclassifiable IIP	9/ 50 (18.0)	14/ 64 (21.9)	95.5	0/ 3 (0.0)	0/ 2 (0.0)	4.5	1.21 (0.58, 2.52)	0.6187	0.0	0.9195
HP	14/ 89 (15.7)	14/ 84 (16.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	15/ 88 (17.0)	12/ 82 (14.6)	97.4	0/ 12 (0.0)	0/ 34 (0.0)	2.6	0.86 (0.43, 1.72)	0.6730	0.0	0.9467
Other ILD	1/ 43 (2.3)	2/ 38 (5.3)	65.4	0/ 5 (0.0)	0/ 6 (0.0)	34.6	1.83 (0.25,13.13)	0.5495	0.0	0.7195
Region										
Europe										
Asia	23/ 76 (30.3)	21/ 79 (26.6)	94.6	1/ 27 (3.7)	1/ 54 (1.9)	5.4	0.86 (0.52, 1.40)	0.5421	0.0	0.6910
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Nasopharyngitis

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	48/331 (14.5)	54/332 (16.3)	90.2	1/ 27 (3.7)	1/ 54 (1.9)	9.8	1.41 (-3.60, 6.42)	0.0	0.4644
Age									
<65 years	20/121 (16.5)	24/139 (17.3)	90.2	0/ 9 (0.0)	1/ 25 (4.0)	9.8	1.03 (-7.31, 9.38)	0.0	0.7222
>=65 years	28/210 (13.3)	30/193 (15.5)	89.7	1/ 18 (5.6)	0/ 29 (0.0)	10.3	1.43 (-4.87, 7.74)	2.7	0.3106
Sex									
Male	30/177 (16.9)	27/179 (15.1)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-1.71 (-8.75, 5.33)	0.0	0.7828
Female	18/154 (11.7)	27/153 (17.6)	88.3	1/ 16 (6.3)	1/ 28 (3.6)	11.7	4.95 (-2.20, 12.09)	12.7	0.2845
Baseline FVC percent predicted									
<=70%	24/193 (12.4)	31/196 (15.8)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	3.16 (-3.36, 9.68)	0.0	0.6668
>70%	24/138 (17.4)	23/136 (16.9)	85.5	1/ 17 (5.9)	1/ 37 (2.7)	14.5	-0.87 (-8.71, 6.97)	0.0	0.7283
Baseline HRCT pattern									
UIP-like	33/206 (16.0)	40/206 (19.4)	87.1	1/ 23 (4.3)	1/ 45 (2.2)	12.9	2.69 (-3.84, 9.22)	0.0	0.3641
Other fibrotic patterns	15/125 (12.0)	14/126 (11.1)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-0.85 (-8.49, 6.80)	0.0	0.9512
Underlying ILD diagnosis									
iNSIP	9/ 61 (14.8)	12/ 64 (18.8)	88.0	1/ 7 (14.3)	1/ 11 (9.1)	12.0	2.89 (-9.19, 14.97)	0.0	0.5923
Unclassifiable IIP	9/ 50 (18.0)	14/ 64 (21.9)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	3.66 (-10.53, 17.84)	0.0	0.8900
HP	14/ 89 (15.7)	14/ 84 (16.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	15/ 88 (17.0)	12/ 82 (14.6)	82.1	0/ 12 (0.0)	0/ 34 (0.0)	17.9	-1.98 (-11.13, 7.17)	0.0	0.7413
Other ILD	1/ 43 (2.3)	2/ 38 (5.3)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	2.53 (-5.75, 10.82)	0.0	0.8492
Region									
Europe									
Asia	23/ 76 (30.3)	21/ 79 (26.6)	68.3	1/ 27 (3.7)	1/ 54 (1.9)	31.7	-3.10 (-13.12, 6.92)	0.0	0.8258
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Nasopharyngitis

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid				
Overall	48/331 (14.5)	54/332 (16.3)	96.9	1/ 27 (3.7)	1/ 54 (1.9)	3.1	1.12 (0.74, 1.71)	0.0	0.5589
Age									
<65 years	20/121 (16.5)	24/139 (17.3)	98.0	0/ 9 (0.0)	1/ 25 (4.0)	2.0	1.08 (0.57, 2.05)	0.0	0.6937
>=65 years	28/210 (13.3)	30/193 (15.5)	93.1	1/ 18 (5.6)	0/ 29 (0.0)	6.9	1.13 (0.66, 1.95)	0.0	0.3382
Sex									
Male	30/177 (16.9)	27/179 (15.1)	98.4	0/ 11 (0.0)	0/ 26 (0.0)	1.6	0.87 (0.50, 1.53)	0.0	0.9505
Female	18/154 (11.7)	27/153 (17.6)	92.3	1/ 16 (6.3)	1/ 28 (3.6)	7.7	1.54 (0.82, 2.88)	0.0	0.4720
Baseline FVC percent predicted									
<=70%	24/193 (12.4)	31/196 (15.8)	97.8	0/ 10 (0.0)	0/ 17 (0.0)	2.2	1.32 (0.74, 2.32)	0.0	0.8953
>70%	24/138 (17.4)	23/136 (16.9)	93.7	1/ 17 (5.9)	1/ 37 (2.7)	6.3	0.93 (0.51, 1.72)	0.0	0.5997
Baseline HRCT pattern									
UIP-like	33/206 (16.0)	40/206 (19.4)	95.4	1/ 23 (4.3)	1/ 45 (2.2)	4.6	1.23 (0.75, 2.02)	0.0	0.5259
Other fibrotic patterns	15/125 (12.0)	14/126 (11.1)	97.1	0/ 4 (0.0)	0/ 9 (0.0)	2.9	0.92 (0.43, 1.97)	0.0	0.9695
Underlying ILD diagnosis									
iNSIP	9/ 61 (14.8)	12/ 64 (18.8)	87.1	1/ 7 (14.3)	1/ 11 (9.1)	12.9	1.24 (0.50, 3.04)	0.0	0.6135
Unclassifiable IIP	9/ 50 (18.0)	14/ 64 (21.9)	95.0	0/ 3 (0.0)	0/ 2 (0.0)	5.0	1.26 (0.51, 3.14)	0.0	0.9141
HP	14/ 89 (15.7)	14/ 84 (16.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	15/ 88 (17.0)	12/ 82 (14.6)	97.0	0/ 12 (0.0)	0/ 34 (0.0)	3.0	0.84 (0.37, 1.89)	0.0	0.9383
Other ILD	1/ 43 (2.3)	2/ 38 (5.3)	66.0	0/ 5 (0.0)	0/ 6 (0.0)	34.0	1.88 (0.24,14.99)	0.0	0.7277
Region									
Europe									
Asia	23/ 76 (30.3)	21/ 79 (26.6)	92.9	1/ 27 (3.7)	1/ 54 (1.9)	7.1	0.81 (0.41, 1.60)	0.0	0.7194
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	30/331 (9.1)	36/332 (10.8)	79.0	6/ 27 (22.2)	6/ 54 (11.1)	21.0	1.05 (0.69, 1.59)	0.8182	56.3	0.1305
Age										
<65 years	9/121 (7.4)	17/139 (12.2)	76.6	2/ 9 (22.2)	1/ 25 (4.0)	23.4	1.30 (0.65, 2.60)	0.4555	69.3	0.0712
>=65 years	21/210 (10.0)	19/193 (9.8)	80.3	4/ 18 (22.2)	5/ 29 (17.2)	19.7	0.94 (0.56, 1.60)	0.8283	0.0	0.7227
Sex										
Male	16/177 (9.0)	23/179 (12.8)	79.2	3/ 11 (27.3)	6/ 26 (23.1)	20.8	1.30 (0.76, 2.23)	0.3363	0.0	0.4470
Female	14/154 (9.1)	13/153 (8.5)	76.5	3/ 16 (18.8)	0/ 28 (0.0)	23.5	0.74 (0.38, 1.44)	0.3744	58.9	0.1186
Baseline FVC percent predicted										
<=70%	24/193 (12.4)	27/196 (13.8)	86.5	3/ 10 (30.0)	2/ 17 (11.8)	13.5	1.01 (0.62, 1.64)	0.9643	31.1	0.2283
>70%	6/138 (4.3)	9/136 (6.6)	59.2	3/ 17 (17.6)	4/ 37 (10.8)	40.8	1.15 (0.52, 2.56)	0.7305	8.2	0.2967
Baseline HRCT pattern										
UIP-like	18/206 (8.7)	24/206 (11.7)	69.4	6/ 23 (26.1)	5/ 45 (11.1)	30.6	1.06 (0.64, 1.74)	0.8315	70.2	0.0671
Other fibrotic patterns	12/125 (9.6)	12/126 (9.5)	96.6	0/ 4 (0.0)	1/ 9 (11.1)	3.4	1.04 (0.50, 2.19)	0.9142	0.0	0.6382
Underlying ILD diagnosis										
iNSIP	8/ 61 (13.1)	3/ 64 (4.7)	77.0	2/ 7 (28.6)	1/ 11 (9.1)	23.0	0.35 (0.11, 1.06)	0.0625	0.0	0.9288
Unclassifiable IIP	4/ 50 (8.0)	9/ 64 (14.1)	90.3	0/ 3 (0.0)	0/ 2 (0.0)	9.7	1.68 (0.58, 4.90)	0.3385	0.0	0.7751
HP	8/ 89 (9.0)	6/ 84 (7.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	8/ 88 (9.1)	14/ 82 (17.1)	72.3	2/ 12 (16.7)	4/ 34 (11.8)	27.7	1.55 (0.76, 3.16)	0.2245	15.4	0.2770
Other ILD	2/ 43 (4.7)	4/ 38 (10.5)	46.2	2/ 5 (40.0)	1/ 6 (16.7)	53.8	1.27 (0.38, 4.21)	0.6956	36.0	0.2114
Region										
Europe										
Asia	10/ 76 (13.2)	9/ 79 (11.4)	56.0	6/ 27 (22.2)	6/ 54 (11.1)	44.0	0.70 (0.37, 1.35)	0.2908	0.0	0.4197
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	30/331 (9.1)	36/332 (10.8)	90.2	6/ 27 (22.2)	6/ 54 (11.1)	9.8	0.52 (-3.95, 4.98)	47.2	0.1687
Age									
<65 years	9/121 (7.4)	17/139 (12.2)	90.7	2/ 9 (22.2)	1/ 25 (4.0)	9.3	2.66 (-4.36, 9.68)	58.3	0.1214
>=65 years	21/210 (10.0)	19/193 (9.8)	90.1	4/ 18 (22.2)	5/ 29 (17.2)	9.9	-0.64 (-6.40, 5.13)	0.0	0.6975
Sex									
Male	16/177 (9.0)	23/179 (12.8)	92.0	3/ 11 (27.3)	6/ 26 (23.1)	8.0	3.17 (-3.28, 9.62)	0.0	0.6192
Female	14/154 (9.1)	13/153 (8.5)	87.8	3/ 16 (18.8)	0/ 28 (0.0)	12.2	-2.71 (-8.78, 3.36)	62.2	0.1040
Baseline FVC percent predicted									
<=70%	24/193 (12.4)	27/196 (13.8)	93.9	3/ 10 (30.0)	2/ 17 (11.8)	6.1	0.15 (-6.45, 6.75)	26.2	0.2444
>70%	6/138 (4.3)	9/136 (6.6)	85.5	3/ 17 (17.6)	4/ 37 (10.8)	14.5	0.95 (-4.55, 6.45)	0.0	0.4041
Baseline HRCT pattern									
UIP-like	18/206 (8.7)	24/206 (11.7)	87.1	6/ 23 (26.1)	5/ 45 (11.1)	12.9	0.61 (-5.10, 6.32)	64.2	0.0948
Other fibrotic patterns	12/125 (9.6)	12/126 (9.5)	95.2	0/ 4 (0.0)	1/ 9 (11.1)	4.8	0.39 (-6.70, 7.49)	0.0	0.5619
Underlying ILD diagnosis									
iNSIP	8/ 61 (13.1)	3/ 64 (4.7)	88.0	2/ 7 (28.6)	1/ 11 (9.1)	12.0	-9.76 (-19.59, 0.07)	0.0	0.5768
Unclassifiable IIP	4/ 50 (8.0)	9/ 64 (14.1)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	5.72 (-5.41, 16.85)	0.0	0.8262
HP	8/ 89 (9.0)	6/ 84 (7.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	8/ 88 (9.1)	14/ 82 (17.1)	82.7	2/ 12 (16.7)	4/ 34 (11.8)	17.3	5.76 (-3.56, 15.07)	0.0	0.3272
Other ILD	2/ 43 (4.7)	4/ 38 (10.5)	88.1	2/ 5 (40.0)	1/ 6 (16.7)	11.9	2.40 (-9.58, 14.37)	12.5	0.2851
Region									
Europe									
Asia	10/ 76 (13.2)	9/ 79 (11.4)	68.3	6/ 27 (22.2)	6/ 54 (11.1)	31.7	-4.73 (-13.77, 4.30)	0.0	0.3731
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	30/331 (9.1)	36/332 (10.8)	79.0	6/ 27 (22.2)	6/ 54 (11.1)	21.0	1.06 (0.66, 1.69)	55.4	0.1344
Age									
<65 years	9/121 (7.4)	17/139 (12.2)	74.9	2/ 9 (22.2)	1/ 25 (4.0)	25.1	1.34 (0.61, 2.90)	69.5	0.0703
>=65 years	21/210 (10.0)	19/193 (9.8)	81.6	4/ 18 (22.2)	5/ 29 (17.2)	18.4	0.94 (0.51, 1.70)	0.0	0.7163
Sex									
Male	16/177 (9.0)	23/179 (12.8)	81.2	3/ 11 (27.3)	6/ 26 (23.1)	18.8	1.36 (0.73, 2.52)	0.0	0.4881
Female	14/154 (9.1)	13/153 (8.5)	75.3	3/ 16 (18.8)	0/ 28 (0.0)	24.7	0.72 (0.35, 1.50)	61.3	0.1078
Baseline FVC percent predicted									
<=70%	24/193 (12.4)	27/196 (13.8)	86.2	3/ 10 (30.0)	2/ 17 (11.8)	13.8	1.01 (0.58, 1.78)	31.4	0.2273
>70%	6/138 (4.3)	9/136 (6.6)	60.3	3/ 17 (17.6)	4/ 37 (10.8)	39.7	1.16 (0.48, 2.81)	4.8	0.3053
Baseline HRCT pattern									
UIP-like	18/206 (8.7)	24/206 (11.7)	69.3	6/ 23 (26.1)	5/ 45 (11.1)	30.7	1.06 (0.60, 1.88)	69.7	0.0692
Other fibrotic patterns	12/125 (9.6)	12/126 (9.5)	96.8	0/ 4 (0.0)	1/ 9 (11.1)	3.2	1.05 (0.46, 2.37)	0.0	0.6286
Underlying ILD diagnosis									
iNSIP	8/ 61 (13.1)	3/ 64 (4.7)	77.8	2/ 7 (28.6)	1/ 11 (9.1)	22.2	0.31 (0.09, 1.05)	0.0	0.8612
Unclassifiable IIP	4/ 50 (8.0)	9/ 64 (14.1)	90.4	0/ 3 (0.0)	0/ 2 (0.0)	9.6	1.80 (0.55, 5.89)	0.0	0.7828
HP	8/ 89 (9.0)	6/ 84 (7.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	8/ 88 (9.1)	14/ 82 (17.1)	71.0	2/ 12 (16.7)	4/ 34 (11.8)	29.0	1.66 (0.72, 3.78)	12.9	0.2838
Other ILD	2/ 43 (4.7)	4/ 38 (10.5)	48.0	2/ 5 (40.0)	1/ 6 (16.7)	52.0	1.31 (0.33, 5.29)	34.7	0.2159
Region									
Europe									
Asia	10/ 76 (13.2)	9/ 79 (11.4)	56.0	6/ 27 (22.2)	6/ 54 (11.1)	44.0	0.67 (0.31, 1.43)	0.0	0.4085
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Respiratory tract infection

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	15/331 (4.5)	20/332 (6.0)	84.9	2/ 27 (7.4)	1/ 54 (1.9)	15.1	1.17 (0.63, 2.15)	0.6225	44.3	0.1803
Age										
<65 years	5/121 (4.1)	12/139 (8.6)	93.2	0/ 9 (0.0)	0/ 25 (0.0)	6.8	2.02 (0.75, 5.40)	0.1633	0.0	0.7481
>=65 years	10/210 (4.8)	8/193 (4.1)	79.5	2/ 18 (11.1)	1/ 29 (3.4)	20.5	0.76 (0.33, 1.74)	0.5102	0.0	0.4185
Sex										
Male	9/177 (5.1)	13/179 (7.3)	86.6	1/ 11 (9.1)	1/ 26 (3.8)	13.4	1.29 (0.59, 2.81)	0.5169	0.0	0.3952
Female	6/154 (3.9)	7/153 (4.6)	77.5	1/ 16 (6.3)	0/ 28 (0.0)	22.5	0.97 (0.37, 2.57)	0.9513	0.0	0.3492
Baseline FVC percent predicted										
<=70%	12/193 (6.2)	16/196 (8.2)	96.3	0/ 10 (0.0)	1/ 17 (5.9)	3.7	1.36 (0.67, 2.75)	0.3927	0.0	0.7087
>70%	3/138 (2.2)	4/136 (2.9)	48.4	2/ 17 (11.8)	0/ 37 (0.0)	51.6	0.73 (0.23, 2.27)	0.5812	55.0	0.1362
Baseline HRCT pattern										
UIP-like	7/206 (3.4)	10/206 (4.9)	72.6	2/ 23 (8.7)	1/ 45 (2.2)	27.4	1.11 (0.48, 2.56)	0.8128	43.7	0.1826
Other fibrotic patterns	8/125 (6.4)	10/126 (7.9)	95.0	0/ 4 (0.0)	0/ 9 (0.0)	5.0	1.23 (0.51, 2.95)	0.6456	0.0	0.9200
Underlying ILD diagnosis										
iNSIP	2/ 61 (3.3)	1/ 64 (1.6)	81.2	0/ 7 (0.0)	0/ 11 (0.0)	18.8	0.58 (0.08, 4.28)	0.5890	0.0	0.7512
Unclassifiable IIP	0/ 50 (0.0)	2/ 64 (3.1)	50.6	0/ 3 (0.0)	0/ 2 (0.0)	49.4	2.80 (0.27,28.74)	0.3852	0.0	0.5424
HP	9/ 89 (10.1)	10/ 84 (11.9)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	1/ 88 (1.1)	4/ 82 (4.9)	24.6	2/ 12 (16.7)	1/ 34 (2.9)	75.4	1.19 (0.35, 4.01)	0.7801	74.3	0.0484
Other ILD	3/ 43 (7.0)	3/ 38 (7.9)	85.0	0/ 5 (0.0)	0/ 6 (0.0)	15.0	1.11 (0.27, 4.63)	0.8841	0.0	0.9527
Region										
Europe										
Asia	0/ 76 (0.0)	1/ 79 (1.3)	15.8	2/ 27 (7.4)	1/ 54 (1.9)	84.2	0.68 (0.14, 3.37)	0.6348	32.6	0.2233
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Respiratory tract infection

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	15/331 (4.5)	20/332 (6.0)	90.2	2/ 27 (7.4)	1/ 54 (1.9)	9.8	0.80 (-2.43, 4.04)	36.0	0.2112
Age									
<65 years	5/121 (4.1)	12/139 (8.6)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	4.06 (-1.36, 9.48)	0.0	0.5137
>=65 years	10/210 (4.8)	8/193 (4.1)	90.1	2/ 18 (11.1)	1/ 29 (3.4)	9.9	-1.32 (-5.28, 2.64)	0.0	0.4016
Sex									
Male	9/177 (5.1)	13/179 (7.3)	92.0	1/ 11 (9.1)	1/ 26 (3.8)	8.0	1.58 (-3.24, 6.41)	0.0	0.4483
Female	6/154 (3.9)	7/153 (4.6)	87.8	1/ 16 (6.3)	0/ 28 (0.0)	12.2	-0.13 (-4.45, 4.18)	0.0	0.3792
Baseline FVC percent predicted									
<=70%	12/193 (6.2)	16/196 (8.2)	93.5	0/ 10 (0.0)	1/ 17 (5.9)	6.5	2.18 (-2.75, 7.10)	0.0	0.6972
>70%	3/138 (2.2)	4/136 (2.9)	85.0	2/ 17 (11.8)	0/ 37 (0.0)	15.0	-1.05 (-5.06, 2.96)	50.3	0.1561
Baseline HRCT pattern									
UIP-like	7/206 (3.4)	10/206 (4.9)	87.1	2/ 23 (8.7)	1/ 45 (2.2)	12.9	0.44 (-3.26, 4.14)	31.3	0.2275
Other fibrotic patterns	8/125 (6.4)	10/126 (7.9)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	1.46 (-4.75, 7.67)	0.0	0.9146
Underlying ILD diagnosis									
iNSIP	2/ 61 (3.3)	1/ 64 (1.6)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	-1.49 (-6.85, 3.87)	0.0	0.8686
Unclassifiable IIP	0/ 50 (0.0)	2/ 64 (3.1)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	2.90 (-2.95, 8.76)	0.0	0.9099
HP	9/ 89 (10.1)	10/ 84 (11.9)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	1/ 88 (1.1)	4/ 82 (4.9)	82.7	2/ 12 (16.7)	1/ 34 (2.9)	17.3	0.72 (-4.98, 6.42)	57.0	0.1271
Other ILD	3/ 43 (7.0)	3/ 38 (7.9)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	0.79 (-9.88, 11.46)	0.0	0.9541
Region									
Europe									
Asia	0/ 76 (0.0)	1/ 79 (1.3)	68.6	2/ 27 (7.4)	1/ 54 (1.9)	31.4	-0.89 (-4.96, 3.18)	31.1	0.2283
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Respiratory tract infection

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	15/331 (4.5)	20/332 (6.0)	84.4	2/ 27 (7.4)	1/ 54 (1.9)	15.6	1.18 (0.61, 2.26)	44.8	0.1785
Age									
<65 years	5/121 (4.1)	12/139 (8.6)	92.8	0/ 9 (0.0)	0/ 25 (0.0)	7.2	2.11 (0.74, 5.99)	0.0	0.7398
>=65 years	10/210 (4.8)	8/193 (4.1)	79.4	2/ 18 (11.1)	1/ 29 (3.4)	20.6	0.75 (0.31, 1.80)	0.0	0.4134
Sex									
Male	9/177 (5.1)	13/179 (7.3)	86.1	1/ 11 (9.1)	1/ 26 (3.8)	13.9	1.31 (0.57, 3.03)	0.0	0.3969
Female	6/154 (3.9)	7/153 (4.6)	77.1	1/ 16 (6.3)	0/ 28 (0.0)	22.9	0.97 (0.35, 2.70)	0.0	0.3472
Baseline FVC percent predicted									
<=70%	12/193 (6.2)	16/196 (8.2)	96.3	0/ 10 (0.0)	1/ 17 (5.9)	3.7	1.39 (0.65, 2.97)	0.0	0.7069
>70%	3/138 (2.2)	4/136 (2.9)	48.1	2/ 17 (11.8)	0/ 37 (0.0)	51.9	0.72 (0.21, 2.45)	56.2	0.1308
Baseline HRCT pattern									
UIP-like	7/206 (3.4)	10/206 (4.9)	72.0	2/ 23 (8.7)	1/ 45 (2.2)	28.0	1.11 (0.46, 2.70)	44.0	0.1814
Other fibrotic patterns	8/125 (6.4)	10/126 (7.9)	94.9	0/ 4 (0.0)	0/ 9 (0.0)	5.1	1.25 (0.49, 3.20)	0.0	0.9196
Underlying ILD diagnosis									
iNSIP	2/ 61 (3.3)	1/ 64 (1.6)	81.7	0/ 7 (0.0)	0/ 11 (0.0)	18.3	0.57 (0.07, 4.40)	0.0	0.7560
Unclassifiable IIP	0/ 50 (0.0)	2/ 64 (3.1)	53.5	0/ 3 (0.0)	0/ 2 (0.0)	46.5	2.98 (0.27,33.45)	0.0	0.5733
HP	9/ 89 (10.1)	10/ 84 (11.9)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	1/ 88 (1.1)	4/ 82 (4.9)	24.2	2/ 12 (16.7)	1/ 34 (2.9)	75.8	1.20 (0.30, 4.73)	74.6	0.0472
Other ILD	3/ 43 (7.0)	3/ 38 (7.9)	85.0	0/ 5 (0.0)	0/ 6 (0.0)	15.0	1.12 (0.24, 5.24)	0.0	0.9528
Region									
Europe									
Asia	0/ 76 (0.0)	1/ 79 (1.3)	15.8	2/ 27 (7.4)	1/ 54 (1.9)	84.2	0.67 (0.12, 3.74)	33.7	0.2193
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Sinusitis

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo: Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	10/331 (3.0)	10/332 (3.0)	95.8	0/ 27 (0.0)	0/ 54 (0.0)	4.2	1.00 (0.43, 2.32)	0.9947	0.0	0.9989
Age										
<65 years	5/121 (4.1)	6/139 (4.3)	93.2	0/ 9 (0.0)	0/ 25 (0.0)	6.8	1.04 (0.34, 3.20)	0.9433	0.0	0.9849
>=65 years	5/210 (2.4)	4/193 (2.1)	91.0	0/ 18 (0.0)	0/ 29 (0.0)	9.0	0.88 (0.26, 3.04)	0.8423	0.0	0.9483
Sex										
Male	3/177 (1.7)	3/179 (1.7)	87.8	0/ 11 (0.0)	0/ 26 (0.0)	12.2	0.99 (0.22, 4.38)	0.9896	0.0	0.9961
Female	7/154 (4.5)	7/153 (4.6)	93.8	0/ 16 (0.0)	0/ 28 (0.0)	6.2	1.01 (0.37, 2.71)	0.9904	0.0	0.9975
Baseline FVC percent predicted										
<=70%	7/193 (3.6)	6/196 (3.1)	93.8	0/ 10 (0.0)	0/ 17 (0.0)	6.2	0.85 (0.30, 2.40)	0.7646	0.0	0.9359
>70%	3/138 (2.2)	4/136 (2.9)	87.3	0/ 17 (0.0)	0/ 37 (0.0)	12.7	1.31 (0.33, 5.26)	0.7052	0.0	0.8937
Baseline HRCT pattern										
UIP-like	4/206 (1.9)	2/206 (1.0)	89.9	0/ 23 (0.0)	0/ 45 (0.0)	10.1	0.55 (0.12, 2.59)	0.4500	0.0	0.7599
Other fibrotic patterns	6/125 (4.8)	8/126 (6.3)	93.4	0/ 4 (0.0)	0/ 9 (0.0)	6.6	1.30 (0.48, 3.53)	0.6048	0.0	0.8969
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	1/ 64 (1.6)	68.3	0/ 7 (0.0)	0/ 11 (0.0)	31.7	0.97 (0.10, 9.19)	0.9774	0.0	0.9843
Unclassifiable IIP	2/ 50 (4.0)	0/ 64 (0.0)	85.1	0/ 3 (0.0)	0/ 2 (0.0)	14.9	0.30 (0.04, 2.57)	0.2730	0.0	0.4735
HP	5/ 89 (5.6)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	1/ 88 (1.1)	3/ 82 (3.7)	71.4	0/ 12 (0.0)	0/ 34 (0.0)	28.6	2.59 (0.37,18.22)	0.3403	0.0	0.6436
Other ILD	1/ 43 (2.3)	1/ 38 (2.6)	65.4	0/ 5 (0.0)	0/ 6 (0.0)	34.6	1.09 (0.12, 9.97)	0.9418	0.0	0.9586
Region										
Europe										
Asia	1/ 76 (1.3)	0/ 79 (0.0)	77.4	0/ 27 (0.0)	0/ 54 (0.0)	22.6	0.48 (0.04, 5.48)	0.5554	0.0	0.6755
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Sinusitis

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	10/331 (3.0)	10/332 (3.0)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	-0.01 (-2.40, 2.39)	0.0	0.9975
Age									
<65 years	5/121 (4.1)	6/139 (4.3)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	0.17 (-4.41, 4.74)	0.0	0.9780
>=65 years	5/210 (2.4)	4/193 (2.1)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	-0.28 (-2.99, 2.44)	0.0	0.9442
Sex									
Male	3/177 (1.7)	3/179 (1.7)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-0.02 (-2.63, 2.60)	0.0	0.9974
Female	7/154 (4.5)	7/153 (4.6)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	0.03 (-4.21, 4.26)	0.0	0.9953
Baseline FVC percent predicted									
<=70%	7/193 (3.6)	6/196 (3.1)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-0.53 (-3.99, 2.93)	0.0	0.9378
>70%	3/138 (2.2)	4/136 (2.9)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	0.65 (-2.72, 4.02)	0.0	0.8571
Baseline HRCT pattern									
UIP-like	4/206 (1.9)	2/206 (1.0)	86.8	0/ 23 (0.0)	0/ 45 (0.0)	13.2	-0.84 (-2.99, 1.31)	0.0	0.7631
Other fibrotic patterns	6/125 (4.8)	8/126 (6.3)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	1.47 (-4.08, 7.03)	0.0	0.9134
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	1/ 64 (1.6)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	-0.07 (-4.68, 4.55)	0.0	0.9940
Unclassifiable IIP	2/ 50 (4.0)	0/ 64 (0.0)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	-3.71 (-10.34, 2.91)	0.0	0.8850
HP	5/ 89 (5.6)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	1/ 88 (1.1)	3/ 82 (3.7)	82.1	0/ 12 (0.0)	0/ 34 (0.0)	17.9	2.07 (-2.07, 6.21)	0.0	0.6313
Other ILD	1/ 43 (2.3)	1/ 38 (2.6)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	0.26 (-6.84, 7.36)	0.0	0.9840
Region									
Europe									
Asia	1/ 76 (1.3)	0/ 79 (0.0)	68.0	0/ 27 (0.0)	0/ 54 (0.0)	32.0	-0.88 (-3.77, 2.00)	0.0	0.6768
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Sinusitis

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid				
Overall	10/331 (3.0)	10/332 (3.0)	95.7	0/ 27 (0.0)	0/ 54 (0.0)	4.3	1.00 (0.42, 2.38)	0.0	0.9989
Age									
<65 years	5/121 (4.1)	6/139 (4.3)	93.1	0/ 9 (0.0)	0/ 25 (0.0)	6.9	1.04 (0.32, 3.37)	0.0	0.9847
>=65 years	5/210 (2.4)	4/193 (2.1)	91.0	0/ 18 (0.0)	0/ 29 (0.0)	9.0	0.88 (0.25, 3.11)	0.0	0.9483
Sex									
Male	3/177 (1.7)	3/179 (1.7)	87.9	0/ 11 (0.0)	0/ 26 (0.0)	12.1	0.99 (0.22, 4.49)	0.0	0.9961
Female	7/154 (4.5)	7/153 (4.6)	93.6	0/ 16 (0.0)	0/ 28 (0.0)	6.4	1.01 (0.36, 2.84)	0.0	0.9975
Baseline FVC percent predicted									
<=70%	7/193 (3.6)	6/196 (3.1)	93.8	0/ 10 (0.0)	0/ 17 (0.0)	6.2	0.85 (0.29, 2.48)	0.0	0.9359
>70%	3/138 (2.2)	4/136 (2.9)	87.2	0/ 17 (0.0)	0/ 37 (0.0)	12.8	1.32 (0.32, 5.51)	0.0	0.8930
Baseline HRCT pattern									
UIP-like	4/206 (1.9)	2/206 (1.0)	90.0	0/ 23 (0.0)	0/ 45 (0.0)	10.0	0.55 (0.11, 2.60)	0.0	0.7599
Other fibrotic patterns	6/125 (4.8)	8/126 (6.3)	93.4	0/ 4 (0.0)	0/ 9 (0.0)	6.6	1.32 (0.46, 3.81)	0.0	0.8980
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	1/ 64 (1.6)	69.1	0/ 7 (0.0)	0/ 11 (0.0)	30.9	0.97 (0.10, 9.76)	0.0	0.9847
Unclassifiable IIP	2/ 50 (4.0)	0/ 64 (0.0)	86.8	0/ 3 (0.0)	0/ 2 (0.0)	13.2	0.28 (0.03, 2.87)	0.0	0.5095
HP	5/ 89 (5.6)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	1/ 88 (1.1)	3/ 82 (3.7)	71.1	0/ 12 (0.0)	0/ 34 (0.0)	28.9	2.64 (0.35,20.15)	0.0	0.6432
Other ILD	1/ 43 (2.3)	1/ 38 (2.6)	66.6	0/ 5 (0.0)	0/ 6 (0.0)	33.4	1.09 (0.11,11.06)	0.0	0.9601
Region									
Europe									
Asia	1/ 76 (1.3)	0/ 79 (0.0)	77.5	0/ 27 (0.0)	0/ 54 (0.0)	22.5	0.48 (0.04, 5.32)	0.0	0.6754
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Upper respiratory tract infection

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	25/331 (7.6)	26/332 (7.8)	82.4	4/ 27 (14.8)	7/ 54 (13.0)	17.6	1.01 (0.62, 1.63)	0.9725	0.0	0.7909
Age										
<65 years	11/121 (9.1)	9/139 (6.5)	80.0	2/ 9 (22.2)	4/ 25 (16.0)	20.0	0.71 (0.34, 1.50)	0.3731	0.0	0.9902
>=65 years	14/210 (6.7)	17/193 (8.8)	84.5	2/ 18 (11.1)	3/ 29 (10.3)	15.5	1.26 (0.67, 2.37)	0.4710	0.0	0.7064
Sex										
Male	8/177 (4.5)	12/179 (6.7)	74.1	2/ 11 (18.2)	2/ 26 (7.7)	25.9	1.21 (0.56, 2.60)	0.6282	32.1	0.2248
Female	17/154 (11.0)	14/153 (9.2)	86.9	2/ 16 (12.5)	5/ 28 (17.9)	13.1	0.91 (0.49, 1.67)	0.7547	0.0	0.5209
Baseline FVC percent predicted										
<=70%	15/193 (7.8)	12/196 (6.1)	92.3	1/ 10 (10.0)	1/ 17 (5.9)	7.7	0.77 (0.38, 1.56)	0.4734	0.0	0.8356
>70%	10/138 (7.2)	14/136 (10.3)	70.7	3/ 17 (17.6)	6/ 37 (16.2)	29.3	1.27 (0.66, 2.46)	0.4719	0.0	0.5643
Baseline HRCT pattern										
UIP-like	13/206 (6.3)	12/206 (5.8)	71.1	4/ 23 (17.4)	5/ 45 (11.1)	28.9	0.84 (0.44, 1.60)	0.5977	0.0	0.6148
Other fibrotic patterns	12/125 (9.6)	14/126 (11.1)	96.6	0/ 4 (0.0)	2/ 9 (22.2)	3.4	1.25 (0.61, 2.55)	0.5378	0.0	0.5139
Underlying ILD diagnosis										
iNSIP	6/ 61 (9.8)	6/ 64 (9.4)	92.8	0/ 7 (0.0)	1/ 11 (9.1)	7.2	1.07 (0.39, 2.96)	0.8904	0.0	0.5744
Unclassifiable IIP	3/ 50 (6.0)	3/ 64 (4.7)	87.5	0/ 3 (0.0)	0/ 2 (0.0)	12.5	0.81 (0.19, 3.39)	0.7716	0.0	0.9042
HP	10/ 89 (11.2)	8/ 84 (9.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	5/ 88 (5.7)	7/ 82 (8.5)	52.1	3/ 12 (25.0)	6/ 34 (17.6)	47.9	1.12 (0.50, 2.53)	0.7833	0.0	0.3688
Other ILD	1/ 43 (2.3)	2/ 38 (5.3)	37.2	1/ 5 (20.0)	0/ 6 (0.0)	62.8	1.04 (0.20, 5.35)	0.9651	6.6	0.3008
Region										
Europe										
Asia	7/ 76 (9.2)	6/ 79 (7.6)	57.2	4/ 27 (14.8)	7/ 54 (13.0)	42.8	0.85 (0.39, 1.83)	0.6707	0.0	0.9400
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Upper respiratory tract infection

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	25/331 (7.6)	26/332 (7.8)	90.2	4/ 27 (14.8)	7/ 54 (13.0)	9.8	0.07 (-3.92, 4.06)	0.0	0.8017
Age									
<65 years	11/121 (9.1)	9/139 (6.5)	90.7	2/ 9 (22.2)	4/ 25 (16.0)	9.3	-2.95 (-9.55, 3.64)	0.0	0.8220
>=65 years	14/210 (6.7)	17/193 (8.8)	90.1	2/ 18 (11.1)	3/ 29 (10.3)	9.9	1.85 (-3.20, 6.90)	0.0	0.7642
Sex									
Male	8/177 (4.5)	12/179 (6.7)	92.0	2/ 11 (18.2)	2/ 26 (7.7)	8.0	1.17 (-3.65, 6.00)	0.0	0.3289
Female	17/154 (11.0)	14/153 (9.2)	88.3	2/ 16 (12.5)	5/ 28 (17.9)	11.7	-1.04 (-7.50, 5.42)	0.0	0.5291
Baseline FVC percent predicted									
<=70%	15/193 (7.8)	12/196 (6.1)	93.9	1/ 10 (10.0)	1/ 17 (5.9)	6.1	-1.80 (-6.73, 3.13)	0.0	0.8281
>70%	10/138 (7.2)	14/136 (10.3)	85.5	3/ 17 (17.6)	6/ 37 (16.2)	14.5	2.40 (-4.13, 8.93)	0.0	0.6987
Baseline HRCT pattern									
UIP-like	13/206 (6.3)	12/206 (5.8)	87.1	4/ 23 (17.4)	5/ 45 (11.1)	12.9	-1.23 (-5.87, 3.41)	0.0	0.5412
Other fibrotic patterns	12/125 (9.6)	14/126 (11.1)	95.2	0/ 4 (0.0)	2/ 9 (22.2)	4.8	2.37 (-5.00, 9.74)	0.0	0.3319
Underlying ILD diagnosis									
iNSIP	6/ 61 (9.8)	6/ 64 (9.4)	86.8	0/ 7 (0.0)	1/ 11 (9.1)	13.2	0.68 (-8.85, 10.21)	0.0	0.5223
Unclassifiable IIP	3/ 50 (6.0)	3/ 64 (4.7)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	-1.24 (-9.69, 7.21)	0.0	0.9617
HP	10/ 89 (11.2)	8/ 84 (9.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	5/ 88 (5.7)	7/ 82 (8.5)	82.7	3/ 12 (25.0)	6/ 34 (17.6)	17.3	1.09 (-6.90, 9.08)	0.0	0.4859
Other ILD	1/ 43 (2.3)	2/ 38 (5.3)	86.2	1/ 5 (20.0)	0/ 6 (0.0)	13.8	0.20 (-8.90, 9.30)	0.0	0.3396
Region									
Europe									
Asia	7/ 76 (9.2)	6/ 79 (7.6)	68.3	4/ 27 (14.8)	7/ 54 (13.0)	31.7	-1.69 (-9.55, 6.17)	0.0	0.9799
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Upper respiratory tract infection

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	25/331 (7.6)	26/332 (7.8)	83.3	4/ 27 (14.8)	7/ 54 (13.0)	16.7	1.01 (0.60, 1.71)	0.0	0.7920
Age									
<65 years	11/121 (9.1)	9/139 (6.5)	81.7	2/ 9 (22.2)	4/ 25 (16.0)	18.3	0.69 (0.30, 1.57)	0.0	0.9720
>=65 years	14/210 (6.7)	17/193 (8.8)	84.7	2/ 18 (11.1)	3/ 29 (10.3)	15.3	1.29 (0.65, 2.56)	0.0	0.7127
Sex									
Male	8/177 (4.5)	12/179 (6.7)	74.3	2/ 11 (18.2)	2/ 26 (7.7)	25.7	1.22 (0.53, 2.82)	29.8	0.2328
Female	17/154 (11.0)	14/153 (9.2)	88.0	2/ 16 (12.5)	5/ 28 (17.9)	12.0	0.90 (0.45, 1.77)	0.0	0.5211
Baseline FVC percent predicted									
<=70%	15/193 (7.8)	12/196 (6.1)	92.3	1/ 10 (10.0)	1/ 17 (5.9)	7.7	0.76 (0.35, 1.62)	0.0	0.8346
>70%	10/138 (7.2)	14/136 (10.3)	72.1	3/ 17 (17.6)	6/ 37 (16.2)	27.9	1.31 (0.62, 2.75)	0.0	0.5846
Baseline HRCT pattern									
UIP-like	13/206 (6.3)	12/206 (5.8)	72.2	4/ 23 (17.4)	5/ 45 (11.1)	27.8	0.83 (0.41, 1.68)	0.0	0.6018
Other fibrotic patterns	12/125 (9.6)	14/126 (11.1)	97.1	0/ 4 (0.0)	2/ 9 (22.2)	2.9	1.28 (0.58, 2.82)	0.0	0.4842
Underlying ILD diagnosis									
iNSIP	6/ 61 (9.8)	6/ 64 (9.4)	93.1	0/ 7 (0.0)	1/ 11 (9.1)	6.9	1.08 (0.36, 3.29)	0.0	0.5677
Unclassifiable IIP	3/ 50 (6.0)	3/ 64 (4.7)	88.6	0/ 3 (0.0)	0/ 2 (0.0)	11.4	0.80 (0.17, 3.71)	0.0	0.9120
HP	10/ 89 (11.2)	8/ 84 (9.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	5/ 88 (5.7)	7/ 82 (8.5)	54.7	3/ 12 (25.0)	6/ 34 (17.6)	45.3	1.14 (0.44, 2.94)	0.0	0.3826
Other ILD	1/ 43 (2.3)	2/ 38 (5.3)	37.8	1/ 5 (20.0)	0/ 6 (0.0)	62.2	1.04 (0.17, 6.23)	9.1	0.2941
Region									
Europe									
Asia	7/ 76 (9.2)	6/ 79 (7.6)	58.7	4/ 27 (14.8)	7/ 54 (13.0)	41.3	0.83 (0.35, 1.97)	0.0	0.9504
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Urinary tract infection

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo: Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	21/331 (6.3)	22/332 (6.6)	88.7	2/ 27 (7.4)	3/ 54 (5.6)	11.3	1.01 (0.58, 1.75)	0.9678	0.0	0.7217
Age										
<65 years	7/121 (5.8)	5/139 (3.6)	95.1	0/ 9 (0.0)	3/ 25 (12.0)	4.9	0.84 (0.30, 2.36)	0.7437	4.1	0.3071
>=65 years	14/210 (6.7)	17/193 (8.8)	82.0	2/ 18 (11.1)	0/ 29 (0.0)	18.0	1.11 (0.59, 2.10)	0.7424	53.3	0.1435
Sex										
Male	5/177 (2.8)	5/179 (2.8)	73.4	1/ 11 (9.1)	0/ 26 (0.0)	26.6	0.79 (0.27, 2.33)	0.6644	0.0	0.3512
Female	16/154 (10.4)	17/153 (11.1)	92.6	1/ 16 (6.3)	3/ 28 (10.7)	7.4	1.12 (0.60, 2.07)	0.7252	0.0	0.6839
Baseline FVC percent predicted										
<=70%	14/193 (7.3)	13/196 (6.6)	96.8	0/ 10 (0.0)	2/ 17 (11.8)	3.2	1.02 (0.50, 2.06)	0.9587	0.0	0.3860
>70%	7/138 (5.1)	9/136 (6.6)	71.7	2/ 17 (11.8)	1/ 37 (2.7)	28.3	1.00 (0.43, 2.33)	0.9989	45.2	0.1768
Baseline HRCT pattern										
UIP-like	11/206 (5.3)	10/206 (4.9)	80.6	2/ 23 (8.7)	2/ 45 (4.4)	19.4	0.83 (0.39, 1.78)	0.6349	0.0	0.5856
Other fibrotic patterns	10/125 (8.0)	12/126 (9.5)	95.9	0/ 4 (0.0)	1/ 9 (11.1)	4.1	1.24 (0.57, 2.71)	0.5877	0.0	0.7082
Underlying ILD diagnosis										
iNSIP	3/ 61 (4.9)	2/ 64 (3.1)	86.6	0/ 7 (0.0)	1/ 11 (9.1)	13.4	0.90 (0.20, 4.01)	0.8939	0.0	0.4644
Unclassifiable IIP	3/ 50 (6.0)	4/ 64 (6.3)	87.5	0/ 3 (0.0)	0/ 2 (0.0)	12.5	1.04 (0.27, 4.00)	0.9586	0.0	0.9840
HP	6/ 89 (6.7)	7/ 84 (8.3)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	4/ 88 (4.5)	9/ 82 (11.0)	72.3	1/ 12 (8.3)	1/ 34 (2.9)	27.7	1.84 (0.68, 5.00)	0.2292	39.8	0.1973
Other ILD	5/ 43 (11.6)	0/ 38 (0.0)	76.6	1/ 5 (20.0)	0/ 6 (0.0)	23.4	0.15 (0.02, 1.18)	0.0706	0.0	0.5768
Region										
Europe										
Asia	1/ 76 (1.3)	2/ 79 (2.5)	27.7	2/ 27 (7.4)	3/ 54 (5.6)	72.3	1.07 (0.27, 4.21)	0.9177	0.0	0.5301
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Urinary tract infection

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	21/331 (6.3)	22/332 (6.6)	90.2	2/ 27 (7.4)	3/ 54 (5.6)	9.8	0.07 (-3.49, 3.64)	0.0	0.7318
Age									
<65 years	7/121 (5.8)	5/139 (3.6)	90.2	0/ 9 (0.0)	3/ 25 (12.0)	9.8	-0.87 (-5.83, 4.09)	55.6	0.1333
>=65 years	14/210 (6.7)	17/193 (8.8)	89.7	2/ 18 (11.1)	0/ 29 (0.0)	10.3	0.82 (-4.15, 5.79)	55.6	0.1336
Sex									
Male	5/177 (2.8)	5/179 (2.8)	91.6	1/ 11 (9.1)	0/ 26 (0.0)	8.4	-0.75 (-4.28, 2.78)	0.0	0.3851
Female	16/154 (10.4)	17/153 (11.1)	88.3	1/ 16 (6.3)	3/ 28 (10.7)	11.7	1.16 (-5.26, 7.58)	0.0	0.6817
Baseline FVC percent predicted									
<=70%	14/193 (7.3)	13/196 (6.6)	93.5	0/ 10 (0.0)	2/ 17 (11.8)	6.5	0.13 (-4.76, 5.02)	21.5	0.2590
>70%	7/138 (5.1)	9/136 (6.6)	85.5	2/ 17 (11.8)	1/ 37 (2.7)	14.5	0.00 (-5.29, 5.30)	32.3	0.2243
Baseline HRCT pattern									
UIP-like	11/206 (5.3)	10/206 (4.9)	87.1	2/ 23 (8.7)	2/ 45 (4.4)	12.9	-0.97 (-5.03, 3.09)	0.0	0.5893
Other fibrotic patterns	10/125 (8.0)	12/126 (9.5)	95.2	0/ 4 (0.0)	1/ 9 (11.1)	4.8	1.92 (-4.91, 8.75)	0.0	0.6274
Underlying ILD diagnosis									
iNSIP	3/ 61 (4.9)	2/ 64 (3.1)	86.8	0/ 7 (0.0)	1/ 11 (9.1)	13.2	-0.48 (-7.28, 6.32)	0.0	0.4403
Unclassifiable IIP	3/ 50 (6.0)	4/ 64 (6.3)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	0.24 (-8.64, 9.11)	0.0	0.9927
HP	6/ 89 (6.7)	7/ 84 (8.3)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	9/ 82 (11.0)	82.7	1/ 12 (8.3)	1/ 34 (2.9)	17.3	4.39 (-2.86, 11.64)	36.4	0.2099
Other ILD	5/ 43 (11.6)	0/ 38 (0.0)	86.5	1/ 5 (20.0)	0/ 6 (0.0)	13.5	-12.10 (-22.56, -1.64)	0.0	0.7909
Region									
Europe									
Asia	1/ 76 (1.3)	2/ 79 (2.5)	68.3	2/ 27 (7.4)	3/ 54 (5.6)	31.7	0.24 (-4.47, 4.96)	0.0	0.6274
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Urinary tract infection

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	21/331 (6.3)	22/332 (6.6)	88.6	2/ 27 (7.4)	3/ 54 (5.6)	11.4	1.01 (0.56, 1.82)	0.0	0.7223
Age									
<65 years	7/121 (5.8)	5/139 (3.6)	95.6	0/ 9 (0.0)	3/ 25 (12.0)	4.4	0.84 (0.29, 2.39)	9.8	0.2924
>=65 years	14/210 (6.7)	17/193 (8.8)	80.9	2/ 18 (11.1)	0/ 29 (0.0)	19.1	1.12 (0.56, 2.24)	54.8	0.1367
Sex									
Male	5/177 (2.8)	5/179 (2.8)	73.3	1/ 11 (9.1)	0/ 26 (0.0)	26.7	0.78 (0.25, 2.44)	0.0	0.3477
Female	16/154 (10.4)	17/153 (11.1)	92.6	1/ 16 (6.3)	3/ 28 (10.7)	7.4	1.13 (0.57, 2.25)	0.0	0.6831
Baseline FVC percent predicted									
<=70%	14/193 (7.3)	13/196 (6.6)	97.1	0/ 10 (0.0)	2/ 17 (11.8)	2.9	1.02 (0.48, 2.16)	0.0	0.3720
>70%	7/138 (5.1)	9/136 (6.6)	70.9	2/ 17 (11.8)	1/ 37 (2.7)	29.1	1.00 (0.40, 2.50)	45.6	0.1752
Baseline HRCT pattern									
UIP-like	11/206 (5.3)	10/206 (4.9)	80.5	2/ 23 (8.7)	2/ 45 (4.4)	19.5	0.82 (0.37, 1.85)	0.0	0.5848
Other fibrotic patterns	10/125 (8.0)	12/126 (9.5)	96.2	0/ 4 (0.0)	1/ 9 (11.1)	3.8	1.27 (0.54, 2.98)	0.0	0.6984
Underlying ILD diagnosis									
iNSIP	3/ 61 (4.9)	2/ 64 (3.1)	87.8	0/ 7 (0.0)	1/ 11 (9.1)	12.2	0.90 (0.19, 4.22)	0.0	0.4595
Unclassifiable IIP	3/ 50 (6.0)	4/ 64 (6.3)	88.5	0/ 3 (0.0)	0/ 2 (0.0)	11.5	1.04 (0.24, 4.45)	0.0	0.9852
HP	6/ 89 (6.7)	7/ 84 (8.3)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	9/ 82 (11.0)	70.5	1/ 12 (8.3)	1/ 34 (2.9)	29.5	1.92 (0.64, 5.76)	40.3	0.1955
Other ILD	5/ 43 (11.6)	0/ 38 (0.0)	77.8	1/ 5 (20.0)	0/ 6 (0.0)	22.2	0.12 (0.01, 1.11)	0.0	0.6316
Region									
Europe									
Asia	1/ 76 (1.3)	2/ 79 (2.5)	28.3	2/ 27 (7.4)	3/ 54 (5.6)	71.7	1.08 (0.25, 4.63)	0.0	0.5310
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Injury, poisoning and procedural complications
PT: Contusion

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	10/331 (3.0)	5/332 (1.5)	95.8	0/ 27 (0.0)	1/ 54 (1.9)	4.2	0.58 (0.22, 1.58)	0.2886	0.0	0.4106
Age										
<65 years	1/121 (0.8)	2/139 (1.4)	73.3	0/ 9 (0.0)	0/ 25 (0.0)	26.7	1.54 (0.19,12.40)	0.6832	0.0	0.8276
>=65 years	9/210 (4.3)	3/193 (1.6)	94.8	0/ 18 (0.0)	1/ 29 (3.4)	5.2	0.48 (0.15, 1.51)	0.2091	8.5	0.2958
Sex										
Male										
Female										
Baseline FVC percent predicted										
<=70%										
>70%										
Baseline HRCT pattern										
UIP-like	7/206 (3.4)	3/206 (1.5)	94.0	0/ 23 (0.0)	1/ 45 (2.2)	6.0	0.55 (0.17, 1.84)	0.3352	0.0	0.3743
Other fibrotic patterns	3/125 (2.4)	2/126 (1.6)	87.6	0/ 4 (0.0)	0/ 9 (0.0)	12.4	0.70 (0.14, 3.56)	0.6708	0.0	0.8561
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Injury, poisoning and procedural complications
PT: Contusion

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	10/331 (3.0)	5/332 (1.5)	90.0	0/ 27 (0.0)	1/ 54 (1.9)	10.0	-1.18 (-3.31, 0.94)	1.1	0.3146
Age									
<65 years	1/121 (0.8)	2/139 (1.4)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	0.55 (-2.04, 3.15)	0.0	0.9231
>=65 years	9/210 (4.3)	3/193 (1.6)	89.7	0/ 18 (0.0)	1/ 29 (3.4)	10.3	-2.11 (-5.21, 0.99)	17.3	0.2714
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like	7/206 (3.4)	3/206 (1.5)	86.8	0/ 23 (0.0)	1/ 45 (2.2)	13.2	-1.40 (-4.14, 1.34)	6.6	0.3008
Other fibrotic patterns	3/125 (2.4)	2/126 (1.6)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-0.77 (-4.32, 2.77)	0.0	0.9539
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Injury, poisoning and procedural complications
PT: Contusion

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2 p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid			
Overall	10/331 (3.0)	5/332 (1.5)	95.8	0/ 27 (0.0)	1/ 54 (1.9)	4.2	0.58 (0.21, 1.57)	0.0 0.4081
Age								
<65 years	1/121 (0.8)	2/139 (1.4)	73.6	0/ 9 (0.0)	0/ 25 (0.0)	26.4	1.55 (0.18,13.10)	0.0 0.8298
>=65 years	9/210 (4.3)	3/193 (1.6)	95.0	0/ 18 (0.0)	1/ 29 (3.4)	5.0	0.47 (0.15, 1.49)	9.3 0.2936
Sex								
Male								
Female								
Baseline FVC percent predicted								
<=70%								
>70%								
Baseline HRCT pattern								
UIP-like	7/206 (3.4)	3/206 (1.5)	94.1	0/ 23 (0.0)	1/ 45 (2.2)	5.9	0.55 (0.16, 1.83)	0.0 0.3719
Other fibrotic patterns	3/125 (2.4)	2/126 (1.6)	88.2	0/ 4 (0.0)	0/ 9 (0.0)	11.8	0.70 (0.13, 3.66)	0.0 0.8619
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia								
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Injury, poisoning and procedural complications
PT: Fall

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk ratio (95% CI)	p-value	I^2	p-value
Overall	13/331 (3.9)	12/332 (3.6)	96.7	0/ 27 (0.0)	0/ 54 (0.0)	3.3	0.92 (0.43, 1.97)	0.8354	0.0	0.9691
Age										
<65 years	1/121 (0.8)	1/139 (0.7)	73.3	0/ 9 (0.0)	0/ 25 (0.0)	26.7	0.91 (0.09, 9.35)	0.9333	0.0	0.9581
>=65 years	12/210 (5.7)	11/193 (5.7)	96.1	0/ 18 (0.0)	0/ 29 (0.0)	3.9	1.00 (0.46, 2.17)	0.9950	0.0	0.9990
Sex										
Male	7/177 (4.0)	5/179 (2.8)	94.4	0/ 11 (0.0)	0/ 26 (0.0)	5.6	0.72 (0.24, 2.15)	0.5592	0.0	0.8764
Female	6/154 (3.9)	7/153 (4.6)	92.8	0/ 16 (0.0)	0/ 28 (0.0)	7.2	1.16 (0.41, 3.26)	0.7757	0.0	0.9398
Baseline FVC percent predicted										
<=70%	11/193 (5.7)	3/196 (1.5)	96.0	0/ 10 (0.0)	0/ 17 (0.0)	4.0	0.30 (0.09, 0.98)	0.0455	0.0	0.5379
>70%	2/138 (1.4)	9/136 (6.6)	82.1	0/ 17 (0.0)	0/ 37 (0.0)	17.9	3.93 (0.98,15.81)	0.0541	0.0	0.5033
Baseline HRCT pattern										
UIP-like	7/206 (3.4)	8/206 (3.9)	94.0	0/ 23 (0.0)	0/ 45 (0.0)	6.0	1.13 (0.43, 2.99)	0.7986	0.0	0.9507
Other fibrotic patterns	6/125 (4.8)	4/126 (3.2)	93.4	0/ 4 (0.0)	0/ 9 (0.0)	6.6	0.68 (0.21, 2.24)	0.5298	0.0	0.8500
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	2/ 76 (2.6)	1/ 79 (1.3)	82.1	0/ 27 (0.0)	0/ 54 (0.0)	17.9	0.57 (0.07, 4.40)	0.5933	0.0	0.7636
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Injury, poisoning and procedural complications
PT: Fall

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	13/331 (3.9)	12/332 (3.6)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	-0.28 (-2.94, 2.38)	0.0	0.9152
Age									
<65 years	1/121 (0.8)	1/139 (0.7)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	-0.10 (-2.36, 2.17)	0.0	0.9865
>=65 years	12/210 (5.7)	11/193 (5.7)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	-0.01 (-4.16, 4.14)	0.0	0.9975
Sex									
Male	7/177 (4.0)	5/179 (2.8)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-1.06 (-4.62, 2.49)	0.0	0.8429
Female	6/154 (3.9)	7/153 (4.6)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	0.60 (-3.50, 4.69)	0.0	0.8925
Baseline FVC percent predicted									
<=70%	11/193 (5.7)	3/196 (1.5)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-3.90 (-7.47, -0.33)	0.0	0.5661
>70%	2/138 (1.4)	9/136 (6.6)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	4.39 (0.30, 8.49)	24.8	0.2490
Baseline HRCT pattern									
UIP-like	7/206 (3.4)	8/206 (3.9)	86.8	0/ 23 (0.0)	0/ 45 (0.0)	13.2	0.42 (-2.81, 3.66)	0.0	0.8903
Other fibrotic patterns	6/125 (4.8)	4/126 (3.2)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-1.55 (-6.34, 3.24)	0.0	0.9087
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	2/ 76 (2.6)	1/ 79 (1.3)	67.7	0/ 27 (0.0)	0/ 54 (0.0)	32.3	-0.93 (-4.29, 2.44)	0.0	0.6859
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Injury, poisoning and procedural complications
PT: Fall

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid				
Overall	13/331 (3.9)	12/332 (3.6)	96.6	0/ 27 (0.0)	0/ 54 (0.0)	3.4	0.92 (0.42, 2.02)	0.0	0.9683
Age									
<65 years	1/121 (0.8)	1/139 (0.7)	73.7	0/ 9 (0.0)	0/ 25 (0.0)	26.3	0.90 (0.09, 9.57)	0.0	0.9587
>=65 years	12/210 (5.7)	11/193 (5.7)	95.9	0/ 18 (0.0)	0/ 29 (0.0)	4.1	1.00 (0.44, 2.28)	0.0	0.9990
Sex									
Male	7/177 (4.0)	5/179 (2.8)	94.4	0/ 11 (0.0)	0/ 26 (0.0)	5.6	0.71 (0.23, 2.20)	0.0	0.8754
Female	6/154 (3.9)	7/153 (4.6)	92.6	0/ 16 (0.0)	0/ 28 (0.0)	7.4	1.17 (0.40, 3.43)	0.0	0.9386
Baseline FVC percent predicted									
<=70%	11/193 (5.7)	3/196 (1.5)	96.0	0/ 10 (0.0)	0/ 17 (0.0)	4.0	0.29 (0.09, 0.96)	0.0	0.5386
>70%	2/138 (1.4)	9/136 (6.6)	81.4	0/ 17 (0.0)	0/ 37 (0.0)	18.6	4.11 (0.97,17.40)	0.0	0.4964
Baseline HRCT pattern									
UIP-like	7/206 (3.4)	8/206 (3.9)	93.8	0/ 23 (0.0)	0/ 45 (0.0)	6.2	1.14 (0.42, 3.11)	0.0	0.9496
Other fibrotic patterns	6/125 (4.8)	4/126 (3.2)	93.6	0/ 4 (0.0)	0/ 9 (0.0)	6.4	0.67 (0.20, 2.31)	0.0	0.8539
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	2/ 76 (2.6)	1/ 79 (1.3)	82.1	0/ 27 (0.0)	0/ 54 (0.0)	17.9	0.57 (0.07, 4.41)	0.0	0.7623
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Investigations
PT: Alanine aminotransferase increased

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid					
Overall	13/331 (3.9)	49/332 (14.8)	90.7	1/ 27 (3.7)	10/ 54 (18.5)	9.3	3.87 (2.19, 6.85)	<.0001	0.0	0.7887
Age										
<65 years	8/121 (6.6)	23/139 (16.5)	95.6	0/ 9 (0.0)	6/ 25 (24.0)	4.4	2.79 (1.31, 5.95)	0.0078	0.0	0.5131
>=65 years	5/210 (2.4)	26/193 (13.5)	79.5	1/ 18 (5.6)	4/ 29 (13.8)	20.5	5.01 (2.14,11.70)	0.0002	0.0	0.4845
Sex										
Male	5/177 (2.8)	12/179 (6.7)	78.2	1/ 11 (9.1)	4/ 26 (15.4)	21.8	2.22 (0.89, 5.55)	0.0868	0.0	0.7745
Female	8/154 (5.2)	37/153 (24.2)	94.5	0/ 16 (0.0)	6/ 28 (21.4)	5.5	4.97 (2.43,10.19)	<.0001	0.0	0.6384
Baseline FVC percent predicted										
<=70%	9/193 (4.7)	33/196 (16.8)	87.8	1/ 10 (10.0)	3/ 17 (17.6)	12.2	3.39 (1.73, 6.62)	0.0004	0.0	0.5310
>70%	4/138 (2.9)	16/136 (11.8)	90.2	0/ 17 (0.0)	7/ 37 (18.9)	9.8	4.76 (1.69,13.42)	0.0032	0.0	0.5881
Baseline HRCT pattern										
UIP-like	4/206 (1.9)	32/206 (15.5)	89.9	0/ 23 (0.0)	6/ 45 (13.3)	10.1	8.21 (3.07,21.95)	<.0001	0.0	0.8996
Other fibrotic patterns	9/125 (7.2)	17/126 (13.5)	86.7	1/ 4 (25.0)	4/ 9 (44.4)	13.3	1.86 (0.91, 3.79)	0.0868	0.0	0.9589
Underlying ILD diagnosis										
iNSIP	2/ 61 (3.3)	10/ 64 (15.6)	81.2	0/ 7 (0.0)	1/ 11 (9.1)	18.8	4.36 (1.13,16.79)	0.0321	0.0	0.7533
Unclassifiable IIP	1/ 50 (2.0)	9/ 64 (14.1)	70.1	0/ 3 (0.0)	1/ 2 (50.0)	29.9	5.97 (1.14,31.33)	0.0345	0.0	0.6800
HP	5/ 89 (5.6)	13/ 84 (15.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	3/ 88 (3.4)	14/ 82 (17.1)	88.2	0/ 12 (0.0)	6/ 34 (17.6)	11.8	5.49 (1.70,17.79)	0.0045	0.0	0.7715
Other ILD	2/ 43 (4.7)	3/ 38 (7.9)	63.2	1/ 5 (20.0)	2/ 6 (33.3)	36.8	1.69 (0.44, 6.43)	0.4446	0.0	0.9895
Region										
Europe										
Asia	3/ 76 (3.9)	18/ 79 (22.8)	69.6	1/ 27 (3.7)	10/ 54 (18.5)	30.4	5.54 (2.00,15.35)	0.0010	0.0	0.9037
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Investigations
PT: Alanine aminotransferase increased

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	13/331 (3.9)	49/332 (14.8)	90.2	1/ 27 (3.7)	10/ 54 (18.5)	9.8	11.22 (7.11, 15.34)	0.0	0.5574
Age									
<65 years	8/121 (6.6)	23/139 (16.5)	90.2	0/ 9 (0.0)	6/ 25 (24.0)	9.8	11.18 (4.06, 18.30)	29.0	0.2352
>=65 years	5/210 (2.4)	26/193 (13.5)	90.1	1/ 18 (5.6)	4/ 29 (13.8)	9.9	10.81 (5.81, 15.80)	0.0	0.7456
Sex									
Male	5/177 (2.8)	12/179 (6.7)	92.0	1/ 11 (9.1)	4/ 26 (15.4)	8.0	4.07 (-0.34, 8.49)	0.0	0.8324
Female	8/154 (5.2)	37/153 (24.2)	87.8	0/ 16 (0.0)	6/ 28 (21.4)	12.2	19.17 (12.16, 26.18)	0.0	0.8721
Baseline FVC percent predicted									
<=70%	9/193 (4.7)	33/196 (16.8)	93.9	1/ 10 (10.0)	3/ 17 (17.6)	6.1	11.90 (6.02, 17.77)	0.0	0.7392
>70%	4/138 (2.9)	16/136 (11.8)	85.0	0/ 17 (0.0)	7/ 37 (18.9)	15.0	10.27 (4.68, 15.87)	30.2	0.2313
Baseline HRCT pattern									
UIP-like	4/206 (1.9)	32/206 (15.5)	86.8	0/ 23 (0.0)	6/ 45 (13.3)	13.2	13.51 (8.68, 18.33)	0.0	0.9192
Other fibrotic patterns	9/125 (7.2)	17/126 (13.5)	95.8	1/ 4 (25.0)	4/ 9 (44.4)	4.2	6.85 (-0.67, 14.37)	0.0	0.6328
Underlying ILD diagnosis									
iNSIP	2/ 61 (3.3)	10/ 64 (15.6)	86.8	0/ 7 (0.0)	1/ 11 (9.1)	13.2	11.80 (2.58, 21.02)	0.0	0.7566
Unclassifiable IIP	1/ 50 (2.0)	9/ 64 (14.1)	94.4	0/ 3 (0.0)	1/ 2 (50.0)	5.6	13.40 (3.78, 23.02)	0.0	0.4960
HP	5/ 89 (5.6)	13/ 84 (15.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	3/ 88 (3.4)	14/ 82 (17.1)	82.1	0/ 12 (0.0)	6/ 34 (17.6)	17.9	14.25 (6.39, 22.10)	0.0	0.7177
Other ILD	2/ 43 (4.7)	3/ 38 (7.9)	88.1	1/ 5 (20.0)	2/ 6 (33.3)	11.9	4.45 (-6.75, 15.64)	0.0	0.7069
Region									
Europe									
Asia	3/ 76 (3.9)	18/ 79 (22.8)	68.3	1/ 27 (3.7)	10/ 54 (18.5)	31.7	17.56 (9.52, 25.61)	0.0	0.6267
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Investigations
PT: Alanine aminotransferase increased

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid				
Overall	13/331 (3.9)	49/332 (14.8)	91.1	1/ 27 (3.7)	10/ 54 (18.5)	8.9	4.38 (2.39, 8.03)	0.0	0.7672
Age									
<65 years	8/121 (6.6)	23/139 (16.5)	96.1	0/ 9 (0.0)	6/ 25 (24.0)	3.9	3.16 (1.39, 7.16)	0.0	0.4828
>=65 years	5/210 (2.4)	26/193 (13.5)	79.6	1/ 18 (5.6)	4/ 29 (13.8)	20.4	5.63 (2.30,13.81)	0.0	0.4998
Sex									
Male	5/177 (2.8)	12/179 (6.7)	79.8	1/ 11 (9.1)	4/ 26 (15.4)	20.2	2.34 (0.89, 6.16)	0.0	0.8133
Female	8/154 (5.2)	37/153 (24.2)	94.4	0/ 16 (0.0)	6/ 28 (21.4)	5.6	6.23 (2.86,13.59)	0.0	0.6460
Baseline FVC percent predicted									
<=70%	9/193 (4.7)	33/196 (16.8)	87.9	1/ 10 (10.0)	3/ 17 (17.6)	12.1	3.87 (1.87, 8.03)	0.0	0.5544
>70%	4/138 (2.9)	16/136 (11.8)	91.0	0/ 17 (0.0)	7/ 37 (18.9)	9.0	5.30 (1.83,15.39)	0.0	0.5596
Baseline HRCT pattern									
UIP-like	4/206 (1.9)	32/206 (15.5)	89.8	0/ 23 (0.0)	6/ 45 (13.3)	10.2	9.52 (3.45,26.31)	0.0	0.9053
Other fibrotic patterns	9/125 (7.2)	17/126 (13.5)	91.0	1/ 4 (25.0)	4/ 9 (44.4)	9.0	2.05 (0.91, 4.59)	0.0	0.8995
Underlying ILD diagnosis									
iNSIP	2/ 61 (3.3)	10/ 64 (15.6)	80.7	0/ 7 (0.0)	1/ 11 (9.1)	19.3	4.97 (1.19,20.80)	0.0	0.7512
Unclassifiable IIP	1/ 50 (2.0)	9/ 64 (14.1)	80.1	0/ 3 (0.0)	1/ 2 (50.0)	19.9	7.62 (1.22,47.56)	0.0	0.8916
HP	5/ 89 (5.6)	13/ 84 (15.5)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	3/ 88 (3.4)	14/ 82 (17.1)	88.5	0/ 12 (0.0)	6/ 34 (17.6)	11.5	6.43 (1.88,21.97)	0.0	0.7650
Other ILD	2/ 43 (4.7)	3/ 38 (7.9)	70.4	1/ 5 (20.0)	2/ 6 (33.3)	29.6	1.83 (0.39, 8.49)	0.0	0.9393
Region									
Europe									
Asia	3/ 76 (3.9)	18/ 79 (22.8)	68.5	1/ 27 (3.7)	10/ 54 (18.5)	31.5	6.78 (2.27,20.21)	0.0	0.8768
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Investigations
PT: Aspartate aminotransferase increased

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo			Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk ratio (95% CI)	p-value	I^2	p-value
Overall	13/331 (3.9)	43/332 (13.0)	83.0	2/ 27 (7.4)	8/ 54 (14.8)	17.0	3.08 (1.77, 5.36)	<.0001	0.0	0.5393
Age										
<65 years	8/121 (6.6)	17/139 (12.2)	95.6	0/ 9 (0.0)	3/ 25 (12.0)	4.4	1.99 (0.90, 4.38)	0.0872	0.0	0.6166
>=65 years	5/210 (2.4)	26/193 (13.5)	66.0	2/ 18 (11.1)	5/ 29 (17.2)	34.0	4.26 (1.96, 9.28)	0.0003	49.9	0.1577
Sex										
Male	6/177 (3.4)	13/179 (7.3)	81.1	1/ 11 (9.1)	2/ 26 (7.7)	18.9	1.90 (0.80, 4.50)	0.1463	0.0	0.4631
Female	7/154 (4.5)	30/153 (19.6)	84.6	1/ 16 (6.3)	6/ 28 (21.4)	15.4	4.18 (2.00, 8.73)	0.0001	0.0	0.8361
Baseline FVC percent predicted										
<=70%	9/193 (4.7)	30/196 (15.3)	78.3	2/ 10 (20.0)	1/ 17 (5.9)	21.7	2.63 (1.38, 5.04)	0.0034	74.6	0.0470
>70%	4/138 (2.9)	13/136 (9.6)	90.2	0/ 17 (0.0)	7/ 37 (18.9)	9.8	4.07 (1.42,11.73)	0.0092	0.0	0.5151
Baseline HRCT pattern										
UIP-like	5/206 (2.4)	26/206 (12.6)	91.8	0/ 23 (0.0)	5/ 45 (11.1)	8.2	5.48 (2.20,13.60)	0.0002	0.0	0.7839
Other fibrotic patterns	8/125 (6.4)	17/126 (13.5)	74.4	2/ 4 (50.0)	3/ 9 (33.3)	25.6	1.74 (0.87, 3.47)	0.1170	51.7	0.1502
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	10/ 64 (15.6)	68.3	0/ 7 (0.0)	1/ 11 (9.1)	31.7	7.35 (1.34,40.28)	0.0216	0.0	0.5231
Unclassifiable IIP	2/ 50 (4.0)	8/ 64 (12.5)	82.4	0/ 3 (0.0)	1/ 2 (50.0)	17.6	3.19 (0.85,11.93)	0.0845	0.0	0.9414
HP	4/ 89 (4.5)	12/ 84 (14.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	4/ 88 (4.5)	11/ 82 (13.4)	90.9	0/ 12 (0.0)	5/ 34 (14.7)	9.1	3.39 (1.15, 9.95)	0.0264	0.0	0.6376
Other ILD	2/ 43 (4.7)	2/ 38 (5.3)	46.2	2/ 5 (40.0)	1/ 6 (16.7)	53.8	0.75 (0.19, 2.95)	0.6773	0.0	0.4889
Region										
Europe										
Asia	2/ 76 (2.6)	17/ 79 (21.5)	43.3	2/ 27 (7.4)	8/ 54 (14.8)	56.7	4.68 (1.74,12.54)	0.0022	44.4	0.1799
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Investigations
PT: Aspartate aminotransferase increased

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	13/331 (3.9)	43/332 (13.0)	90.2	2/ 27 (7.4)	8/ 54 (14.8)	9.8	8.87 (4.87, 12.86)	0.0	0.8247
Age									
<65 years	8/121 (6.6)	17/139 (12.2)	90.2	0/ 9 (0.0)	3/ 25 (12.0)	9.8	6.18 (-0.37, 12.72)	0.0	0.5400
>=65 years	5/210 (2.4)	26/193 (13.5)	90.1	2/ 18 (11.1)	5/ 29 (17.2)	9.9	10.60 (5.48, 15.72)	0.0	0.6381
Sex									
Male	6/177 (3.4)	13/179 (7.3)	92.0	1/ 11 (9.1)	2/ 26 (7.7)	8.0	3.45 (-1.11, 8.01)	0.0	0.6121
Female	7/154 (4.5)	30/153 (19.6)	88.3	1/ 16 (6.3)	6/ 28 (21.4)	11.7	15.08 (8.41, 21.74)	0.0	0.9912
Baseline FVC percent predicted									
<=70%	9/193 (4.7)	30/196 (15.3)	93.9	2/ 10 (20.0)	1/ 17 (5.9)	6.1	9.14 (3.40, 14.88)	67.1	0.0811
>70%	4/138 (2.9)	13/136 (9.6)	85.0	0/ 17 (0.0)	7/ 37 (18.9)	15.0	8.40 (3.13, 13.67)	55.2	0.1351
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	26/206 (12.6)	86.8	0/ 23 (0.0)	5/ 45 (11.1)	13.2	10.27 (5.72, 14.83)	0.0	0.9200
Other fibrotic patterns	8/125 (6.4)	17/126 (13.5)	95.8	2/ 4 (50.0)	3/ 9 (33.3)	4.2	6.09 (-1.36, 13.54)	0.0	0.4248
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	10/ 64 (15.6)	86.8	0/ 7 (0.0)	1/ 11 (9.1)	13.2	13.22 (4.41, 22.03)	0.0	0.6635
Unclassifiable IIP	2/ 50 (4.0)	8/ 64 (12.5)	94.4	0/ 3 (0.0)	1/ 2 (50.0)	5.6	10.04 (0.08, 20.00)	0.0	0.4338
HP	4/ 89 (4.5)	12/ 84 (14.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	11/ 82 (13.4)	82.1	0/ 12 (0.0)	5/ 34 (14.7)	17.9	9.80 (2.31, 17.30)	0.0	0.5426
Other ILD	2/ 43 (4.7)	2/ 38 (5.3)	88.1	2/ 5 (40.0)	1/ 6 (16.7)	11.9	-2.24 (-12.66, 8.18)	0.0	0.3771
Region									
Europe									
Asia	2/ 76 (2.6)	17/ 79 (21.5)	68.3	2/ 27 (7.4)	8/ 54 (14.8)	31.7	15.25 (7.30, 23.19)	44.2	0.1806
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Investigations
PT: Aspartate aminotransferase increased

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo	Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	I^2	p-value
Overall	13/331 (3.9)	43/332 (13.0)	83.3	2/ 27 (7.4)	8/ 54 (14.8)	16.7	3.39 (1.87, 6.16)	0.0	0.5629
Age									
<65 years	8/121 (6.6)	17/139 (12.2)	95.7	0/ 9 (0.0)	3/ 25 (12.0)	4.3	2.13 (0.91, 4.99)	0.0	0.6092
>=65 years	5/210 (2.4)	26/193 (13.5)	67.0	2/ 18 (11.1)	5/ 29 (17.2)	33.0	4.83 (2.08,11.18)	41.6	0.1908
Sex									
Male	6/177 (3.4)	13/179 (7.3)	81.2	1/ 11 (9.1)	2/ 26 (7.7)	18.8	1.97 (0.79, 4.94)	0.0	0.4744
Female	7/154 (4.5)	30/153 (19.6)	84.9	1/ 16 (6.3)	6/ 28 (21.4)	15.1	4.97 (2.23,11.05)	0.0	0.8529
Baseline FVC percent predicted									
<=70%	9/193 (4.7)	30/196 (15.3)	76.4	2/ 10 (20.0)	1/ 17 (5.9)	23.6	2.88 (1.42, 5.86)	74.6	0.0473
>70%	4/138 (2.9)	13/136 (9.6)	91.2	0/ 17 (0.0)	7/ 37 (18.9)	8.8	4.44 (1.51,13.06)	0.0	0.4823
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	26/206 (12.6)	91.7	0/ 23 (0.0)	5/ 45 (11.1)	8.3	6.12 (2.38,15.72)	0.0	0.7863
Other fibrotic patterns	8/125 (6.4)	17/126 (13.5)	79.0	2/ 4 (50.0)	3/ 9 (33.3)	21.0	1.91 (0.85, 4.30)	26.1	0.2446
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	10/ 64 (15.6)	67.7	0/ 7 (0.0)	1/ 11 (9.1)	32.3	8.45 (1.42,50.19)	0.0	0.5276
Unclassifiable IIP	2/ 50 (4.0)	8/ 64 (12.5)	89.1	0/ 3 (0.0)	1/ 2 (50.0)	10.9	3.71 (0.85,16.09)	0.0	0.7806
HP	4/ 89 (4.5)	12/ 84 (14.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	11/ 82 (13.4)	91.2	0/ 12 (0.0)	5/ 34 (14.7)	8.8	3.77 (1.22,11.67)	0.0	0.6285
Other ILD	2/ 43 (4.7)	2/ 38 (5.3)	49.4	2/ 5 (40.0)	1/ 6 (16.7)	50.6	0.71 (0.15, 3.52)	0.0	0.4476
Region									
Europe									
Asia	2/ 76 (2.6)	17/ 79 (21.5)	41.3	2/ 27 (7.4)	8/ 54 (14.8)	58.7	5.47 (1.87,15.99)	46.3	0.1725
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Investigations
PT: Gamma-glutamyltransferase increased

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	7/331 (2.1)	22/332 (6.6)	84.0	1/ 27 (3.7)	10/ 54 (18.5)	16.0	3.43 (1.58, 7.45)	0.0018	0.0	0.6731
Age										
<65 years	2/121 (1.7)	10/139 (7.2)	59.3	1/ 9 (11.1)	3/ 25 (12.0)	40.7	3.02 (0.92, 9.88)	0.0678	9.1	0.2944
>=65 years	5/210 (2.4)	12/193 (6.2)	91.0	0/ 18 (0.0)	7/ 29 (24.1)	9.0	3.49 (1.32, 9.21)	0.0117	0.0	0.3641
Sex										
Male	4/177 (2.3)	7/179 (3.9)	90.6	0/ 11 (0.0)	5/ 26 (19.2)	9.4	2.33 (0.75, 7.28)	0.1453	0.0	0.4278
Female	3/154 (1.9)	15/153 (9.8)	70.1	1/ 16 (6.3)	5/ 28 (17.9)	29.9	4.38 (1.55,12.43)	0.0054	0.0	0.6427
Baseline FVC percent predicted										
<=70%	4/193 (2.1)	14/196 (7.1)	89.6	0/ 10 (0.0)	2/ 17 (11.8)	10.4	3.52 (1.24, 9.97)	0.0177	0.0	0.9150
>70%	3/138 (2.2)	8/136 (5.9)	68.5	1/ 17 (5.9)	8/ 37 (21.6)	31.5	3.01 (1.01, 9.02)	0.0488	0.0	0.8014
Baseline HRCT pattern										
UIP-like	5/206 (2.4)	13/206 (6.3)	79.1	1/ 23 (4.3)	9/ 45 (20.0)	20.9	3.02 (1.22, 7.47)	0.0168	0.0	0.6185
Other fibrotic patterns	2/125 (1.6)	9/126 (7.1)	82.5	0/ 4 (0.0)	1/ 9 (11.1)	17.5	4.11 (1.02,16.53)	0.0465	0.0	0.7668
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	1/ 76 (1.3)	9/ 79 (11.4)	43.3	1/ 27 (3.7)	10/ 54 (18.5)	56.7	6.59 (1.60,27.16)	0.0091	0.0	0.7067
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Investigations
PT: Gamma-glutamyltransferase increased

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk difference (95% CI)		I^2	p-value
Overall	7/331 (2.1)	22/332 (6.6)	90.2	1/ 27 (3.7)	10/ 54 (18.5)	9.8	5.52 (2.47, 8.57)		58.9	0.1188
Age										
<65 years	2/121 (1.7)	10/139 (7.2)	90.7	1/ 9 (11.1)	3/ 25 (12.0)	9.3	5.11 (0.16, 10.06)		0.0	0.7114
>=65 years	5/210 (2.4)	12/193 (6.2)	89.7	0/ 18 (0.0)	7/ 29 (24.1)	10.3	5.83 (1.86, 9.80)		79.3	0.0278
Sex										
Male	4/177 (2.3)	7/179 (3.9)	91.6	0/ 11 (0.0)	5/ 26 (19.2)	8.4	3.04 (-0.56, 6.65)		69.1	0.0719
Female	3/154 (1.9)	15/153 (9.8)	88.3	1/ 16 (6.3)	5/ 28 (17.9)	11.7	8.30 (3.22, 13.37)		0.0	0.7019
Baseline FVC percent predicted										
<=70%	4/193 (2.1)	14/196 (7.1)	93.5	0/ 10 (0.0)	2/ 17 (11.8)	6.5	5.45 (1.39, 9.51)		0.0	0.5620
>70%	3/138 (2.2)	8/136 (5.9)	85.5	1/ 17 (5.9)	8/ 37 (21.6)	14.5	5.46 (0.76, 10.16)		42.0	0.1892
Baseline HRCT pattern										
UIP-like	5/206 (2.4)	13/206 (6.3)	87.1	1/ 23 (4.3)	9/ 45 (20.0)	12.9	5.40 (1.51, 9.29)		58.4	0.1212
Other fibrotic patterns	2/125 (1.6)	9/126 (7.1)	95.2	0/ 4 (0.0)	1/ 9 (11.1)	4.8	5.74 (0.73, 10.75)		0.0	0.8045
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	1/ 76 (1.3)	9/ 79 (11.4)	68.3	1/ 27 (3.7)	10/ 54 (18.5)	31.7	11.58 (5.11, 18.05)		0.0	0.5253
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Investigations
PT: Gamma-glutamyltransferase increased

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	7/331 (2.1)	22/332 (6.6)	85.8	1/ 27 (3.7)	10/ 54 (18.5)	14.2	3.66 (1.65, 8.12)	0.0	0.6141
Age									
<65 years	2/121 (1.7)	10/139 (7.2)	60.5	1/ 9 (11.1)	3/ 25 (12.0)	39.5	3.22 (0.90,11.48)	0.0	0.3221
>=65 years	5/210 (2.4)	12/193 (6.2)	92.7	0/ 18 (0.0)	7/ 29 (24.1)	7.3	3.70 (1.39, 9.88)	1.4	0.3139
Sex									
Male	4/177 (2.3)	7/179 (3.9)	92.1	0/ 11 (0.0)	5/ 26 (19.2)	7.9	2.41 (0.77, 7.55)	0.0	0.3901
Female	3/154 (1.9)	15/153 (9.8)	72.1	1/ 16 (6.3)	5/ 28 (17.9)	27.9	4.85 (1.62,14.54)	0.0	0.6935
Baseline FVC percent predicted									
<=70%	4/193 (2.1)	14/196 (7.1)	90.4	0/ 10 (0.0)	2/ 17 (11.8)	9.6	3.74 (1.28,10.96)	0.0	0.8909
>70%	3/138 (2.2)	8/136 (5.9)	72.3	1/ 17 (5.9)	8/ 37 (21.6)	27.7	3.26 (1.04,10.18)	0.0	0.7293
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	13/206 (6.3)	81.6	1/ 23 (4.3)	9/ 45 (20.0)	18.4	3.22 (1.27, 8.20)	0.0	0.5591
Other fibrotic patterns	2/125 (1.6)	9/126 (7.1)	83.9	0/ 4 (0.0)	1/ 9 (11.1)	16.1	4.41 (1.04,18.75)	0.0	0.8016
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	1/ 76 (1.3)	9/ 79 (11.4)	45.4	1/ 27 (3.7)	10/ 54 (18.5)	54.6	7.60 (1.72,33.54)	0.0	0.7468
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Investigations
PT: Weight decreased

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk ratio (95% CI)	p-value	I^2	p-value
Overall	18/331 (5.4)	49/332 (14.8)	81.8	3/ 27 (11.1)	7/ 54 (13.0)	18.2	2.43 (1.51, 3.91)	0.0002	31.2	0.2280
Age										
<65 years	2/121 (1.7)	19/139 (13.7)	59.3	1/ 9 (11.1)	3/ 25 (12.0)	40.7	5.34 (1.73,16.51)	0.0036	58.5	0.1206
>=65 years	16/210 (7.6)	30/193 (15.5)	86.1	2/ 18 (11.1)	4/ 29 (13.8)	13.9	1.93 (1.13, 3.31)	0.0168	0.0	0.5651
Sex										
Male	9/177 (5.1)	27/179 (15.1)	86.6	1/ 11 (9.1)	4/ 26 (15.4)	13.4	2.80 (1.41, 5.53)	0.0031	0.0	0.6167
Female	9/154 (5.8)	22/153 (14.4)	77.9	2/ 16 (12.5)	3/ 28 (10.7)	22.1	2.11 (1.08, 4.11)	0.0290	21.0	0.2606
Baseline FVC percent predicted										
<=70%	13/193 (6.7)	25/196 (12.8)	91.2	1/ 10 (10.0)	3/ 17 (17.6)	8.8	1.88 (1.02, 3.47)	0.0431	0.0	0.9503
>70%	5/138 (3.6)	24/136 (17.6)	64.4	2/ 17 (11.8)	4/ 37 (10.8)	35.6	3.46 (1.60, 7.49)	0.0016	68.0	0.0773
Baseline HRCT pattern										
UIP-like	7/206 (3.4)	33/206 (16.0)	72.6	2/ 23 (8.7)	5/ 45 (11.1)	27.4	3.77 (1.89, 7.52)	0.0002	53.2	0.1438
Other fibrotic patterns	11/125 (8.8)	16/126 (12.7)	88.9	1/ 4 (25.0)	2/ 9 (22.2)	11.1	1.38 (0.70, 2.74)	0.3561	0.0	0.6680
Underlying ILD diagnosis										
iNSIP	3/ 61 (4.9)	12/ 64 (18.8)	71.5	1/ 7 (14.3)	2/ 11 (18.2)	28.5	3.09 (1.08, 8.80)	0.0346	0.0	0.3932
Unclassifiable IIP	6/ 50 (12.0)	12/ 64 (18.8)	93.3	0/ 3 (0.0)	0/ 2 (0.0)	6.7	1.53 (0.63, 3.68)	0.3474	0.0	0.8186
HP	7/ 89 (7.9)	12/ 84 (14.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	2/ 88 (2.3)	10/ 82 (12.2)	56.6	1/ 12 (8.3)	3/ 34 (8.8)	43.4	3.50 (1.09,11.21)	0.0351	31.8	0.2260
Other ILD	0/ 43 (0.0)	3/ 38 (7.9)	31.3	1/ 5 (20.0)	2/ 6 (33.3)	68.7	3.46 (0.67,17.90)	0.1385	0.0	0.4090
Region										
Europe										
Asia	7/ 76 (9.2)	18/ 79 (22.8)	64.1	3/ 27 (11.1)	7/ 54 (13.0)	35.9	2.00 (1.02, 3.94)	0.0439	0.0	0.3292
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Investigations
PT: Weight decreased

Subgroup / Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo: Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	18/331 (5.4)	49/332 (14.8)	90.2	3/ 27 (11.1)	7/ 54 (13.0)	9.8	8.59 (4.25, 12.93)	0.0	0.3460
Age									
<65 years	2/121 (1.7)	19/139 (13.7)	90.7	1/ 9 (11.1)	3/ 25 (12.0)	9.3	10.98 (4.97, 16.99)	0.0	0.3817
>=65 years	16/210 (7.6)	30/193 (15.5)	90.1	2/ 18 (11.1)	4/ 29 (13.8)	9.9	7.40 (1.46, 13.34)	0.0	0.6106
Sex									
Male	9/177 (5.1)	27/179 (15.1)	92.0	1/ 11 (9.1)	4/ 26 (15.4)	8.0	9.70 (3.77, 15.64)	0.0	0.7499
Female	9/154 (5.8)	22/153 (14.4)	88.3	2/ 16 (12.5)	3/ 28 (10.7)	11.7	7.33 (0.99, 13.67)	0.0	0.3340
Baseline FVC percent predicted									
<=70%	13/193 (6.7)	25/196 (12.8)	93.9	1/ 10 (10.0)	3/ 17 (17.6)	6.1	6.12 (0.39, 11.84)	0.0	0.9046
>70%	5/138 (3.6)	24/136 (17.6)	85.5	2/ 17 (11.8)	4/ 37 (10.8)	14.5	11.85 (5.20, 18.49)	55.3	0.1348
Baseline HRCT pattern									
UIP-like	7/206 (3.4)	33/206 (16.0)	87.1	2/ 23 (8.7)	5/ 45 (11.1)	12.9	11.31 (6.08, 16.53)	38.0	0.2041
Other fibrotic patterns	11/125 (8.8)	16/126 (12.7)	95.8	1/ 4 (25.0)	2/ 9 (22.2)	4.2	3.62 (-4.01, 11.24)	0.0	0.7974
Underlying ILD diagnosis									
iNSIP	3/ 61 (4.9)	12/ 64 (18.8)	88.0	1/ 7 (14.3)	2/ 11 (18.2)	12.0	12.64 (2.11, 23.16)	0.0	0.5909
Unclassifiable IIP	6/ 50 (12.0)	12/ 64 (18.8)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	6.37 (-6.38, 19.12)	0.0	0.8083
HP	7/ 89 (7.9)	12/ 84 (14.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	2/ 88 (2.3)	10/ 82 (12.2)	82.7	1/ 12 (8.3)	3/ 34 (8.8)	17.3	8.29 (1.15, 15.43)	0.0	0.3525
Other ILD	0/ 43 (0.0)	3/ 38 (7.9)	88.3	1/ 5 (20.0)	2/ 6 (33.3)	11.7	8.36 (-1.96, 18.69)	0.0	0.8331
Region									
Europe									
Asia	7/ 76 (9.2)	18/ 79 (22.8)	68.3	3/ 27 (11.1)	7/ 54 (13.0)	31.7	9.86 (0.81, 18.90)	34.0	0.2185
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Investigations
PT: Weight decreased

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid				
Overall	18/331 (5.4)	49/332 (14.8)	81.5	3/ 27 (11.1)	7/ 54 (13.0)	18.5	2.67 (1.58, 4.51)	27.6	0.2398
Age									
<65 years	2/121 (1.7)	19/139 (13.7)	58.8	1/ 9 (11.1)	3/ 25 (12.0)	41.2	5.99 (1.78,20.11)	55.4	0.1343
>=65 years	16/210 (7.6)	30/193 (15.5)	85.9	2/ 18 (11.1)	4/ 29 (13.8)	14.1	2.10 (1.15, 3.84)	0.0	0.5704
Sex									
Male	9/177 (5.1)	27/179 (15.1)	86.6	1/ 11 (9.1)	4/ 26 (15.4)	13.4	3.12 (1.48, 6.56)	0.0	0.6300
Female	9/154 (5.8)	22/153 (14.4)	77.2	2/ 16 (12.5)	3/ 28 (10.7)	22.8	2.28 (1.09, 4.78)	18.4	0.2682
Baseline FVC percent predicted									
<=70%	13/193 (6.7)	25/196 (12.8)	91.7	1/ 10 (10.0)	3/ 17 (17.6)	8.3	2.02 (1.03, 3.96)	0.0	0.9699
>70%	5/138 (3.6)	24/136 (17.6)	62.6	2/ 17 (11.8)	4/ 37 (10.8)	37.4	3.91 (1.67, 9.12)	67.2	0.0808
Baseline HRCT pattern									
UIP-like	7/206 (3.4)	33/206 (16.0)	71.4	2/ 23 (8.7)	5/ 45 (11.1)	28.6	4.25 (2.02, 8.95)	52.5	0.1469
Other fibrotic patterns	11/125 (8.8)	16/126 (12.7)	90.0	1/ 4 (25.0)	2/ 9 (22.2)	10.0	1.44 (0.66, 3.14)	0.0	0.7000
Underlying ILD diagnosis									
iNSIP	3/ 61 (4.9)	12/ 64 (18.8)	71.4	1/ 7 (14.3)	2/ 11 (18.2)	28.6	3.57 (1.12,11.39)	0.0	0.4187
Unclassifiable IIP	6/ 50 (12.0)	12/ 64 (18.8)	93.0	0/ 3 (0.0)	0/ 2 (0.0)	7.0	1.64 (0.59, 4.58)	0.0	0.8167
HP	7/ 89 (7.9)	12/ 84 (14.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	2/ 88 (2.3)	10/ 82 (12.2)	55.7	1/ 12 (8.3)	3/ 34 (8.8)	44.3	3.80 (1.07,13.52)	30.0	0.2320
Other ILD	0/ 43 (0.0)	3/ 38 (7.9)	38.4	1/ 5 (20.0)	2/ 6 (33.3)	61.6	4.31 (0.63,29.70)	0.0	0.4992
Region									
Europe									
Asia	7/ 76 (9.2)	18/ 79 (22.8)	61.3	3/ 27 (11.1)	7/ 54 (13.0)	38.7	2.24 (1.03, 4.91)	3.5	0.3086
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid					
Overall	23/331 (6.9)	54/332 (16.3)	98.1	0/ 27 (0.0)	5/ 54 (9.3)	1.9	2.46 (1.55, 3.89)	0.0001	0.0	0.4695
Age										
<65 years	2/121 (1.7)	22/139 (15.8)	84.6	0/ 9 (0.0)	2/ 25 (8.0)	15.4	8.67 (2.30,32.75)	0.0014	0.0	0.6569
>=65 years	21/210 (10.0)	32/193 (16.6)	97.7	0/ 18 (0.0)	3/ 29 (10.3)	2.3	1.75 (1.06, 2.92)	0.0300	0.0	0.4560
Sex										
Male	13/177 (7.3)	27/179 (15.1)	96.9	0/ 11 (0.0)	4/ 26 (15.4)	3.1	2.20 (1.18, 4.09)	0.0129	0.0	0.5310
Female	10/154 (6.5)	27/153 (17.6)	95.6	0/ 16 (0.0)	1/ 28 (3.6)	4.4	2.71 (1.38, 5.34)	0.0039	0.0	0.9760
Baseline FVC percent predicted										
<=70%	13/193 (6.7)	31/196 (15.8)	96.6	0/ 10 (0.0)	4/ 17 (23.5)	3.4	2.52 (1.38, 4.62)	0.0028	0.0	0.5002
>70%	10/138 (7.2)	23/136 (16.9)	95.8	0/ 17 (0.0)	1/ 37 (2.7)	4.2	2.34 (1.17, 4.67)	0.0162	0.0	0.9786
Baseline HRCT pattern										
UIP-like	14/206 (6.8)	37/206 (18.0)	96.9	0/ 23 (0.0)	5/ 45 (11.1)	3.1	2.83 (1.59, 5.04)	0.0004	0.0	0.5086
Other fibrotic patterns	9/125 (7.2)	17/126 (13.5)	95.5	0/ 4 (0.0)	0/ 9 (0.0)	4.5	1.83 (0.86, 3.90)	0.1151	0.0	0.7681
Underlying ILD diagnosis										
iNSIP	3/ 61 (4.9)	10/ 64 (15.6)	86.6	0/ 7 (0.0)	2/ 11 (18.2)	13.4	3.32 (1.04,10.62)	0.0426	0.0	0.8673
Unclassifiable IIP	3/ 50 (6.0)	13/ 64 (20.3)	87.5	0/ 3 (0.0)	0/ 2 (0.0)	12.5	3.09 (1.00, 9.56)	0.0506	0.0	0.5393
HP	13/ 89 (14.6)	9/ 84 (10.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	1/ 88 (1.1)	15/ 82 (18.3)	71.4	0/ 12 (0.0)	2/ 34 (5.9)	28.6	12.56 (2.22,70.98)	0.0042	0.0	0.5168
Other ILD	3/ 43 (7.0)	7/ 38 (18.4)	85.0	0/ 5 (0.0)	1/ 6 (16.7)	15.0	2.67 (0.82, 8.73)	0.1044	0.0	0.9673
Region										
Europe										
Asia	8/ 76 (10.5)	20/ 79 (25.3)	94.8	0/ 27 (0.0)	5/ 54 (9.3)	5.2	2.72 (1.29, 5.73)	0.0085	0.0	0.4852
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
	Placebo	Nin 150bid Wt	Placebo	Nin 150bid Wt			
Overall	23/331 (6.9)	54/332 (16.3) 90.0	0/ 27 (0.0)	5/ 54 (9.3) 10.0	9.29 (4.86, 13.72)	0.0	0.9570
Age							
<65 years	2/121 (1.7)	22/139 (15.8) 90.2	0/ 9 (0.0)	2/ 25 (8.0) 9.8	13.53 (7.49, 19.57)	0.0	0.4425
>=65 years	21/210 (10.0)	32/193 (16.6) 89.7	0/ 18 (0.0)	3/ 29 (10.3) 10.3	6.93 (0.82, 13.03)	0.0	0.6578
Sex							
Male	13/177 (7.3)	27/179 (15.1) 91.6	0/ 11 (0.0)	4/ 26 (15.4) 8.4	8.31 (2.19, 14.43)	0.0	0.4555
Female	10/154 (6.5)	27/153 (17.6) 87.8	0/ 16 (0.0)	1/ 28 (3.6) 12.2	10.21 (3.76, 16.66)	26.2	0.2444
Baseline FVC percent predicted							
<=70%	13/193 (6.7)	31/196 (15.8) 93.5	0/ 10 (0.0)	4/ 17 (23.5) 6.5	9.91 (3.92, 15.91)	12.0	0.2863
>70%	10/138 (7.2)	23/136 (16.9) 85.0	0/ 17 (0.0)	1/ 37 (2.7) 15.0	8.61 (1.97, 15.24)	27.6	0.2400
Baseline HRCT pattern							
UIP-like	14/206 (6.8)	37/206 (18.0) 86.8	0/ 23 (0.0)	5/ 45 (11.1) 13.2	11.12 (5.50, 16.73)	0.0	0.9528
Other fibrotic patterns	9/125 (7.2)	17/126 (13.5) 95.2	0/ 4 (0.0)	0/ 9 (0.0) 4.8	5.99 (-1.26, 13.24)	0.0	0.6637
Underlying ILD diagnosis							
iNSIP	3/ 61 (4.9)	10/ 64 (15.6) 86.8	0/ 7 (0.0)	2/ 11 (18.2) 13.2	11.45 (1.70, 21.21)	0.0	0.7072
Unclassifiable IIP	3/ 50 (6.0)	13/ 64 (20.3) 94.4	0/ 3 (0.0)	0/ 2 (0.0) 5.6	13.50 (1.93, 25.08)	0.0	0.6049
HP	13/ 89 (14.6)	9/ 84 (10.7) NC	0/ 0 (NC)	0/ 1 (0.0) NC	NC (NC, NC)	NC	NC
Autoimmune ILD	1/ 88 (1.1)	15/ 82 (18.3) 82.1	0/ 12 (0.0)	2/ 34 (5.9) 17.9	15.09 (7.68, 22.51)	57.9	0.1233
Other ILD	3/ 43 (7.0)	7/ 38 (18.4) 86.2	0/ 5 (0.0)	1/ 6 (16.7) 13.8	11.81 (-1.69, 25.31)	0.0	0.8962
Region							
Europe							
Asia	8/ 76 (10.5)	20/ 79 (25.3) 67.7	0/ 27 (0.0)	5/ 54 (9.3) 32.3	12.93 (4.43, 21.44)	0.0	0.4469
Canada and USA							
Rest of the World							

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	23/331 (6.9)	54/332 (16.3)	98.0	0/ 27 (0.0)	5/ 54 (9.3)	2.0	2.74 (1.65, 4.54)	0.0	0.4812
Age									
<65 years	2/121 (1.7)	22/139 (15.8)	83.8	0/ 9 (0.0)	2/ 25 (8.0)	16.2	10.03 (2.52,39.88)	0.0	0.6434
>=65 years	21/210 (10.0)	32/193 (16.6)	97.6	0/ 18 (0.0)	3/ 29 (10.3)	2.4	1.90 (1.07, 3.39)	0.0	0.4603
Sex									
Male	13/177 (7.3)	27/179 (15.1)	97.0	0/ 11 (0.0)	4/ 26 (15.4)	3.0	2.41 (1.22, 4.76)	0.0	0.5212
Female	10/154 (6.5)	27/153 (17.6)	94.9	0/ 16 (0.0)	1/ 28 (3.6)	5.1	3.06 (1.45, 6.48)	0.0	0.9384
Baseline FVC percent predicted									
<=70%	13/193 (6.7)	31/196 (15.8)	96.9	0/ 10 (0.0)	4/ 17 (23.5)	3.1	2.81 (1.45, 5.46)	0.0	0.4691
>70%	10/138 (7.2)	23/136 (16.9)	95.2	0/ 17 (0.0)	1/ 37 (2.7)	4.8	2.60 (1.21, 5.61)	0.0	0.9878
Baseline HRCT pattern									
UIP-like	14/206 (6.8)	37/206 (18.0)	96.7	0/ 23 (0.0)	5/ 45 (11.1)	3.3	3.22 (1.71, 6.08)	0.0	0.5226
Other fibrotic patterns	9/125 (7.2)	17/126 (13.5)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	1.96 (0.85, 4.52)	0.0	0.7598
Underlying ILD diagnosis									
iNSIP	3/ 61 (4.9)	10/ 64 (15.6)	87.4	0/ 7 (0.0)	2/ 11 (18.2)	12.6	3.78 (1.08,13.21)	0.0	0.8484
Unclassifiable IIP	3/ 50 (6.0)	13/ 64 (20.3)	86.7	0/ 3 (0.0)	0/ 2 (0.0)	13.3	3.60 (1.04,12.40)	0.0	0.5480
HP	13/ 89 (14.6)	9/ 84 (10.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	1/ 88 (1.1)	15/ 82 (18.3)	68.9	0/ 12 (0.0)	2/ 34 (5.9)	31.1	14.64 (2.37,90.46)	0.0	0.4913
Other ILD	3/ 43 (7.0)	7/ 38 (18.4)	85.6	0/ 5 (0.0)	1/ 6 (16.7)	14.4	3.06 (0.81,11.51)	0.0	0.9567
Region									
Europe									
Asia	8/ 76 (10.5)	20/ 79 (25.3)	93.9	0/ 27 (0.0)	5/ 54 (9.3)	6.1	3.28 (1.39, 7.72)	0.0	0.5254
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	11/331 (3.3)	2/332 (0.6)	80.5	2/ 27 (7.4)	1/ 54 (1.9)	19.5	0.19 (0.05, 0.70)	0.0119	0.0	0.8215
Age										
<65 years										
>=65 years										
Sex										
Male										
Female										
Baseline FVC percent predicted										
<=70%										
>70%										
Baseline HRCT pattern										
UIP-like										
Other fibrotic patterns										
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	11/331 (3.3)	2/332 (0.6)	90.2	2/ 27 (7.4)	1/ 54 (1.9)	9.8	-3.00 (-5.16, -0.84)	0.0	0.6043
Age									
<65 years									
>=65 years									
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Metabolism and nutrition disorders
PT: Hyperglycaemia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	11/331 (3.3)	2/332 (0.6)	80.7	2/ 27 (7.4)	1/ 54 (1.9)	19.3	0.19 (0.05, 0.68)	0.0	0.8429
Age									
<65 years									
>=65 years									
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid					
Overall	24/331 (7.3)	13/332 (3.9)	94.7	1/ 27 (3.7)	1/ 54 (1.9)	5.3	0.54 (0.28, 1.02)	0.0574	0.0	0.9572
Age										
<65 years	8/121 (6.6)	7/139 (5.0)	85.3	1/ 9 (11.1)	1/ 25 (4.0)	14.7	0.70 (0.28, 1.76)	0.4516	0.0	0.6052
>=65 years	16/210 (7.6)	6/193 (3.1)	97.0	0/ 18 (0.0)	0/ 29 (0.0)	3.0	0.43 (0.17, 1.04)	0.0602	0.0	0.6679
Sex										
Male	16/177 (9.0)	9/179 (5.0)	97.5	0/ 11 (0.0)	0/ 26 (0.0)	2.5	0.57 (0.26, 1.23)	0.1520	0.0	0.7895
Female	8/154 (5.2)	4/153 (2.6)	86.2	1/ 16 (6.3)	1/ 28 (3.6)	13.8	0.51 (0.17, 1.51)	0.2259	0.0	0.9327
Baseline FVC percent predicted										
<=70%	15/193 (7.8)	6/196 (3.1)	89.8	1/ 10 (10.0)	0/ 17 (0.0)	10.2	0.38 (0.16, 0.92)	0.0318	0.0	0.8077
>70%	9/138 (6.5)	7/136 (5.1)	95.4	0/ 17 (0.0)	1/ 37 (2.7)	4.6	0.87 (0.34, 2.18)	0.7597	0.0	0.5662
Baseline HRCT pattern										
UIP-like	12/206 (5.8)	9/206 (4.4)	90.1	1/ 23 (4.3)	1/ 45 (2.2)	9.9	0.73 (0.33, 1.62)	0.4355	0.0	0.7922
Other fibrotic patterns	12/125 (9.6)	4/126 (3.2)	96.6	0/ 4 (0.0)	0/ 9 (0.0)	3.4	0.35 (0.12, 1.02)	0.0541	0.0	0.6097
Underlying ILD diagnosis										
iNSIP	3/ 61 (4.9)	1/ 64 (1.6)	86.6	0/ 7 (0.0)	0/ 11 (0.0)	13.4	0.41 (0.06, 2.72)	0.3549	0.0	0.6184
Unclassifiable IIP	1/ 50 (2.0)	0/ 64 (0.0)	77.1	0/ 3 (0.0)	0/ 2 (0.0)	22.9	0.46 (0.05, 4.55)	0.5099	0.0	0.6281
HP	11/ 89 (12.4)	4/ 84 (4.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	7/ 88 (8.0)	7/ 82 (8.5)	82.0	1/ 12 (8.3)	1/ 34 (2.9)	18.0	0.94 (0.37, 2.38)	0.9026	0.0	0.4481
Other ILD	2/ 43 (4.7)	1/ 38 (2.6)	79.1	0/ 5 (0.0)	0/ 6 (0.0)	20.9	0.66 (0.09, 4.80)	0.6784	0.0	0.8023
Region										
Europe										
Asia	4/ 76 (5.3)	3/ 79 (3.8)	75.4	1/ 27 (3.7)	1/ 54 (1.9)	24.6	0.67 (0.18, 2.42)	0.5372	0.0	0.8166
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2 p-value
Overall	24/331 (7.3)	13/332 (3.9)	90.2	1/ 27 (3.7)	1/ 54 (1.9)	9.8	-3.19 (-6.43, 0.05)	0.0 0.7385
Age								
<65 years	8/121 (6.6)	7/139 (5.0)	90.7	1/ 9 (11.1)	1/ 25 (4.0)	9.3	-2.09 (-7.67, 3.49)	0.0 0.6321
>=65 years	16/210 (7.6)	6/193 (3.1)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	-4.04 (-8.03, -0.06)	0.0 0.3382
Sex								
Male	16/177 (9.0)	9/179 (5.0)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-3.68 (-8.62, 1.27)	0.0 0.5151
Female	8/154 (5.2)	4/153 (2.6)	88.3	1/ 16 (6.3)	1/ 28 (3.6)	11.7	-2.59 (-6.73, 1.55)	0.0 0.9893
Baseline FVC percent predicted								
<=70%	15/193 (7.8)	6/196 (3.1)	93.5	1/ 10 (10.0)	0/ 17 (0.0)	6.5	-5.01 (-9.43, -0.59)	0.0 0.6833
>70%	9/138 (6.5)	7/136 (5.1)	85.0	0/ 17 (0.0)	1/ 37 (2.7)	15.0	-0.78 (-5.68, 4.12)	0.0 0.4590
Baseline HRCT pattern								
UIP-like	12/206 (5.8)	9/206 (4.4)	87.1	1/ 23 (4.3)	1/ 45 (2.2)	12.9	-1.54 (-5.43, 2.35)	0.0 0.8986
Other fibrotic patterns	12/125 (9.6)	4/126 (3.2)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-6.11 (-11.98, -0.25)	0.0 0.6529
Underlying ILD diagnosis								
iNSIP	3/ 61 (4.9)	1/ 64 (1.6)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	-2.91 (-8.90, 3.07)	0.0 0.7490
Unclassifiable IIP	1/ 50 (2.0)	0/ 64 (0.0)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	-1.86 (-7.48, 3.77)	0.0 0.9422
HP	11/ 89 (12.4)	4/ 84 (4.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC NC
Autoimmune ILD	7/ 88 (8.0)	7/ 82 (8.5)	82.7	1/ 12 (8.3)	1/ 34 (2.9)	17.3	-0.45 (-7.88, 6.98)	0.0 0.5286
Other ILD	2/ 43 (4.7)	1/ 38 (2.6)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	-1.74 (-9.79, 6.31)	0.0 0.8957
Region								
Europe								
Asia	4/ 76 (5.3)	3/ 79 (3.8)	68.3	1/ 27 (3.7)	1/ 54 (1.9)	31.7	-1.59 (-6.73, 3.55)	0.0 0.9416
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	24/331 (7.3)	13/332 (3.9)	94.6	1/ 27 (3.7)	1/ 54 (1.9)	5.4	0.52 (0.27, 1.02)	0.0	0.9672
Age									
<65 years	8/121 (6.6)	7/139 (5.0)	85.2	1/ 9 (11.1)	1/ 25 (4.0)	14.8	0.69 (0.26, 1.84)	0.0	0.6050
>=65 years	16/210 (7.6)	6/193 (3.1)	97.0	0/ 18 (0.0)	0/ 29 (0.0)	3.0	0.41 (0.16, 1.03)	0.0	0.6584
Sex									
Male	16/177 (9.0)	9/179 (5.0)	97.4	0/ 11 (0.0)	0/ 26 (0.0)	2.6	0.54 (0.24, 1.24)	0.0	0.7803
Female	8/154 (5.2)	4/153 (2.6)	86.4	1/ 16 (6.3)	1/ 28 (3.6)	13.6	0.50 (0.16, 1.53)	0.0	0.9365
Baseline FVC percent predicted									
<=70%	15/193 (7.8)	6/196 (3.1)	89.8	1/ 10 (10.0)	0/ 17 (0.0)	10.2	0.36 (0.14, 0.91)	0.0	0.7954
>70%	9/138 (6.5)	7/136 (5.1)	95.4	0/ 17 (0.0)	1/ 37 (2.7)	4.6	0.86 (0.33, 2.26)	0.0	0.5618
Baseline HRCT pattern									
UIP-like	12/206 (5.8)	9/206 (4.4)	89.9	1/ 23 (4.3)	1/ 45 (2.2)	10.1	0.71 (0.31, 1.67)	0.0	0.7958
Other fibrotic patterns	12/125 (9.6)	4/126 (3.2)	96.7	0/ 4 (0.0)	0/ 9 (0.0)	3.3	0.33 (0.11, 1.00)	0.0	0.6124
Underlying ILD diagnosis									
iNSIP	3/ 61 (4.9)	1/ 64 (1.6)	87.0	0/ 7 (0.0)	0/ 11 (0.0)	13.0	0.40 (0.06, 2.75)	0.0	0.6236
Unclassifiable IIP	1/ 50 (2.0)	0/ 64 (0.0)	79.6	0/ 3 (0.0)	0/ 2 (0.0)	20.4	0.44 (0.04, 5.25)	0.0	0.6564
HP	11/ 89 (12.4)	4/ 84 (4.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	7/ 88 (8.0)	7/ 82 (8.5)	81.1	1/ 12 (8.3)	1/ 34 (2.9)	18.9	0.94 (0.34, 2.61)	0.0	0.4510
Other ILD	2/ 43 (4.7)	1/ 38 (2.6)	80.0	0/ 5 (0.0)	0/ 6 (0.0)	20.0	0.64 (0.08, 5.12)	0.0	0.8083
Region									
Europe									
Asia	4/ 76 (5.3)	3/ 79 (3.8)	75.0	1/ 27 (3.7)	1/ 54 (1.9)	25.0	0.66 (0.17, 2.52)	0.0	0.8206
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Musculoskeletal and connective tissue disorders
PT: Back pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	27/331 (8.2)	28/332 (8.4)	95.3	1/ 27 (3.7)	1/ 54 (1.9)	4.7	1.01 (0.61, 1.66)	0.9723	0.0	0.6085
Age										
<65 years	10/121 (8.3)	13/139 (9.4)	96.5	0/ 9 (0.0)	1/ 25 (4.0)	3.5	1.17 (0.54, 2.54)	0.6826	0.0	0.7252
>=65 years	17/210 (8.1)	15/193 (7.8)	90.5	1/ 18 (5.6)	0/ 29 (0.0)	9.5	0.90 (0.47, 1.70)	0.7361	0.0	0.4196
Sex										
Male	15/177 (8.5)	11/179 (6.1)	97.3	0/ 11 (0.0)	0/ 26 (0.0)	2.7	0.73 (0.35, 1.53)	0.4085	0.0	0.8835
Female	12/154 (7.8)	17/153 (11.1)	90.4	1/ 16 (6.3)	1/ 28 (3.6)	9.6	1.34 (0.68, 2.65)	0.3925	0.0	0.5211
Baseline FVC percent predicted										
<=70%	13/193 (6.7)	15/196 (7.7)	96.6	0/ 10 (0.0)	0/ 17 (0.0)	3.4	1.13 (0.56, 2.29)	0.7310	0.0	0.9508
>70%	14/138 (10.1)	13/136 (9.6)	91.0	1/ 17 (5.9)	1/ 37 (2.7)	9.0	0.90 (0.45, 1.79)	0.7622	0.0	0.6158
Baseline HRCT pattern										
UIP-like	16/206 (7.8)	16/206 (7.8)	90.0	1/ 23 (4.3)	0/ 45 (0.0)	10.0	0.93 (0.49, 1.76)	0.8129	0.0	0.3655
Other fibrotic patterns	11/125 (8.8)	12/126 (9.5)	96.3	0/ 4 (0.0)	1/ 9 (11.1)	3.7	1.13 (0.53, 2.42)	0.7480	0.0	0.6713
Underlying ILD diagnosis										
iNSIP	4/ 61 (6.6)	3/ 64 (4.7)	89.6	0/ 7 (0.0)	1/ 11 (9.1)	10.4	0.91 (0.25, 3.35)	0.8929	0.0	0.4875
Unclassifiable IIP	6/ 50 (12.0)	7/ 64 (10.9)	93.3	0/ 3 (0.0)	0/ 2 (0.0)	6.7	0.92 (0.34, 2.47)	0.8642	0.0	0.9623
HP	9/ 89 (10.1)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	5/ 88 (5.7)	8/ 82 (9.8)	92.6	0/ 12 (0.0)	0/ 34 (0.0)	7.4	1.66 (0.59, 4.72)	0.3388	0.0	0.8157
Other ILD	3/ 43 (7.0)	5/ 38 (13.2)	63.9	1/ 5 (20.0)	0/ 6 (0.0)	36.1	1.32 (0.41, 4.21)	0.6405	16.6	0.2735
Region										
Europe										
Asia	10/ 76 (13.2)	5/ 79 (6.3)	88.4	1/ 27 (3.7)	1/ 54 (1.9)	11.6	0.48 (0.18, 1.26)	0.1379	0.0	0.9793
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Musculoskeletal and connective tissue disorders
PT: Back pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	27/331 (8.2)	28/332 (8.4)	90.2	1/ 27 (3.7)	1/ 54 (1.9)	9.8	0.07 (-3.80, 3.94)	0.0	0.6436
Age									
<65 years	10/121 (8.3)	13/139 (9.4)	90.2	0/ 9 (0.0)	1/ 25 (4.0)	9.8	1.35 (-5.02, 7.72)	0.0	0.7364
>=65 years	17/210 (8.1)	15/193 (7.8)	89.7	1/ 18 (5.6)	0/ 29 (0.0)	10.3	-0.84 (-5.76, 4.08)	0.0	0.4801
Sex									
Male	15/177 (8.5)	11/179 (6.1)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-2.13 (-7.17, 2.90)	0.0	0.7065
Female	12/154 (7.8)	17/153 (11.1)	88.3	1/ 16 (6.3)	1/ 28 (3.6)	11.7	2.62 (-3.37, 8.61)	0.0	0.4389
Baseline FVC percent predicted									
<=70%	13/193 (6.7)	15/196 (7.7)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	0.86 (-4.02, 5.74)	0.0	0.9025
>70%	14/138 (10.1)	13/136 (9.6)	85.5	1/ 17 (5.9)	1/ 37 (2.7)	14.5	-0.96 (-7.26, 5.33)	0.0	0.7207
Baseline HRCT pattern									
UIP-like	16/206 (7.8)	16/206 (7.8)	86.8	1/ 23 (4.3)	0/ 45 (0.0)	13.2	-0.56 (-5.23, 4.12)	0.0	0.4589
Other fibrotic patterns	11/125 (8.8)	12/126 (9.5)	95.2	0/ 4 (0.0)	1/ 9 (11.1)	4.8	1.16 (-5.81, 8.12)	0.0	0.5942
Underlying ILD diagnosis									
iNSIP	4/ 61 (6.6)	3/ 64 (4.7)	86.8	0/ 7 (0.0)	1/ 11 (9.1)	13.2	-0.54 (-8.26, 7.18)	0.0	0.4431
Unclassifiable IIP	6/ 50 (12.0)	7/ 64 (10.9)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	-1.00 (-12.54, 10.54)	0.0	0.9694
HP	9/ 89 (10.1)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	5/ 88 (5.7)	8/ 82 (9.8)	82.1	0/ 12 (0.0)	0/ 34 (0.0)	17.9	3.34 (-3.46, 10.15)	0.0	0.5134
Other ILD	3/ 43 (7.0)	5/ 38 (13.2)	86.2	1/ 5 (20.0)	0/ 6 (0.0)	13.8	3.00 (-9.62, 15.61)	14.0	0.2810
Region									
Europe									
Asia	10/ 76 (13.2)	5/ 79 (6.3)	68.3	1/ 27 (3.7)	1/ 54 (1.9)	31.7	-5.25 (-12.09, 1.59)	0.0	0.4262
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Musculoskeletal and connective tissue disorders
PT: Back pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	27/331 (8.2)	28/332 (8.4)	95.0	1/ 27 (3.7)	1/ 54 (1.9)	5.0	1.01 (0.59, 1.74)	0.0	0.6086
Age									
<65 years	10/121 (8.3)	13/139 (9.4)	96.4	0/ 9 (0.0)	1/ 25 (4.0)	3.6	1.19 (0.51, 2.76)	0.0	0.7249
>=65 years	17/210 (8.1)	15/193 (7.8)	90.0	1/ 18 (5.6)	0/ 29 (0.0)	10.0	0.89 (0.44, 1.79)	0.0	0.4191
Sex									
Male	15/177 (8.5)	11/179 (6.1)	97.2	0/ 11 (0.0)	0/ 26 (0.0)	2.8	0.72 (0.32, 1.58)	0.0	0.8778
Female	12/154 (7.8)	17/153 (11.1)	89.7	1/ 16 (6.3)	1/ 28 (3.6)	10.3	1.38 (0.66, 2.92)	0.0	0.5148
Baseline FVC percent predicted									
<=70%	13/193 (6.7)	15/196 (7.7)	96.4	0/ 10 (0.0)	0/ 17 (0.0)	3.6	1.14 (0.54, 2.44)	0.0	0.9488
>70%	14/138 (10.1)	13/136 (9.6)	90.4	1/ 17 (5.9)	1/ 37 (2.7)	9.6	0.89 (0.41, 1.91)	0.0	0.6198
Baseline HRCT pattern									
UIP-like	16/206 (7.8)	16/206 (7.8)	89.4	1/ 23 (4.3)	0/ 45 (0.0)	10.6	0.92 (0.46, 1.85)	0.0	0.3656
Other fibrotic patterns	11/125 (8.8)	12/126 (9.5)	96.6	0/ 4 (0.0)	1/ 9 (11.1)	3.4	1.15 (0.50, 2.64)	0.0	0.6617
Underlying ILD diagnosis									
iNSIP	4/ 61 (6.6)	3/ 64 (4.7)	90.4	0/ 7 (0.0)	1/ 11 (9.1)	9.6	0.91 (0.23, 3.56)	0.0	0.4814
Unclassifiable IIP	6/ 50 (12.0)	7/ 64 (10.9)	93.6	0/ 3 (0.0)	0/ 2 (0.0)	6.4	0.91 (0.30, 2.78)	0.0	0.9634
HP	9/ 89 (10.1)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	5/ 88 (5.7)	8/ 82 (9.8)	92.0	0/ 12 (0.0)	0/ 34 (0.0)	8.0	1.73 (0.56, 5.34)	0.0	0.8056
Other ILD	3/ 43 (7.0)	5/ 38 (13.2)	62.5	1/ 5 (20.0)	0/ 6 (0.0)	37.5	1.36 (0.37, 5.00)	18.5	0.2679
Region									
Europe									
Asia	10/ 76 (13.2)	5/ 79 (6.3)	87.9	1/ 27 (3.7)	1/ 54 (1.9)	12.1	0.45 (0.16, 1.28)	0.0	0.9508
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Musculoskeletal and connective tissue disorders
PT: Musculoskeletal pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	4/331 (1.2)	12/332 (3.6)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	2.79 (0.95, 8.17)	0.0608	0.0	0.6160
Age										
<65 years										
>=65 years										
Sex										
Male										
Female										
Baseline FVC percent predicted										
<=70%	3/193 (1.6)	9/196 (4.6)	86.6	0/ 10 (0.0)	0/ 17 (0.0)	13.4	2.69 (0.80, 9.09)	0.1103	0.0	0.6125
>70%	1/138 (0.7)	3/136 (2.2)	69.7	0/ 17 (0.0)	0/ 37 (0.0)	30.3	2.42 (0.35,16.82)	0.3701	0.0	0.6459
Baseline HRCT pattern										
UIP-like										
Other fibrotic patterns										
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Musculoskeletal and connective tissue disorders
PT: Musculoskeletal pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	4/331	12/332	90.0	0/ 27	0/ 54	10.0	2.17 (0.01, 4.32)	0.0	0.3909
Age									
<65 years									
>=65 years									
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%	3/193	9/196	93.5	0/ 10	0/ 17	6.5	2.84 (-0.47, 6.15)	0.0	0.6744
>70%	1/138	3/136	85.0	0/ 17	0/ 37	15.0	1.26 (-1.41, 3.92)	0.0	0.7164
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Musculoskeletal and connective tissue disorders
PT: Musculoskeletal pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2 p-value
Overall	4/331 (1.2)	12/332 (3.6)	89.8	0/ 27 (0.0)	0/ 54 (0.0)	10.2	2.85 (0.95, 8.56)	0.0 0.6126
Age								
<65 years								
>=65 years								
Sex								
Male								
Female								
Baseline FVC percent predicted								
<=70%	3/193 (1.6)	9/196 (4.6)	86.5	0/ 10 (0.0)	0/ 17 (0.0)	13.5	2.77 (0.79, 9.70)	0.0 0.6145
>70%	1/138 (0.7)	3/136 (2.2)	69.6	0/ 17 (0.0)	0/ 37 (0.0)	30.4	2.46 (0.33,18.02)	0.0 0.6470
Baseline HRCT pattern								
UIP-like								
Other fibrotic patterns								
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia								
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Musculoskeletal and connective tissue disorders
PT: Myalgia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	10/331 (3.0)	4/332 (1.2)	95.8	0/ 27 (0.0)	0/ 54 (0.0)	4.2	0.42 (0.14, 1.28)	0.1269	0.0	0.6744
Age										
<65 years										
>=65 years										
Sex										
Male	2/177 (1.1)	2/179 (1.1)	82.8	0/ 11 (0.0)	0/ 26 (0.0)	17.2	0.99 (0.17, 5.82)	0.9918	0.0	0.9962
Female	8/154 (5.2)	2/153 (1.3)	94.5	0/ 16 (0.0)	0/ 28 (0.0)	5.5	0.29 (0.07, 1.19)	0.0864	0.0	0.5305
Baseline FVC percent predicted										
<=70%										
>70%										
Baseline HRCT pattern										
UIP-like										
Other fibrotic patterns										
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Musculoskeletal and connective tissue disorders
PT: Myalgia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2 p-value
Overall	10/331 (3.0)	4/332 (1.2)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	-1.63 (-3.66, 0.39)	0.0 0.5127
Age								
<65 years								
>=65 years								
Sex								
Male	2/177 (1.1)	2/179 (1.1)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-0.01 (-2.21, 2.19)	0.0 0.9982
Female	8/154 (5.2)	2/153 (1.3)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	-3.41 (-7.04, 0.21)	0.0 0.4276
Baseline FVC percent predicted								
<=70%								
>70%								
Baseline HRCT pattern								
UIP-like								
Other fibrotic patterns								
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia								
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Musculoskeletal and connective tissue disorders
PT: Myalgia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2 p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid			
Overall	10/331 (3.0)	4/332 (1.2)	95.8	0/ 27 (0.0)	0/ 54 (0.0)	4.2	0.42 (0.14, 1.27)	0.0 0.6721
Age								
<65 years								
>=65 years								
Sex								
Male	2/177 (1.1)	2/179 (1.1)	83.0	0/ 11 (0.0)	0/ 26 (0.0)	17.0	0.99 (0.16, 5.96)	0.0 0.9963
Female	8/154 (5.2)	2/153 (1.3)	94.6	0/ 16 (0.0)	0/ 28 (0.0)	5.4	0.28 (0.07, 1.17)	0.0 0.5277
Baseline FVC percent predicted								
<=70%								
>70%								
Baseline HRCT pattern								
UIP-like								
Other fibrotic patterns								
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia								
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Musculoskeletal and connective tissue disorders
PT: Pain in extremity

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid					
Overall	10/331 (3.0)	7/332 (2.1)	95.8	0/ 27 (0.0)	1/ 54 (1.9)	4.2	0.77 (0.31, 1.93)	0.5827	0.0	0.5118
Age										
<65 years	3/121 (2.5)	3/139 (2.2)	89.2	0/ 9 (0.0)	0/ 25 (0.0)	10.8	0.88 (0.20, 3.91)	0.8715	0.0	0.9535
>=65 years	7/210 (3.3)	4/193 (2.1)	93.4	0/ 18 (0.0)	1/ 29 (3.4)	6.6	0.75 (0.25, 2.30)	0.6184	0.0	0.4436
Sex										
Male										
Female										
Baseline FVC percent predicted										
<=70%	8/193 (4.1)	3/196 (1.5)	94.5	0/ 10 (0.0)	0/ 17 (0.0)	5.5	0.40 (0.12, 1.39)	0.1500	0.0	0.6419
>70%	2/138 (1.4)	4/136 (2.9)	82.1	0/ 17 (0.0)	1/ 37 (2.7)	17.9	2.11 (0.45, 9.80)	0.3424	0.0	0.9272
Baseline HRCT pattern										
UIP-like	3/206 (1.5)	4/206 (1.9)	87.0	0/ 23 (0.0)	1/ 45 (2.2)	13.0	1.49 (0.38, 5.85)	0.5710	0.0	0.7536
Other fibrotic patterns	7/125 (5.6)	3/126 (2.4)	94.3	0/ 4 (0.0)	0/ 9 (0.0)	5.7	0.46 (0.13, 1.61)	0.2233	0.0	0.6975
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Musculoskeletal and connective tissue disorders
PT: Pain in extremity

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2 p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid			
Overall	10/331 (3.0)	7/332 (2.1)	90.0	0/ 27 (0.0)	1/ 54 (1.9)	10.0	-0.64 (-2.89, 1.61)	0.0 0.4140
Age								
<65 years	3/121 (2.5)	3/139 (2.2)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	-0.29 (-3.81, 3.23)	0.0 0.9605
>=65 years	7/210 (3.3)	4/193 (2.1)	89.7	0/ 18 (0.0)	1/ 29 (3.4)	10.3	-0.79 (-3.81, 2.23)	0.0 0.4041
Sex								
Male								
Female								
Baseline FVC percent predicted								
<=70%	8/193 (4.1)	3/196 (1.5)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-2.44 (-5.65, 0.76)	0.0 0.7171
>70%	2/138 (1.4)	4/136 (2.9)	85.0	0/ 17 (0.0)	1/ 37 (2.7)	15.0	1.66 (-1.58, 4.90)	0.0 0.8202
Baseline HRCT pattern								
UIP-like	3/206 (1.5)	4/206 (1.9)	86.8	0/ 23 (0.0)	1/ 45 (2.2)	13.2	0.71 (-1.66, 3.07)	0.0 0.6661
Other fibrotic patterns	7/125 (5.6)	3/126 (2.4)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-3.06 (-7.85, 1.72)	0.0 0.8203
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia								
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Musculoskeletal and connective tissue disorders
PT: Pain in extremity

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2 p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid			
Overall	10/331 (3.0)	7/332 (2.1)	95.8	0/ 27 (0.0)	1/ 54 (1.9)	4.2	0.77 (0.30, 1.94)	0.0 0.5094
Age								
<65 years	3/121 (2.5)	3/139 (2.2)	89.2	0/ 9 (0.0)	0/ 25 (0.0)	10.8	0.88 (0.19, 4.04)	0.0 0.9537
>=65 years	7/210 (3.3)	4/193 (2.1)	93.6	0/ 18 (0.0)	1/ 29 (3.4)	6.4	0.75 (0.24, 2.32)	0.0 0.4412
Sex								
Male								
Female								
Baseline FVC percent predicted								
<=70%	8/193 (4.1)	3/196 (1.5)	94.6	0/ 10 (0.0)	0/ 17 (0.0)	5.4	0.39 (0.11, 1.39)	0.0 0.6443
>70%	2/138 (1.4)	4/136 (2.9)	82.4	0/ 17 (0.0)	1/ 37 (2.7)	17.6	2.14 (0.45,10.24)	0.0 0.9244
Baseline HRCT pattern								
UIP-like	3/206 (1.5)	4/206 (1.9)	87.2	0/ 23 (0.0)	1/ 45 (2.2)	12.8	1.50 (0.37, 5.98)	0.0 0.7515
Other fibrotic patterns	7/125 (5.6)	3/126 (2.4)	94.5	0/ 4 (0.0)	0/ 9 (0.0)	5.5	0.44 (0.12, 1.62)	0.0 0.7053
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia								
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Nervous system disorders
PT: Dizziness

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk ratio (95% CI)	p-value	I^2	p-value
Overall	15/331 (4.5)	19/332 (5.7)	91.8	1/ 27 (3.7)	2/ 54 (3.7)	8.2	1.24 (0.66, 2.34)	0.5044	0.0	0.8517
Age										
<65 years	6/121 (5.0)	4/139 (2.9)	94.3	0/ 9 (0.0)	2/ 25 (8.0)	5.7	0.76 (0.24, 2.37)	0.6360	0.0	0.3759
>=65 years	9/210 (4.3)	15/193 (7.8)	83.5	1/ 18 (5.6)	0/ 29 (0.0)	16.5	1.56 (0.74, 3.31)	0.2463	31.3	0.2275
Sex										
Male	5/177 (2.8)	9/179 (5.0)	92.3	0/ 11 (0.0)	0/ 26 (0.0)	7.7	1.72 (0.61, 4.86)	0.3058	0.0	0.7958
Female	10/154 (6.5)	10/153 (6.5)	88.7	1/ 16 (6.3)	2/ 28 (7.1)	11.3	1.02 (0.46, 2.27)	0.9573	0.0	0.9197
Baseline FVC percent predicted										
<=70%	10/193 (5.2)	12/196 (6.1)	95.6	0/ 10 (0.0)	1/ 17 (5.9)	4.4	1.24 (0.56, 2.74)	0.5889	0.0	0.6678
>70%	5/138 (3.6)	7/136 (5.1)	78.4	1/ 17 (5.9)	1/ 37 (2.7)	21.6	1.21 (0.44, 3.36)	0.7107	0.0	0.4510
Baseline HRCT pattern										
UIP-like	7/206 (3.4)	10/206 (4.9)	84.1	1/ 23 (4.3)	2/ 45 (4.4)	15.9	1.36 (0.57, 3.28)	0.4875	0.0	0.7955
Other fibrotic patterns	8/125 (6.4)	9/126 (7.1)	95.0	0/ 4 (0.0)	0/ 9 (0.0)	5.0	1.11 (0.45, 2.72)	0.8193	0.0	0.9592
Underlying ILD diagnosis										
iNSIP	3/ 61 (4.9)	2/ 64 (3.1)	86.6	0/ 7 (0.0)	0/ 11 (0.0)	13.4	0.68 (0.14, 3.38)	0.6412	0.0	0.8360
Unclassifiable IIP	1/ 50 (2.0)	6/ 64 (9.4)	70.1	0/ 3 (0.0)	0/ 2 (0.0)	29.9	3.58 (0.61,21.04)	0.1576	0.0	0.4762
HP	6/ 89 (6.7)	5/ 84 (6.0)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	2/ 88 (2.3)	5/ 82 (6.1)	56.6	1/ 12 (8.3)	1/ 34 (2.9)	43.4	1.67 (0.47, 5.98)	0.4292	37.7	0.2052
Other ILD	3/ 43 (7.0)	1/ 38 (2.6)	85.0	0/ 5 (0.0)	0/ 6 (0.0)	15.0	0.47 (0.07, 3.09)	0.4322	0.0	0.6630
Region										
Europe										
Asia	2/ 76 (2.6)	2/ 79 (2.5)	60.5	1/ 27 (3.7)	2/ 54 (3.7)	39.5	0.98 (0.22, 4.36)	0.9757	0.0	0.9801
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Nervous system disorders
PT: Dizziness

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	15/331 (4.5)	19/332 (5.7)	90.2	1/ 27 (3.7)	2/ 54 (3.7)	9.8	1.07 (-2.07, 4.22)	0.0	0.8028
Age									
<65 years	6/121 (5.0)	4/139 (2.9)	90.2	0/ 9 (0.0)	2/ 25 (8.0)	9.8	-1.14 (-5.70, 3.42)	25.4	0.2469
>=65 years	9/210 (4.3)	15/193 (7.8)	89.7	1/ 18 (5.6)	0/ 29 (0.0)	10.3	2.58 (-1.81, 6.97)	37.4	0.2063
Sex									
Male	5/177 (2.8)	9/179 (5.0)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	2.02 (-1.78, 5.82)	0.0	0.7091
Female	10/154 (6.5)	10/153 (6.5)	88.3	1/ 16 (6.3)	2/ 28 (7.1)	11.7	0.14 (-5.05, 5.33)	0.0	0.9180
Baseline FVC percent predicted									
<=70%	10/193 (5.2)	12/196 (6.1)	93.5	0/ 10 (0.0)	1/ 17 (5.9)	6.5	1.24 (-3.19, 5.67)	0.0	0.6143
>70%	5/138 (3.6)	7/136 (5.1)	85.5	1/ 17 (5.9)	1/ 37 (2.7)	14.5	0.84 (-3.68, 5.36)	0.0	0.4870
Baseline HRCT pattern									
UIP-like	7/206 (3.4)	10/206 (4.9)	87.1	1/ 23 (4.3)	2/ 45 (4.4)	12.9	1.28 (-2.32, 4.88)	0.0	0.8081
Other fibrotic patterns	8/125 (6.4)	9/126 (7.1)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	0.71 (-5.35, 6.77)	0.0	0.9586
Underlying ILD diagnosis									
iNSIP	3/ 61 (4.9)	2/ 64 (3.1)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	-1.56 (-8.08, 4.97)	0.0	0.8657
Unclassifiable IIP	1/ 50 (2.0)	6/ 64 (9.4)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	6.96 (-1.27, 15.19)	0.0	0.7872
HP	6/ 89 (6.7)	5/ 84 (6.0)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	2/ 88 (2.3)	5/ 82 (6.1)	82.7	1/ 12 (8.3)	1/ 34 (2.9)	17.3	2.23 (-3.53, 8.00)	4.0	0.3074
Other ILD	3/ 43 (7.0)	1/ 38 (2.6)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	-3.75 (-12.60, 5.11)	0.0	0.7801
Region									
Europe									
Asia	2/ 76 (2.6)	2/ 79 (2.5)	68.3	1/ 27 (3.7)	2/ 54 (3.7)	31.7	-0.07 (-4.46, 4.32)	0.0	0.9845
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Nervous system disorders
PT: Dizziness

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	15/331 (4.5)	19/332 (5.7)	91.7	1/ 27 (3.7)	2/ 54 (3.7)	8.3	1.26 (0.64, 2.45)	0.0	0.8497
Age									
<65 years	6/121 (5.0)	4/139 (2.9)	94.7	0/ 9 (0.0)	2/ 25 (8.0)	5.3	0.75 (0.24, 2.39)	0.0	0.3672
>=65 years	9/210 (4.3)	15/193 (7.8)	82.6	1/ 18 (5.6)	0/ 29 (0.0)	17.4	1.60 (0.72, 3.57)	32.6	0.2233
Sex									
Male	5/177 (2.8)	9/179 (5.0)	92.1	0/ 11 (0.0)	0/ 26 (0.0)	7.9	1.76 (0.60, 5.17)	0.0	0.7933
Female	10/154 (6.5)	10/153 (6.5)	88.7	1/ 16 (6.3)	2/ 28 (7.1)	11.3	1.02 (0.44, 2.40)	0.0	0.9196
Baseline FVC percent predicted									
<=70%	10/193 (5.2)	12/196 (6.1)	95.7	0/ 10 (0.0)	1/ 17 (5.9)	4.3	1.26 (0.55, 2.91)	0.0	0.6636
>70%	5/138 (3.6)	7/136 (5.1)	77.9	1/ 17 (5.9)	1/ 37 (2.7)	22.1	1.22 (0.42, 3.59)	0.0	0.4516
Baseline HRCT pattern									
UIP-like	7/206 (3.4)	10/206 (4.9)	84.0	1/ 23 (4.3)	2/ 45 (4.4)	16.0	1.38 (0.55, 3.45)	0.0	0.7960
Other fibrotic patterns	8/125 (6.4)	9/126 (7.1)	94.9	0/ 4 (0.0)	0/ 9 (0.0)	5.1	1.12 (0.43, 2.93)	0.0	0.9591
Underlying ILD diagnosis									
iNSIP	3/ 61 (4.9)	2/ 64 (3.1)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	0.67 (0.13, 3.53)	0.0	0.8374
Unclassifiable IIP	1/ 50 (2.0)	6/ 64 (9.4)	71.2	0/ 3 (0.0)	0/ 2 (0.0)	28.8	3.90 (0.62,24.53)	0.0	0.5099
HP	6/ 89 (6.7)	5/ 84 (6.0)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	2/ 88 (2.3)	5/ 82 (6.1)	55.8	1/ 12 (8.3)	1/ 34 (2.9)	44.2	1.71 (0.43, 6.80)	37.0	0.2077
Other ILD	3/ 43 (7.0)	1/ 38 (2.6)	85.7	0/ 5 (0.0)	0/ 6 (0.0)	14.3	0.45 (0.06, 3.21)	0.0	0.6705
Region									
Europe									
Asia	2/ 76 (2.6)	2/ 79 (2.5)	60.7	1/ 27 (3.7)	2/ 54 (3.7)	39.3	0.98 (0.21, 4.56)	0.0	0.9803
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Nervous system disorders
PT: Headache

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo: Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	27/331 (8.2)	37/332 (11.1)	98.4	0/ 27 (0.0)	2/ 54 (3.7)	1.6	1.41 (0.88, 2.25)	0.1509	0.0	0.5589
Age										
<65 years	13/121 (10.7)	16/139 (11.5)	97.3	0/ 9 (0.0)	0/ 25 (0.0)	2.7	1.07 (0.54, 2.11)	0.8469	0.0	0.9757
>=65 years	14/210 (6.7)	21/193 (10.9)	96.6	0/ 18 (0.0)	2/ 29 (6.9)	3.4	1.72 (0.91, 3.25)	0.0936	0.0	0.5824
Sex										
Male	6/177 (3.4)	12/179 (6.7)	93.5	0/ 11 (0.0)	0/ 26 (0.0)	6.5	1.91 (0.75, 4.86)	0.1719	0.0	0.7581
Female	21/154 (13.6)	25/153 (16.3)	97.8	0/ 16 (0.0)	2/ 28 (7.1)	2.2	1.26 (0.74, 2.14)	0.3874	0.0	0.4818
Baseline FVC percent predicted										
<=70%	14/193 (7.3)	21/196 (10.7)	96.8	0/ 10 (0.0)	0/ 17 (0.0)	3.2	1.46 (0.77, 2.77)	0.2433	0.0	0.8499
>70%	13/138 (9.4)	16/136 (11.8)	96.8	0/ 17 (0.0)	2/ 37 (5.4)	3.2	1.34 (0.68, 2.63)	0.4039	0.0	0.5462
Baseline HRCT pattern										
UIP-like	15/206 (7.3)	21/206 (10.2)	97.1	0/ 23 (0.0)	2/ 45 (4.4)	2.9	1.48 (0.79, 2.75)	0.2206	0.0	0.5655
Other fibrotic patterns	12/125 (9.6)	16/126 (12.7)	96.6	0/ 4 (0.0)	0/ 9 (0.0)	3.4	1.31 (0.65, 2.63)	0.4448	0.0	0.8952
Underlying ILD diagnosis										
iNSIP	4/ 61 (6.6)	5/ 64 (7.8)	89.6	0/ 7 (0.0)	0/ 11 (0.0)	10.4	1.17 (0.35, 3.91)	0.7969	0.0	0.9336
Unclassifiable IIP	3/ 50 (6.0)	11/ 64 (17.2)	87.5	0/ 3 (0.0)	0/ 2 (0.0)	12.5	2.63 (0.83, 8.32)	0.0995	0.0	0.5969
HP	16/ 89 (18.0)	9/ 84 (10.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	4/ 88 (4.5)	7/ 82 (8.5)	90.9	0/ 12 (0.0)	2/ 34 (5.9)	9.1	2.04 (0.65, 6.43)	0.2213	0.0	0.7476
Other ILD	0/ 43 (0.0)	5/ 38 (13.2)	50.1	0/ 5 (0.0)	0/ 6 (0.0)	49.9	6.34 (0.83,48.52)	0.0752	4.8	0.3054
Region										
Europe										
Asia	5/ 76 (6.6)	2/ 79 (2.5)	92.0	0/ 27 (0.0)	2/ 54 (3.7)	8.0	0.67 (0.18, 2.52)	0.5584	27.1	0.2414
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Nervous system disorders
PT: Headache

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	27/331 (8.2)	37/332 (11.1)	90.0	0/ 27 (0.0)	2/ 54 (3.7)	10.0	3.05 (-1.05, 7.15)	0.0	0.8820
Age									
<65 years	13/121 (10.7)	16/139 (11.5)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	0.69 (-6.32, 7.70)	0.0	0.9167
>=65 years	14/210 (6.7)	21/193 (10.9)	89.7	0/ 18 (0.0)	2/ 29 (6.9)	10.3	4.46 (-0.65, 9.58)	0.0	0.7198
Sex									
Male	6/177 (3.4)	12/179 (6.7)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	3.04 (-1.21, 7.29)	0.0	0.5808
Female	21/154 (13.6)	25/153 (16.3)	87.8	0/ 16 (0.0)	2/ 28 (7.1)	12.2	3.21 (-3.97, 10.38)	0.0	0.5854
Baseline FVC percent predicted									
<=70%	14/193 (7.3)	21/196 (10.7)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	3.24 (-2.14, 8.61)	0.0	0.6484
>70%	13/138 (9.4)	16/136 (11.8)	85.0	0/ 17 (0.0)	2/ 37 (5.4)	15.0	2.77 (-3.60, 9.15)	0.0	0.6531
Baseline HRCT pattern									
UIP-like	15/206 (7.3)	21/206 (10.2)	86.8	0/ 23 (0.0)	2/ 45 (4.4)	13.2	3.10 (-1.75, 7.95)	0.0	0.7803
Other fibrotic patterns	12/125 (9.6)	16/126 (12.7)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	2.95 (-4.57, 10.47)	0.0	0.8309
Underlying ILD diagnosis									
iNSIP	4/ 61 (6.6)	5/ 64 (7.8)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	1.09 (-7.18, 9.36)	0.0	0.9092
Unclassifiable IIP	3/ 50 (6.0)	11/ 64 (17.2)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	10.56 (-0.56, 21.67)	0.0	0.6853
HP	16/ 89 (18.0)	9/ 84 (10.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	7/ 82 (8.5)	82.1	0/ 12 (0.0)	2/ 34 (5.9)	17.9	4.29 (-2.19, 10.76)	0.0	0.8174
Other ILD	0/ 43 (0.0)	5/ 38 (13.2)	86.5	0/ 5 (0.0)	0/ 6 (0.0)	13.5	11.11 (0.51, 21.71)	0.0	0.4204
Region									
Europe									
Asia	5/ 76 (6.6)	2/ 79 (2.5)	67.7	0/ 27 (0.0)	2/ 54 (3.7)	32.3	-1.58 (-6.56, 3.40)	59.5	0.1163
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Nervous system disorders
PT: Headache

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	27/331 (8.2)	37/332 (11.1)	98.3	0/ 27 (0.0)	2/ 54 (3.7)	1.7	1.46 (0.87, 2.44)	0.0	0.5644
Age									
<65 years	13/121 (10.7)	16/139 (11.5)	97.0	0/ 9 (0.0)	0/ 25 (0.0)	3.0	1.08 (0.50, 2.32)	0.0	0.9735
>=65 years	14/210 (6.7)	21/193 (10.9)	96.5	0/ 18 (0.0)	2/ 29 (6.9)	3.5	1.81 (0.91, 3.60)	0.0	0.5851
Sex									
Male	6/177 (3.4)	12/179 (6.7)	93.3	0/ 11 (0.0)	0/ 26 (0.0)	6.7	1.98 (0.74, 5.26)	0.0	0.7527
Female	21/154 (13.6)	25/153 (16.3)	97.7	0/ 16 (0.0)	2/ 28 (7.1)	2.3	1.31 (0.71, 2.42)	0.0	0.4827
Baseline FVC percent predicted									
<=70%	14/193 (7.3)	21/196 (10.7)	96.5	0/ 10 (0.0)	0/ 17 (0.0)	3.5	1.52 (0.75, 3.05)	0.0	0.8413
>70%	13/138 (9.4)	16/136 (11.8)	96.6	0/ 17 (0.0)	2/ 37 (5.4)	3.4	1.38 (0.65, 2.92)	0.0	0.5472
Baseline HRCT pattern									
UIP-like	15/206 (7.3)	21/206 (10.2)	97.0	0/ 23 (0.0)	2/ 45 (4.4)	3.0	1.53 (0.78, 3.00)	0.0	0.5693
Other fibrotic patterns	12/125 (9.6)	16/126 (12.7)	96.4	0/ 4 (0.0)	0/ 9 (0.0)	3.6	1.36 (0.62, 2.96)	0.0	0.8902
Underlying ILD diagnosis									
iNSIP	4/ 61 (6.6)	5/ 64 (7.8)	89.3	0/ 7 (0.0)	0/ 11 (0.0)	10.7	1.19 (0.32, 4.33)	0.0	0.9322
Unclassifiable IIP	3/ 50 (6.0)	11/ 64 (17.2)	87.1	0/ 3 (0.0)	0/ 2 (0.0)	12.9	2.96 (0.84,10.42)	0.0	0.6094
HP	16/ 89 (18.0)	9/ 84 (10.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	7/ 82 (8.5)	90.8	0/ 12 (0.0)	2/ 34 (5.9)	9.2	2.14 (0.64, 7.12)	0.0	0.7488
Other ILD	0/ 43 (0.0)	5/ 38 (13.2)	48.3	0/ 5 (0.0)	0/ 6 (0.0)	51.7	6.99 (0.83,59.27)	3.7	0.3083
Region									
Europe									
Asia	5/ 76 (6.6)	2/ 79 (2.5)	92.2	0/ 27 (0.0)	2/ 54 (3.7)	7.8	0.67 (0.18, 2.49)	29.1	0.2351
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Psychiatric disorders
PT: Depression

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid					
Overall	10/331 (3.0)	9/332 (2.7)	95.8	0/ 27 (0.0)	0/ 54 (0.0)	4.2	0.90 (0.38, 2.15)	0.8151	0.0	0.9599
Age										
<65 years	4/121 (3.3)	3/139 (2.2)	91.7	0/ 9 (0.0)	0/ 25 (0.0)	8.3	0.68 (0.17, 2.76)	0.5910	0.0	0.8565
>=65 years	6/210 (2.9)	6/193 (3.1)	92.4	0/ 18 (0.0)	0/ 29 (0.0)	7.6	1.08 (0.37, 3.16)	0.8864	0.0	0.9681
Sex										
Male	3/177 (1.7)	3/179 (1.7)	87.8	0/ 11 (0.0)	0/ 26 (0.0)	12.2	0.99 (0.22, 4.38)	0.9896	0.0	0.9961
Female	7/154 (4.5)	6/153 (3.9)	93.8	0/ 16 (0.0)	0/ 28 (0.0)	6.2	0.87 (0.31, 2.44)	0.7935	0.0	0.9447
Baseline FVC percent predicted										
<=70%	6/193 (3.1)	5/196 (2.6)	92.8	0/ 10 (0.0)	0/ 17 (0.0)	7.2	0.83 (0.27, 2.56)	0.7503	0.0	0.9257
>70%	4/138 (2.9)	4/136 (2.9)	90.2	0/ 17 (0.0)	0/ 37 (0.0)	9.8	1.01 (0.28, 3.71)	0.9841	0.0	0.9948
Baseline HRCT pattern										
UIP-like	9/206 (4.4)	7/206 (3.4)	95.3	0/ 23 (0.0)	0/ 45 (0.0)	4.7	0.79 (0.31, 2.02)	0.6208	0.0	0.9072
Other fibrotic patterns	1/125 (0.8)	2/126 (1.6)	70.2	0/ 4 (0.0)	0/ 9 (0.0)	29.8	1.69 (0.22,13.07)	0.6146	0.0	0.7772
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	0/ 76 (0.0)	0/ 79 (0.0)	52.9	0/ 27 (0.0)	0/ 54 (0.0)	47.1	1.00 (0.06,17.11)	1.0000	0.0	1.0000
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Psychiatric disorders
PT: Depression

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2 p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid			
Overall	10/331 (3.0)	9/332 (2.7)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	-0.28 (-2.62, 2.06)	0.0 0.9134
Age								
<65 years	4/121 (3.3)	3/139 (2.2)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	-1.04 (-4.83, 2.76)	0.0 0.8606
>=65 years	6/210 (2.9)	6/193 (3.1)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	0.23 (-2.87, 3.33)	0.0 0.9553
Sex								
Male	3/177 (1.7)	3/179 (1.7)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-0.02 (-2.63, 2.60)	0.0 0.9974
Female	7/154 (4.5)	6/153 (3.9)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	-0.55 (-4.64, 3.55)	0.0 0.9012
Baseline FVC percent predicted								
<=70%	6/193 (3.1)	5/196 (2.6)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-0.52 (-3.73, 2.69)	0.0 0.9384
>70%	4/138 (2.9)	4/136 (2.9)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	0.04 (-3.53, 3.61)	0.0 0.9921
Baseline HRCT pattern								
UIP-like	9/206 (4.4)	7/206 (3.4)	86.8	0/ 23 (0.0)	0/ 45 (0.0)	13.2	-0.84 (-4.17, 2.49)	0.0 0.7845
Other fibrotic patterns	1/125 (0.8)	2/126 (1.6)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	0.75 (-2.13, 3.63)	0.0 0.9552
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia	0/ 76 (0.0)	0/ 79 (0.0)	68.0	0/ 27 (0.0)	0/ 54 (0.0)	32.0	0.00 (-2.32, 2.32)	0.0 1.0000
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Psychiatric disorders
PT: Depression

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2 p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid			
Overall	10/331 (3.0)	9/332 (2.7)	95.7	0/ 27 (0.0)	0/ 54 (0.0)	4.3	0.90 (0.37, 2.19)	0.0 0.9593
Age								
<65 years	4/121 (3.3)	3/139 (2.2)	91.7	0/ 9 (0.0)	0/ 25 (0.0)	8.3	0.67 (0.16, 2.82)	0.0 0.8567
>=65 years	6/210 (2.9)	6/193 (3.1)	92.3	0/ 18 (0.0)	0/ 29 (0.0)	7.7	1.08 (0.36, 3.28)	0.0 0.9679
Sex								
Male	3/177 (1.7)	3/179 (1.7)	87.9	0/ 11 (0.0)	0/ 26 (0.0)	12.1	0.99 (0.22, 4.49)	0.0 0.9961
Female	7/154 (4.5)	6/153 (3.9)	93.7	0/ 16 (0.0)	0/ 28 (0.0)	6.3	0.87 (0.30, 2.54)	0.0 0.9436
Baseline FVC percent predicted								
<=70%	6/193 (3.1)	5/196 (2.6)	92.9	0/ 10 (0.0)	0/ 17 (0.0)	7.1	0.83 (0.26, 2.63)	0.0 0.9261
>70%	4/138 (2.9)	4/136 (2.9)	90.1	0/ 17 (0.0)	0/ 37 (0.0)	9.9	1.01 (0.27, 3.85)	0.0 0.9948
Baseline HRCT pattern								
UIP-like	9/206 (4.4)	7/206 (3.4)	95.2	0/ 23 (0.0)	0/ 45 (0.0)	4.8	0.78 (0.29, 2.08)	0.0 0.9050
Other fibrotic patterns	1/125 (0.8)	2/126 (1.6)	71.3	0/ 4 (0.0)	0/ 9 (0.0)	28.7	1.71 (0.21,14.20)	0.0 0.7865
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia	0/ 76 (0.0)	0/ 79 (0.0)	53.1	0/ 27 (0.0)	0/ 54 (0.0)	46.9	1.00 (0.06,17.56)	0.0 1.0000
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Psychiatric disorders
PT: Insomnia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	18/331 (5.4)	18/332 (5.4)	91.0	1/ 27 (3.7)	0/ 54 (0.0)	9.0	0.93 (0.50, 1.72)	0.8166	0.0	0.3618
Age										
<65 years	5/121 (4.1)	10/139 (7.2)	93.2	0/ 9 (0.0)	0/ 25 (0.0)	6.8	1.69 (0.61, 4.67)	0.3106	0.0	0.8093
>=65 years	13/210 (6.2)	8/193 (4.1)	87.9	1/ 18 (5.6)	0/ 29 (0.0)	12.1	0.62 (0.27, 1.41)	0.2559	0.0	0.5727
Sex										
Male	9/177 (5.1)	11/179 (6.1)	95.6	0/ 11 (0.0)	0/ 26 (0.0)	4.4	1.20 (0.52, 2.78)	0.6711	0.0	0.9315
Female	9/154 (5.8)	7/153 (4.6)	83.8	1/ 16 (6.3)	0/ 28 (0.0)	16.2	0.70 (0.28, 1.72)	0.4366	0.0	0.4916
Baseline FVC percent predicted										
<=70%	13/193 (6.7)	13/196 (6.6)	96.6	0/ 10 (0.0)	0/ 17 (0.0)	3.4	0.99 (0.47, 2.04)	0.9681	0.0	0.9941
>70%	5/138 (3.6)	5/136 (3.7)	73.4	1/ 17 (5.9)	0/ 37 (0.0)	26.6	0.81 (0.27, 2.39)	0.7000	0.0	0.3632
Baseline HRCT pattern										
UIP-like	11/206 (5.3)	16/206 (7.8)	86.1	1/ 23 (4.3)	0/ 45 (0.0)	13.9	1.29 (0.64, 2.60)	0.4807	23.7	0.2524
Other fibrotic patterns	7/125 (5.6)	2/126 (1.6)	94.3	0/ 4 (0.0)	0/ 9 (0.0)	5.7	0.32 (0.08, 1.35)	0.1224	0.0	0.5732
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	3/ 64 (4.7)	68.3	0/ 7 (0.0)	0/ 11 (0.0)	31.7	2.27 (0.34,15.21)	0.3982	0.0	0.6481
Unclassifiable IIP	4/ 50 (8.0)	6/ 64 (9.4)	90.3	0/ 3 (0.0)	0/ 2 (0.0)	9.7	1.16 (0.37, 3.65)	0.8057	0.0	0.9364
HP	5/ 89 (5.6)	2/ 84 (2.4)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	6/ 88 (6.8)	6/ 82 (7.3)	75.6	1/ 12 (8.3)	0/ 34 (0.0)	24.4	0.86 (0.32, 2.30)	0.7666	13.4	0.2827
Other ILD	2/ 43 (4.7)	1/ 38 (2.6)	79.1	0/ 5 (0.0)	0/ 6 (0.0)	20.9	0.66 (0.09, 4.80)	0.6784	0.0	0.8023
Region										
Europe										
Asia	10/ 76 (13.2)	10/ 79 (12.7)	85.1	1/ 27 (3.7)	0/ 54 (0.0)	14.9	0.86 (0.39, 1.86)	0.6945	0.0	0.3814
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Psychiatric disorders
PT: Insomnia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	18/331 (5.4)	18/332 (5.4)	90.0	1/ 27 (3.7)	0/ 54 (0.0)	10.0	-0.38 (-3.60, 2.84)	0.0	0.4412
Age									
<65 years	5/121 (4.1)	10/139 (7.2)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	2.76 (-2.40, 7.93)	0.0	0.6538
>=65 years	13/210 (6.2)	8/193 (4.1)	89.7	1/ 18 (5.6)	0/ 29 (0.0)	10.3	-2.38 (-6.47, 1.70)	0.0	0.6349
Sex									
Male	9/177 (5.1)	11/179 (6.1)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	0.97 (-3.50, 5.44)	0.0	0.8609
Female	9/154 (5.8)	7/153 (4.6)	87.8	1/ 16 (6.3)	0/ 28 (0.0)	12.2	-1.84 (-6.53, 2.85)	0.0	0.5379
Baseline FVC percent predicted									
<=70%	13/193 (6.7)	13/196 (6.6)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-0.10 (-4.82, 4.63)	0.0	0.9890
>70%	5/138 (3.6)	5/136 (3.7)	85.0	1/ 17 (5.9)	0/ 37 (0.0)	15.0	-0.81 (-5.05, 3.44)	0.0	0.4127
Baseline HRCT pattern									
UIP-like	11/206 (5.3)	16/206 (7.8)	86.8	1/ 23 (4.3)	0/ 45 (0.0)	13.2	1.55 (-2.80, 5.89)	28.8	0.2360
Other fibrotic patterns	7/125 (5.6)	2/126 (1.6)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-3.82 (-8.38, 0.74)	0.0	0.7767
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	3/ 64 (4.7)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	2.65 (-3.23, 8.52)	0.0	0.7709
Unclassifiable IIP	4/ 50 (8.0)	6/ 64 (9.4)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	1.30 (-8.93, 11.53)	0.0	0.9601
HP	5/ 89 (5.6)	2/ 84 (2.4)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	6/ 88 (6.8)	6/ 82 (7.3)	82.1	1/ 12 (8.3)	0/ 34 (0.0)	17.9	-1.02 (-8.07, 6.03)	0.0	0.3804
Other ILD	2/ 43 (4.7)	1/ 38 (2.6)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	-1.74 (-9.79, 6.31)	0.0	0.8957
Region									
Europe									
Asia	10/ 76 (13.2)	10/ 79 (12.7)	67.7	1/ 27 (3.7)	0/ 54 (0.0)	32.3	-1.50 (-9.16, 6.15)	0.0	0.6522
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Psychiatric disorders
PT: Insomnia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo	Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	I^2	p-value
Overall	18/331 (5.4)	18/332 (5.4)	90.7	1/ 27 (3.7)	0/ 54 (0.0)	9.3	0.93 (0.48, 1.78)	0.0	0.3616
Age									
<65 years	5/121 (4.1)	10/139 (7.2)	92.9	0/ 9 (0.0)	0/ 25 (0.0)	7.1	1.74 (0.60, 5.09)	0.0	0.8041
>=65 years	13/210 (6.2)	8/193 (4.1)	87.7	1/ 18 (5.6)	0/ 29 (0.0)	12.3	0.61 (0.26, 1.44)	0.0	0.5729
Sex									
Male	9/177 (5.1)	11/179 (6.1)	95.4	0/ 11 (0.0)	0/ 26 (0.0)	4.6	1.21 (0.50, 2.95)	0.0	0.9294
Female	9/154 (5.8)	7/153 (4.6)	83.4	1/ 16 (6.3)	0/ 28 (0.0)	16.6	0.69 (0.26, 1.78)	0.0	0.4907
Baseline FVC percent predicted									
<=70%	13/193 (6.7)	13/196 (6.6)	96.4	0/ 10 (0.0)	0/ 17 (0.0)	3.6	0.98 (0.45, 2.15)	0.0	0.9939
>70%	5/138 (3.6)	5/136 (3.7)	73.0	1/ 17 (5.9)	0/ 37 (0.0)	27.0	0.80 (0.26, 2.52)	0.0	0.3620
Baseline HRCT pattern									
UIP-like	11/206 (5.3)	16/206 (7.8)	85.3	1/ 23 (4.3)	0/ 45 (0.0)	14.7	1.31 (0.62, 2.79)	24.8	0.2487
Other fibrotic patterns	7/125 (5.6)	2/126 (1.6)	94.6	0/ 4 (0.0)	0/ 9 (0.0)	5.4	0.31 (0.07, 1.34)	0.0	0.5851
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	3/ 64 (4.7)	68.4	0/ 7 (0.0)	0/ 11 (0.0)	31.6	2.33 (0.32,16.83)	0.0	0.6531
Unclassifiable IIP	4/ 50 (8.0)	6/ 64 (9.4)	90.8	0/ 3 (0.0)	0/ 2 (0.0)	9.2	1.17 (0.33, 4.15)	0.0	0.9400
HP	5/ 89 (5.6)	2/ 84 (2.4)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	6/ 88 (6.8)	6/ 82 (7.3)	74.6	1/ 12 (8.3)	0/ 34 (0.0)	25.4	0.85 (0.29, 2.50)	13.0	0.2835
Other ILD	2/ 43 (4.7)	1/ 38 (2.6)	80.0	0/ 5 (0.0)	0/ 6 (0.0)	20.0	0.64 (0.08, 5.12)	0.0	0.8083
Region									
Europe									
Asia	10/ 76 (13.2)	10/ 79 (12.7)	83.5	1/ 27 (3.7)	0/ 54 (0.0)	16.5	0.84 (0.35, 2.04)	0.0	0.3865
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Acute respiratory failure

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	7/331 (2.1)	16/332 (4.8)	94.0	0/ 27 (0.0)	0/ 54 (0.0)	6.0	2.20 (0.94, 5.17)	0.0697	0.0	0.7023
Age										
<65 years	3/121 (2.5)	3/139 (2.2)	89.2	0/ 9 (0.0)	0/ 25 (0.0)	10.8	0.88 (0.20, 3.91)	0.8715	0.0	0.9535
>=65 years	4/210 (1.9)	13/193 (6.7)	89.0	0/ 18 (0.0)	0/ 29 (0.0)	11.0	3.26 (1.14, 9.33)	0.0278	0.0	0.5499
Sex										
Male	4/177 (2.3)	9/179 (5.0)	90.6	0/ 11 (0.0)	0/ 26 (0.0)	9.4	2.11 (0.69, 6.42)	0.1886	0.0	0.7210
Female	3/154 (1.9)	7/153 (4.6)	86.6	0/ 16 (0.0)	0/ 28 (0.0)	13.4	2.17 (0.62, 7.62)	0.2277	0.0	0.6934
Baseline FVC percent predicted										
<=70%	7/193 (3.6)	10/196 (5.1)	93.8	0/ 10 (0.0)	0/ 17 (0.0)	6.2	1.38 (0.55, 3.46)	0.4907	0.0	0.8704
>70%	0/138 (0.0)	6/136 (4.4)	53.7	0/ 17 (0.0)	0/ 37 (0.0)	46.3	7.49 (0.87,64.13)	0.0661	0.0	0.3197
Baseline HRCT pattern										
UIP-like	5/206 (2.4)	11/206 (5.3)	91.8	0/ 23 (0.0)	0/ 45 (0.0)	8.2	2.10 (0.77, 5.73)	0.1470	0.0	0.7157
Other fibrotic patterns	2/125 (1.6)	5/126 (4.0)	82.5	0/ 4 (0.0)	0/ 9 (0.0)	17.5	2.22 (0.50, 9.89)	0.2948	0.0	0.6865
Underlying ILD diagnosis										
iNSIP	0/ 61 (0.0)	2/ 64 (3.1)	51.3	0/ 7 (0.0)	0/ 11 (0.0)	48.7	3.00 (0.31,29.36)	0.3447	0.0	0.5300
Unclassifiable IIP	0/ 50 (0.0)	3/ 64 (4.7)	50.6	0/ 3 (0.0)	0/ 2 (0.0)	49.4	3.71 (0.38,35.94)	0.2584	0.0	0.4543
HP	3/ 89 (3.4)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	2/ 88 (2.3)	1/ 82 (1.2)	83.3	0/ 12 (0.0)	0/ 34 (0.0)	16.7	0.61 (0.08, 4.91)	0.6455	0.0	0.8079
Other ILD	2/ 43 (4.7)	3/ 38 (7.9)	79.1	0/ 5 (0.0)	0/ 6 (0.0)	20.9	1.55 (0.32, 7.45)	0.5833	0.0	0.8032
Region										
Europe										
Asia	0/ 76 (0.0)	0/ 79 (0.0)	52.9	0/ 27 (0.0)	0/ 54 (0.0)	47.1	1.00 (0.06,17.11)	1.0000	0.0	1.0000
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Acute respiratory failure

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	7/331 (2.1)	16/332 (4.8)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	2.43 (-0.11, 4.98)	0.0	0.3525
Age									
<65 years	3/121 (2.5)	3/139 (2.2)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	-0.29 (-3.81, 3.23)	0.0	0.9605
>=65 years	4/210 (1.9)	13/193 (6.7)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	4.33 (0.66, 8.01)	8.3	0.2965
Sex									
Male	4/177 (2.3)	9/179 (5.0)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	2.54 (-1.13, 6.20)	0.0	0.6378
Female	3/154 (1.9)	7/153 (4.6)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	2.31 (-1.34, 5.95)	0.0	0.5923
Baseline FVC percent predicted									
<=70%	7/193 (3.6)	10/196 (5.1)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	1.38 (-2.52, 5.27)	0.0	0.8402
>70%	0/138 (0.0)	6/136 (4.4)	85.1	0/ 17 (0.0)	0/ 37 (0.0)	14.9	3.73 (0.39, 7.06)	5.8	0.3029
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	11/206 (5.3)	86.8	0/ 23 (0.0)	0/ 45 (0.0)	13.2	2.53 (-0.79, 5.85)	0.0	0.4117
Other fibrotic patterns	2/125 (1.6)	5/126 (4.0)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	2.25 (-1.83, 6.33)	0.0	0.8667
Underlying ILD diagnosis									
iNSIP	0/ 61 (0.0)	2/ 64 (3.1)	87.0	0/ 7 (0.0)	0/ 11 (0.0)	13.0	2.68 (-2.50, 7.85)	0.0	0.7661
Unclassifiable IIP	0/ 50 (0.0)	3/ 64 (4.7)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	4.35 (-2.10, 10.80)	0.0	0.8654
HP	3/ 89 (3.4)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	2/ 88 (2.3)	1/ 82 (1.2)	82.1	0/ 12 (0.0)	0/ 34 (0.0)	17.9	-0.86 (-4.48, 2.75)	0.0	0.8365
Other ILD	2/ 43 (4.7)	3/ 38 (7.9)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	2.80 (-7.21, 12.81)	0.0	0.8374
Region									
Europe									
Asia	0/ 76 (0.0)	0/ 79 (0.0)	68.0	0/ 27 (0.0)	0/ 54 (0.0)	32.0	0.00 (-2.32, 2.32)	0.0	1.0000
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Acute respiratory failure

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	7/331 (2.1)	16/332 (4.8)	93.8	0/ 27 (0.0)	0/ 54 (0.0)	6.2	2.26 (0.94, 5.46)	0.0	0.6965
Age									
<65 years	3/121 (2.5)	3/139 (2.2)	89.2	0/ 9 (0.0)	0/ 25 (0.0)	10.8	0.88 (0.19, 4.04)	0.0	0.9537
>=65 years	4/210 (1.9)	13/193 (6.7)	88.5	0/ 18 (0.0)	0/ 29 (0.0)	11.5	3.41 (1.15,10.14)	0.0	0.5427
Sex									
Male	4/177 (2.3)	9/179 (5.0)	90.4	0/ 11 (0.0)	0/ 26 (0.0)	9.6	2.17 (0.68, 6.87)	0.0	0.7186
Female	3/154 (1.9)	7/153 (4.6)	86.3	0/ 16 (0.0)	0/ 28 (0.0)	13.7	2.22 (0.61, 8.13)	0.0	0.6909
Baseline FVC percent predicted									
<=70%	7/193 (3.6)	10/196 (5.1)	93.7	0/ 10 (0.0)	0/ 17 (0.0)	6.3	1.40 (0.54, 3.66)	0.0	0.8693
>70%	0/138 (0.0)	6/136 (4.4)	52.9	0/ 17 (0.0)	0/ 37 (0.0)	47.1	7.72 (0.82,72.77)	0.0	0.3183
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	11/206 (5.3)	91.5	0/ 23 (0.0)	0/ 45 (0.0)	8.5	2.16 (0.76, 6.11)	0.0	0.7096
Other fibrotic patterns	2/125 (1.6)	5/126 (4.0)	82.9	0/ 4 (0.0)	0/ 9 (0.0)	17.1	2.28 (0.48,10.72)	0.0	0.6972
Underlying ILD diagnosis									
iNSIP	0/ 61 (0.0)	2/ 64 (3.1)	51.5	0/ 7 (0.0)	0/ 11 (0.0)	48.5	3.09 (0.29,33.11)	0.0	0.5372
Unclassifiable IIP	0/ 50 (0.0)	3/ 64 (4.7)	53.1	0/ 3 (0.0)	0/ 2 (0.0)	46.9	4.00 (0.38,41.73)	0.0	0.4877
HP	3/ 89 (3.4)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	2/ 88 (2.3)	1/ 82 (1.2)	83.5	0/ 12 (0.0)	0/ 34 (0.0)	16.5	0.61 (0.08, 4.91)	0.0	0.8084
Other ILD	2/ 43 (4.7)	3/ 38 (7.9)	79.1	0/ 5 (0.0)	0/ 6 (0.0)	20.9	1.60 (0.30, 8.57)	0.0	0.8058
Region									
Europe									
Asia	0/ 76 (0.0)	0/ 79 (0.0)	53.1	0/ 27 (0.0)	0/ 54 (0.0)	46.9	1.00 (0.06,17.56)	0.0	1.0000
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	51/331 (15.4)	40/332 (12.0)	88.5	5/ 27 (18.5)	6/ 54 (11.1)	11.5	0.76 (0.53, 1.09)	0.1401	0.0	0.6542
Age										
<65 years	23/121 (19.0)	18/139 (12.9)	84.8	3/ 9 (33.3)	4/ 25 (16.0)	15.2	0.65 (0.39, 1.09)	0.1050	0.0	0.6259
>=65 years	28/210 (13.3)	22/193 (11.4)	91.6	2/ 18 (11.1)	2/ 29 (6.9)	8.4	0.84 (0.50, 1.38)	0.4831	0.0	0.7465
Sex										
Male	25/177 (14.1)	25/179 (14.0)	89.9	2/ 11 (18.2)	2/ 26 (7.7)	10.1	0.93 (0.57, 1.52)	0.7789	0.0	0.3811
Female	26/154 (16.9)	15/153 (9.8)	87.2	3/ 16 (18.8)	4/ 28 (14.3)	12.8	0.60 (0.35, 1.04)	0.0698	0.0	0.7207
Baseline FVC percent predicted										
<=70%	36/193 (18.7)	25/196 (12.8)	96.6	1/ 10 (10.0)	1/ 17 (5.9)	3.4	0.68 (0.43, 1.08)	0.1032	0.0	0.9130
>70%	15/138 (10.9)	15/136 (11.0)	73.1	4/ 17 (23.5)	5/ 37 (13.5)	26.9	0.90 (0.50, 1.61)	0.7130	0.0	0.4128
Baseline HRCT pattern										
UIP-like	24/206 (11.7)	25/206 (12.1)	78.4	5/ 23 (21.7)	4/ 45 (8.9)	21.6	0.90 (0.56, 1.46)	0.6808	47.8	0.1662
Other fibrotic patterns	27/125 (21.6)	15/126 (11.9)	98.5	0/ 4 (0.0)	2/ 9 (22.2)	1.5	0.60 (0.34, 1.06)	0.0787	11.0	0.2890
Underlying ILD diagnosis										
iNSIP	6/ 61 (9.8)	4/ 64 (6.3)	71.5	2/ 7 (28.6)	1/ 11 (9.1)	28.5	0.55 (0.19, 1.56)	0.2593	0.0	0.5904
Unclassifiable IIP	9/ 50 (18.0)	11/ 64 (17.2)	92.7	1/ 3 (33.3)	1/ 2 (50.0)	7.3	0.99 (0.47, 2.11)	0.9892	0.0	0.6957
HP	19/ 89 (21.3)	15/ 84 (17.9)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	8/ 88 (9.1)	2/ 82 (2.4)	72.3	2/ 12 (16.7)	4/ 34 (11.8)	27.7	0.39 (0.13, 1.15)	0.0879	0.0	0.3847
Other ILD	9/ 43 (20.9)	8/ 38 (21.1)	94.5	0/ 5 (0.0)	0/ 6 (0.0)	5.5	1.01 (0.44, 2.30)	0.9896	0.0	0.9976
Region										
Europe										
Asia	3/ 76 (3.9)	3/ 79 (3.8)	31.4	5/ 27 (18.5)	6/ 54 (11.1)	68.6	0.71 (0.29, 1.75)	0.4602	0.0	0.6285
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	51/331 (15.4)	40/332 (12.0)	90.2	5/ 27 (18.5)	6/ 54 (11.1)	9.8	-3.76 (-8.76, 1.25)	0.0	0.6535
Age									
<65 years	23/121 (19.0)	18/139 (12.9)	90.7	3/ 9 (33.3)	4/ 25 (16.0)	9.3	-7.10 (-15.81, 1.60)	0.0	0.5295
>=65 years	28/210 (13.3)	22/193 (11.4)	90.1	2/ 18 (11.1)	2/ 29 (6.9)	9.9	-2.16 (-8.19, 3.87)	0.0	0.8077
Sex									
Male	25/177 (14.1)	25/179 (14.0)	92.0	2/ 11 (18.2)	2/ 26 (7.7)	8.0	-0.98 (-7.92, 5.95)	0.0	0.4363
Female	26/154 (16.9)	15/153 (9.8)	88.3	3/ 16 (18.8)	4/ 28 (14.3)	11.7	-6.77 (-13.98, 0.43)	0.0	0.8330
Baseline FVC percent predicted									
<=70%	36/193 (18.7)	25/196 (12.8)	93.9	1/ 10 (10.0)	1/ 17 (5.9)	6.1	-5.79 (-12.69, 1.11)	0.0	0.8787
>70%	15/138 (10.9)	15/136 (11.0)	85.5	4/ 17 (23.5)	5/ 37 (13.5)	14.5	-1.32 (-8.47, 5.83)	0.0	0.4086
Baseline HRCT pattern									
UIP-like	24/206 (11.7)	25/206 (12.1)	87.1	5/ 23 (21.7)	4/ 45 (8.9)	12.9	-1.23 (-7.19, 4.73)	42.6	0.1870
Other fibrotic patterns	27/125 (21.6)	15/126 (11.9)	95.2	0/ 4 (0.0)	2/ 9 (22.2)	4.8	-8.29 (-17.18, 0.59)	59.3	0.1172
Underlying ILD diagnosis									
iNSIP	6/ 61 (9.8)	4/ 64 (6.3)	88.0	2/ 7 (28.6)	1/ 11 (9.1)	12.0	-5.50 (-15.03, 4.03)	0.0	0.4211
Unclassifiable IIP	9/ 50 (18.0)	11/ 64 (17.2)	95.9	1/ 3 (33.3)	1/ 2 (50.0)	4.1	-0.10 (-14.09, 13.89)	0.0	0.6989
HP	19/ 89 (21.3)	15/ 84 (17.9)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	8/ 88 (9.1)	2/ 82 (2.4)	82.7	2/ 12 (16.7)	4/ 34 (11.8)	17.3	-6.35 (-13.36, 0.66)	0.0	0.8895
Other ILD	9/ 43 (20.9)	8/ 38 (21.1)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	0.11 (-15.73, 15.95)	0.0	0.9944
Region									
Europe									
Asia	3/ 76 (3.9)	3/ 79 (3.8)	68.3	5/ 27 (18.5)	6/ 54 (11.1)	31.7	-2.45 (-9.23, 4.32)	0.0	0.4279
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	51/331 (15.4)	40/332 (12.0)	88.3	5/ 27 (18.5)	6/ 54 (11.1)	11.7	0.73 (0.48, 1.11)	0.0	0.6530
Age									
<65 years	23/121 (19.0)	18/139 (12.9)	85.2	3/ 9 (33.3)	4/ 25 (16.0)	14.8	0.60 (0.32, 1.12)	0.0	0.5946
>=65 years	28/210 (13.3)	22/193 (11.4)	91.2	2/ 18 (11.1)	2/ 29 (6.9)	8.8	0.81 (0.46, 1.44)	0.0	0.7524
Sex									
Male	25/177 (14.1)	25/179 (14.0)	89.3	2/ 11 (18.2)	2/ 26 (7.7)	10.7	0.92 (0.52, 1.64)	0.0	0.3859
Female	26/154 (16.9)	15/153 (9.8)	87.7	3/ 16 (18.8)	4/ 28 (14.3)	12.3	0.56 (0.30, 1.04)	0.0	0.7409
Baseline FVC percent predicted									
<=70%	36/193 (18.7)	25/196 (12.8)	96.4	1/ 10 (10.0)	1/ 17 (5.9)	3.6	0.63 (0.37, 1.09)	0.0	0.9335
>70%	15/138 (10.9)	15/136 (11.0)	73.6	4/ 17 (23.5)	5/ 37 (13.5)	26.4	0.88 (0.45, 1.73)	0.0	0.4094
Baseline HRCT pattern									
UIP-like	24/206 (11.7)	25/206 (12.1)	77.8	5/ 23 (21.7)	4/ 45 (8.9)	22.2	0.89 (0.52, 1.54)	47.9	0.1661
Other fibrotic patterns	27/125 (21.6)	15/126 (11.9)	98.7	0/ 4 (0.0)	2/ 9 (22.2)	1.3	0.55 (0.28, 1.06)	22.5	0.2561
Underlying ILD diagnosis									
iNSIP	6/ 61 (9.8)	4/ 64 (6.3)	72.2	2/ 7 (28.6)	1/ 11 (9.1)	27.8	0.51 (0.16, 1.65)	0.0	0.5514
Unclassifiable IIP	9/ 50 (18.0)	11/ 64 (17.2)	95.4	1/ 3 (33.3)	1/ 2 (50.0)	4.6	0.99 (0.39, 2.54)	0.0	0.6987
HP	19/ 89 (21.3)	15/ 84 (17.9)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	8/ 88 (9.1)	2/ 82 (2.4)	74.3	2/ 12 (16.7)	4/ 34 (11.8)	25.7	0.36 (0.11, 1.13)	0.0	0.4283
Other ILD	9/ 43 (20.9)	8/ 38 (21.1)	93.6	0/ 5 (0.0)	0/ 6 (0.0)	6.4	1.01 (0.36, 2.84)	0.0	0.9973
Region									
Europe									
Asia	3/ 76 (3.9)	3/ 79 (3.8)	33.2	5/ 27 (18.5)	6/ 54 (11.1)	66.8	0.69 (0.25, 1.89)	0.0	0.5994
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo			
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	57/331 (17.2)	52/332 (15.7)	99.2	0/ 27 (0.0)	0/ 54 (0.0)	0.8	0.91 (0.65, 1.28)	0.5904	0.0	0.9643
Age										
<65 years	15/121 (12.4)	20/139 (14.4)	97.6	0/ 9 (0.0)	0/ 25 (0.0)	2.4	1.16 (0.62, 2.14)	0.6436	0.0	0.9474
>=65 years	42/210 (20.0)	32/193 (16.6)	98.8	0/ 18 (0.0)	0/ 29 (0.0)	1.2	0.83 (0.55, 1.26)	0.3809	0.0	0.9270
Sex										
Male	31/177 (17.5)	37/179 (20.7)	98.7	0/ 11 (0.0)	0/ 26 (0.0)	1.3	1.18 (0.77, 1.81)	0.4530	0.0	0.9392
Female	26/154 (16.9)	15/153 (9.8)	98.2	0/ 16 (0.0)	0/ 28 (0.0)	1.8	0.59 (0.33, 1.06)	0.0768	0.0	0.7937
Baseline FVC percent predicted										
<=70%	43/193 (22.3)	29/196 (14.8)	98.9	0/ 10 (0.0)	0/ 17 (0.0)	1.1	0.67 (0.44, 1.02)	0.0622	0.0	0.8415
>70%	14/138 (10.1)	23/136 (16.9)	97.0	0/ 17 (0.0)	0/ 37 (0.0)	3.0	1.65 (0.89, 3.04)	0.1110	0.0	0.8127
Baseline HRCT pattern										
UIP-like	30/206 (14.6)	37/206 (18.0)	98.5	0/ 23 (0.0)	0/ 45 (0.0)	1.5	1.23 (0.79, 1.91)	0.3551	0.0	0.9208
Other fibrotic patterns	27/125 (21.6)	15/126 (11.9)	98.5	0/ 4 (0.0)	0/ 9 (0.0)	1.5	0.56 (0.31, 0.99)	0.0466	0.0	0.7781
Underlying ILD diagnosis										
iNSIP	5/ 61 (8.2)	5/ 64 (7.8)	91.5	0/ 7 (0.0)	0/ 11 (0.0)	8.5	0.96 (0.31, 2.99)	0.9398	0.0	0.9817
Unclassifiable IIP	7/ 50 (14.0)	11/ 64 (17.2)	94.2	0/ 3 (0.0)	0/ 2 (0.0)	5.8	1.21 (0.52, 2.84)	0.6536	0.0	0.9159
HP	20/ 89 (22.5)	16/ 84 (19.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	14/ 88 (15.9)	11/ 82 (13.4)	97.2	0/ 12 (0.0)	0/ 34 (0.0)	2.8	0.85 (0.41, 1.74)	0.6528	0.0	0.9405
Other ILD	11/ 43 (25.6)	9/ 38 (23.7)	95.4	0/ 5 (0.0)	0/ 6 (0.0)	4.6	0.93 (0.44, 1.97)	0.8480	0.0	0.9688
Region										
Europe										
Asia	4/ 76 (5.3)	5/ 79 (6.3)	90.2	0/ 27 (0.0)	0/ 54 (0.0)	9.8	1.18 (0.35, 4.00)	0.7874	0.0	0.9334
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk difference (95% CI)		I^2	p-value
Overall	57/331 (17.2)	52/332 (15.7)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	-1.40 (-6.50, 3.70)		0.0	0.6849
Age										
<65 years	15/121 (12.4)	20/139 (14.4)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	1.80 (-5.77, 9.36)		0.0	0.7908
>=65 years	42/210 (20.0)	32/193 (16.6)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	-3.07 (-9.88, 3.74)		0.0	0.5458
Sex										
Male	31/177 (17.5)	37/179 (20.7)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	2.89 (-4.64, 10.42)		0.0	0.6487
Female	26/154 (16.9)	15/153 (9.8)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	-6.22 (-12.94, 0.51)		30.4	0.2306
Baseline FVC percent predicted										
<=70%	43/193 (22.3)	29/196 (14.8)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-7.00 (-14.24, 0.25)		0.0	0.3519
>70%	14/138 (10.1)	23/136 (16.9)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	5.75 (-1.20, 12.70)		31.3	0.2276
Baseline HRCT pattern										
UIP-like	30/206 (14.6)	37/206 (18.0)	86.8	0/ 23 (0.0)	0/ 45 (0.0)	13.2	2.95 (-3.28, 9.18)		0.0	0.4706
Other fibrotic patterns	27/125 (21.6)	15/126 (11.9)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-9.23 (-18.05, -0.40)		0.0	0.5101
Underlying ILD diagnosis										
iNSIP	5/ 61 (8.2)	5/ 64 (7.8)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	-0.33 (-8.99, 8.32)		0.0	0.9724
Unclassifiable IIP	7/ 50 (14.0)	11/ 64 (17.2)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	3.01 (-9.93, 15.94)		0.0	0.9089
HP	20/ 89 (22.5)	16/ 84 (19.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)		NC	NC
Autoimmune ILD	14/ 88 (15.9)	11/ 82 (13.4)	82.1	0/ 12 (0.0)	0/ 34 (0.0)	17.9	-2.05 (-10.92, 6.83)		0.0	0.7279
Other ILD	11/ 43 (25.6)	9/ 38 (23.7)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	-1.64 (-18.32, 15.05)		0.0	0.9145
Region										
Europe										
Asia	4/ 76 (5.3)	5/ 79 (6.3)	67.7	0/ 27 (0.0)	0/ 54 (0.0)	32.3	0.72 (-4.51, 5.95)		0.0	0.8140
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	57/331 (17.2)	52/332 (15.7)	99.1	0/ 27 (0.0)	0/ 54 (0.0)	0.9	0.89 (0.59, 1.35)	0.0	0.9578
Age									
<65 years	15/121 (12.4)	20/139 (14.4)	97.3	0/ 9 (0.0)	0/ 25 (0.0)	2.7	1.18 (0.58, 2.41)	0.0	0.9411
>=65 years	42/210 (20.0)	32/193 (16.6)	98.6	0/ 18 (0.0)	0/ 29 (0.0)	1.4	0.80 (0.48, 1.32)	0.0	0.9128
Sex									
Male	31/177 (17.5)	37/179 (20.7)	98.4	0/ 11 (0.0)	0/ 26 (0.0)	1.6	1.22 (0.72, 2.07)	0.0	0.9270
Female	26/154 (16.9)	15/153 (9.8)	98.1	0/ 16 (0.0)	0/ 28 (0.0)	1.9	0.54 (0.28, 1.06)	0.0	0.7691
Baseline FVC percent predicted									
<=70%	43/193 (22.3)	29/196 (14.8)	98.8	0/ 10 (0.0)	0/ 17 (0.0)	1.2	0.61 (0.36, 1.02)	0.0	0.8134
>70%	14/138 (10.1)	23/136 (16.9)	96.5	0/ 17 (0.0)	0/ 37 (0.0)	3.5	1.77 (0.88, 3.58)	0.0	0.7890
Baseline HRCT pattern									
UIP-like	30/206 (14.6)	37/206 (18.0)	98.2	0/ 23 (0.0)	0/ 45 (0.0)	1.8	1.28 (0.76, 2.16)	0.0	0.9071
Other fibrotic patterns	27/125 (21.6)	15/126 (11.9)	98.4	0/ 4 (0.0)	0/ 9 (0.0)	1.6	0.50 (0.25, 0.98)	0.0	0.7537
Underlying ILD diagnosis									
iNSIP	5/ 61 (8.2)	5/ 64 (7.8)	91.3	0/ 7 (0.0)	0/ 11 (0.0)	8.7	0.95 (0.28, 3.27)	0.0	0.9811
Unclassifiable IIP	7/ 50 (14.0)	11/ 64 (17.2)	94.1	0/ 3 (0.0)	0/ 2 (0.0)	5.9	1.26 (0.46, 3.42)	0.0	0.9147
HP	20/ 89 (22.5)	16/ 84 (19.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	14/ 88 (15.9)	11/ 82 (13.4)	96.9	0/ 12 (0.0)	0/ 34 (0.0)	3.1	0.82 (0.36, 1.91)	0.0	0.9320
Other ILD	11/ 43 (25.6)	9/ 38 (23.7)	94.5	0/ 5 (0.0)	0/ 6 (0.0)	5.5	0.91 (0.34, 2.43)	0.0	0.9621
Region									
Europe									
Asia	4/ 76 (5.3)	5/ 79 (6.3)	89.7	0/ 27 (0.0)	0/ 54 (0.0)	10.3	1.19 (0.33, 4.34)	0.0	0.9305
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Epistaxis

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	11/331 (3.3)	14/332 (4.2)	96.1	0/ 27 (0.0)	1/ 54 (1.9)	3.9	1.32 (0.62, 2.81)	0.4765	0.0	0.7245
Age										
<65 years	2/121 (1.7)	5/139 (3.6)	84.6	0/ 9 (0.0)	0/ 25 (0.0)	15.4	2.00 (0.44, 9.03)	0.3701	0.0	0.7442
>=65 years	9/210 (4.3)	9/193 (4.7)	94.8	0/ 18 (0.0)	1/ 29 (3.4)	5.2	1.17 (0.49, 2.79)	0.7267	0.0	0.6313
Sex										
Male	5/177 (2.8)	7/179 (3.9)	92.3	0/ 11 (0.0)	1/ 26 (3.8)	7.7	1.46 (0.50, 4.32)	0.4897	0.0	0.7837
Female	6/154 (3.9)	7/153 (4.6)	92.8	0/ 16 (0.0)	0/ 28 (0.0)	7.2	1.16 (0.41, 3.26)	0.7757	0.0	0.9398
Baseline FVC percent predicted										
<=70%	5/193 (2.6)	7/196 (3.6)	91.5	0/ 10 (0.0)	0/ 17 (0.0)	8.5	1.35 (0.45, 3.99)	0.5915	0.0	0.8793
>70%	6/138 (4.3)	7/136 (5.1)	93.2	0/ 17 (0.0)	1/ 37 (2.7)	6.8	1.27 (0.46, 3.53)	0.6465	0.0	0.7141
Baseline HRCT pattern										
UIP-like	5/206 (2.4)	7/206 (3.4)	91.8	0/ 23 (0.0)	1/ 45 (2.2)	8.2	1.49 (0.51, 4.39)	0.4680	0.0	0.7652
Other fibrotic patterns	6/125 (4.8)	7/126 (5.6)	93.4	0/ 4 (0.0)	0/ 9 (0.0)	6.6	1.15 (0.41, 3.21)	0.7937	0.0	0.9461
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	4/ 76 (5.3)	3/ 79 (3.8)	90.2	0/ 27 (0.0)	1/ 54 (1.9)	9.8	0.90 (0.24, 3.39)	0.8719	0.0	0.5396
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Epistaxis

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	11/331 (3.3)	14/332 (4.2)	90.0	0/ 27 (0.0)	1/ 54 (1.9)	10.0	0.99 (-1.69, 3.66)	0.0	0.7900
Age									
<65 years	2/121 (1.7)	5/139 (3.6)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	1.75 (-1.91, 5.42)	0.0	0.7652
>=65 years	9/210 (4.3)	9/193 (4.7)	89.7	0/ 18 (0.0)	1/ 29 (3.4)	10.3	0.68 (-3.10, 4.46)	0.0	0.6025
Sex									
Male	5/177 (2.8)	7/179 (3.9)	91.6	0/ 11 (0.0)	1/ 26 (3.8)	8.4	1.30 (-2.29, 4.90)	0.0	0.7069
Female	6/154 (3.9)	7/153 (4.6)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	0.60 (-3.50, 4.69)	0.0	0.8925
Baseline FVC percent predicted									
<=70%	5/193 (2.6)	7/196 (3.6)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	0.92 (-2.41, 4.25)	0.0	0.8921
>70%	6/138 (4.3)	7/136 (5.1)	85.0	0/ 17 (0.0)	1/ 37 (2.7)	15.0	1.07 (-3.42, 5.56)	0.0	0.7304
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	7/206 (3.4)	86.8	0/ 23 (0.0)	1/ 45 (2.2)	13.2	1.13 (-1.84, 4.10)	0.0	0.7676
Other fibrotic patterns	6/125 (4.8)	7/126 (5.6)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	0.72 (-4.66, 6.10)	0.0	0.9577
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	4/ 76 (5.3)	3/ 79 (3.8)	67.7	0/ 27 (0.0)	1/ 54 (1.9)	32.3	-0.41 (-5.26, 4.44)	0.0	0.4726
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Epistaxis

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	11/331 (3.3)	14/332 (4.2)	96.1	0/ 27 (0.0)	1/ 54 (1.9)	3.9	1.33 (0.61, 2.91)	0.0	0.7252
Age									
<65 years	2/121 (1.7)	5/139 (3.6)	84.5	0/ 9 (0.0)	0/ 25 (0.0)	15.5	2.03 (0.43, 9.63)	0.0	0.7447
>=65 years	9/210 (4.3)	9/193 (4.7)	94.8	0/ 18 (0.0)	1/ 29 (3.4)	5.2	1.18 (0.48, 2.91)	0.0	0.6294
Sex									
Male	5/177 (2.8)	7/179 (3.9)	92.5	0/ 11 (0.0)	1/ 26 (3.8)	7.5	1.48 (0.49, 4.51)	0.0	0.7805
Female	6/154 (3.9)	7/153 (4.6)	92.6	0/ 16 (0.0)	0/ 28 (0.0)	7.4	1.17 (0.40, 3.43)	0.0	0.9386
Baseline FVC percent predicted									
<=70%	5/193 (2.6)	7/196 (3.6)	91.5	0/ 10 (0.0)	0/ 17 (0.0)	8.5	1.36 (0.44, 4.17)	0.0	0.8798
>70%	6/138 (4.3)	7/136 (5.1)	93.2	0/ 17 (0.0)	1/ 37 (2.7)	6.8	1.28 (0.44, 3.72)	0.0	0.7138
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	7/206 (3.4)	91.8	0/ 23 (0.0)	1/ 45 (2.2)	8.2	1.51 (0.50, 4.55)	0.0	0.7649
Other fibrotic patterns	6/125 (4.8)	7/126 (5.6)	93.5	0/ 4 (0.0)	0/ 9 (0.0)	6.5	1.16 (0.39, 3.42)	0.0	0.9469
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	4/ 76 (5.3)	3/ 79 (3.8)	90.1	0/ 27 (0.0)	1/ 54 (1.9)	9.9	0.89 (0.23, 3.49)	0.0	0.5365
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Interstitial lung disease

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	56/331 (16.9)	28/332 (8.4)	85.7	7/ 27 (25.9)	5/ 54 (9.3)	14.3	0.48 (0.32, 0.71)	0.0003	0.0	0.5644
Age										
<65 years	19/121 (15.7)	5/139 (3.6)	77.5	4/ 9 (44.4)	3/ 25 (12.0)	22.5	0.24 (0.11, 0.52)	0.0004	0.0	0.8408
>=65 years	37/210 (17.6)	23/193 (11.9)	90.5	3/ 18 (16.7)	2/ 29 (6.9)	9.5	0.65 (0.41, 1.04)	0.0696	0.0	0.5836
Sex										
Male	34/177 (19.2)	17/179 (9.5)	96.1	1/ 11 (9.1)	2/ 26 (7.7)	3.9	0.51 (0.30, 0.86)	0.0121	0.0	0.6552
Female	22/154 (14.3)	11/153 (7.2)	74.2	6/ 16 (37.5)	3/ 28 (10.7)	25.8	0.45 (0.25, 0.81)	0.0085	0.0	0.4347
Baseline FVC percent predicted										
<=70%	35/193 (18.1)	22/196 (11.2)	87.5	4/ 10 (40.0)	2/ 17 (11.8)	12.5	0.58 (0.36, 0.92)	0.0217	0.0	0.3579
>70%	21/138 (15.2)	6/136 (4.4)	83.5	3/ 17 (17.6)	3/ 37 (8.1)	16.5	0.32 (0.15, 0.68)	0.0031	0.0	0.6022
Baseline HRCT pattern										
UIP-like	43/206 (20.9)	22/206 (10.7)	84.4	6/ 23 (26.1)	2/ 45 (4.4)	15.6	0.46 (0.29, 0.72)	0.0007	45.4	0.1759
Other fibrotic patterns	13/125 (10.4)	6/126 (4.8)	90.4	1/ 4 (25.0)	3/ 9 (33.3)	9.6	0.54 (0.24, 1.24)	0.1478	0.0	0.3292
Underlying ILD diagnosis										
iNSIP	11/ 61 (18.0)	6/ 64 (9.4)	82.2	2/ 7 (28.6)	1/ 11 (9.1)	17.8	0.48 (0.21, 1.14)	0.0959	0.0	0.6877
Unclassifiable IIP	16/ 50 (32.0)	9/ 64 (14.1)	93.3	1/ 3 (33.3)	0/ 2 (0.0)	6.7	0.44 (0.21, 0.88)	0.0216	0.0	0.9226
HP	11/ 89 (12.4)	8/ 84 (9.5)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	12/ 88 (13.6)	5/ 82 (6.1)	72.3	3/ 12 (25.0)	2/ 34 (5.9)	27.7	0.39 (0.17, 0.91)	0.0300	0.0	0.5167
Other ILD	6/ 43 (14.0)	0/ 38 (0.0)	84.9	1/ 5 (20.0)	1/ 6 (16.7)	15.1	0.19 (0.03, 1.16)	0.0729	28.6	0.2367
Region										
Europe										
Asia	28/ 76 (36.8)	14/ 79 (17.7)	75.4	7/ 27 (25.9)	5/ 54 (9.3)	24.6	0.45 (0.28, 0.74)	0.0015	0.0	0.6238
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Interstitial lung disease

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	56/331 (16.9)	28/332 (8.4)	90.2	7/ 27 (25.9)	5/ 54 (9.3)	9.8	-9.29 (-14.16, -4.41)	0.0	0.3969
Age									
<65 years	19/121 (15.7)	5/139 (3.6)	90.7	4/ 9 (44.4)	3/ 25 (12.0)	9.3	-13.99 (-21.27, -6.72)	20.2	0.2629
>=65 years	37/210 (17.6)	23/193 (11.9)	90.1	3/ 18 (16.7)	2/ 29 (6.9)	9.9	-6.11 (-12.61, 0.39)	0.0	0.7002
Sex									
Male	34/177 (19.2)	17/179 (9.5)	92.0	1/ 11 (9.1)	2/ 26 (7.7)	8.0	-9.05 (-15.88, -2.22)	0.0	0.4402
Female	22/154 (14.3)	11/153 (7.2)	88.3	6/ 16 (37.5)	3/ 28 (10.7)	11.7	-9.40 (-16.21, -2.59)	50.2	0.1564
Baseline FVC percent predicted									
<=70%	35/193 (18.1)	22/196 (11.2)	93.9	4/ 10 (40.0)	2/ 17 (11.8)	6.1	-8.21 (-15.10, -1.31)	31.0	0.2287
>70%	21/138 (15.2)	6/136 (4.4)	85.5	3/ 17 (17.6)	3/ 37 (8.1)	14.5	-10.62 (-17.22, -4.03)	0.0	0.9072
Baseline HRCT pattern									
UIP-like	43/206 (20.9)	22/206 (10.7)	87.1	6/ 23 (26.1)	2/ 45 (4.4)	12.9	-11.67 (-18.21, -5.12)	19.2	0.2660
Other fibrotic patterns	13/125 (10.4)	6/126 (4.8)	95.8	1/ 4 (25.0)	3/ 9 (33.3)	4.2	-5.05 (-11.67, 1.58)	0.0	0.6043
Underlying ILD diagnosis									
iNSIP	11/ 61 (18.0)	6/ 64 (9.4)	88.0	2/ 7 (28.6)	1/ 11 (9.1)	12.0	-9.96 (-21.45, 1.52)	0.0	0.5903
Unclassifiable IIP	16/ 50 (32.0)	9/ 64 (14.1)	94.4	1/ 3 (33.3)	0/ 2 (0.0)	5.6	-18.27 (-33.29, -3.25)	0.0	0.8570
HP	11/ 89 (12.4)	8/ 84 (9.5)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	12/ 88 (13.6)	5/ 82 (6.1)	82.7	3/ 12 (25.0)	2/ 34 (5.9)	17.3	-9.54 (-18.10, -0.98)	0.0	0.4045
Other ILD	6/ 43 (14.0)	0/ 38 (0.0)	88.3	1/ 5 (20.0)	1/ 6 (16.7)	11.7	-12.42 (-23.55, -1.29)	0.0	0.6702
Region									
Europe									
Asia	28/ 76 (36.8)	14/ 79 (17.7)	68.3	7/ 27 (25.9)	5/ 54 (9.3)	31.7	-18.34 (-29.36, -7.32)	0.0	0.8332
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Interstitial lung disease

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2 p-value
Overall	56/331 (16.9)	28/332 (8.4)	85.8	7/ 27 (25.9)	5/ 54 (9.3)	14.2	0.43 (0.27, 0.67)	0.0 0.5235
Age								
<65 years	19/121 (15.7)	5/139 (3.6)	79.1	4/ 9 (44.4)	3/ 25 (12.0)	20.9	0.19 (0.08, 0.47)	0.0 0.8776
>=65 years	37/210 (17.6)	23/193 (11.9)	90.1	3/ 18 (16.7)	2/ 29 (6.9)	9.9	0.61 (0.35, 1.04)	0.0 0.5959
Sex								
Male	34/177 (19.2)	17/179 (9.5)	96.0	1/ 11 (9.1)	2/ 26 (7.7)	4.0	0.46 (0.25, 0.84)	0.0 0.6302
Female	22/154 (14.3)	11/153 (7.2)	74.9	6/ 16 (37.5)	3/ 28 (10.7)	25.1	0.40 (0.20, 0.79)	0.0 0.3430
Baseline FVC percent predicted								
<=70%	35/193 (18.1)	22/196 (11.2)	87.6	4/ 10 (40.0)	2/ 17 (11.8)	12.4	0.52 (0.30, 0.91)	2.8 0.3106
>70%	21/138 (15.2)	6/136 (4.4)	84.1	3/ 17 (17.6)	3/ 37 (8.1)	15.9	0.28 (0.12, 0.64)	0.0 0.6374
Baseline HRCT pattern								
UIP-like	43/206 (20.9)	22/206 (10.7)	83.5	6/ 23 (26.1)	2/ 45 (4.4)	16.5	0.40 (0.24, 0.68)	45.7 0.1749
Other fibrotic patterns	13/125 (10.4)	6/126 (4.8)	93.1	1/ 4 (25.0)	3/ 9 (33.3)	6.9	0.50 (0.20, 1.26)	0.0 0.3886
Underlying ILD diagnosis								
iNSIP	11/ 61 (18.0)	6/ 64 (9.4)	82.1	2/ 7 (28.6)	1/ 11 (9.1)	17.9	0.43 (0.16, 1.15)	0.0 0.6625
Unclassifiable IIP	16/ 50 (32.0)	9/ 64 (14.1)	93.4	1/ 3 (33.3)	0/ 2 (0.0)	6.6	0.34 (0.14, 0.84)	0.0 0.9023
HP	11/ 89 (12.4)	8/ 84 (9.5)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC NC
Autoimmune ILD	12/ 88 (13.6)	5/ 82 (6.1)	72.3	3/ 12 (25.0)	2/ 34 (5.9)	27.7	0.35 (0.13, 0.91)	0.0 0.4884
Other ILD	6/ 43 (14.0)	0/ 38 (0.0)	86.9	1/ 5 (20.0)	1/ 6 (16.7)	13.1	0.17 (0.02, 1.12)	19.3 0.2658
Region								
Europe								
Asia	28/ 76 (36.8)	14/ 79 (17.7)	73.5	7/ 27 (25.9)	5/ 54 (9.3)	26.5	0.35 (0.18, 0.66)	0.0 0.7515
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Oropharyngeal pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	8/331 (2.4)	10/332 (3.0)	94.7	0/ 27 (0.0)	1/ 54 (1.9)	5.3	1.31 (0.54, 3.19)	0.5489	0.0	0.7198
Age										
<65 years	3/121 (2.5)	5/139 (3.6)	89.2	0/ 9 (0.0)	0/ 25 (0.0)	10.8	1.40 (0.37, 5.36)	0.6213	0.0	0.8741
>=65 years	5/210 (2.4)	5/193 (2.6)	91.0	0/ 18 (0.0)	1/ 29 (3.4)	9.0	1.23 (0.39, 3.85)	0.7274	0.0	0.6400
Sex										
Male	5/177 (2.8)	5/179 (2.8)	92.3	0/ 11 (0.0)	1/ 26 (3.8)	7.7	1.10 (0.35, 3.49)	0.8730	0.0	0.6625
Female	3/154 (1.9)	5/153 (3.3)	86.6	0/ 16 (0.0)	0/ 28 (0.0)	13.4	1.59 (0.42, 6.00)	0.4962	0.0	0.8123
Baseline FVC percent predicted										
<=70%	6/193 (3.1)	9/196 (4.6)	92.8	0/ 10 (0.0)	1/ 17 (5.9)	7.2	1.56 (0.59, 4.11)	0.3721	0.0	0.7621
>70%	2/138 (1.4)	1/136 (0.7)	82.1	0/ 17 (0.0)	0/ 37 (0.0)	17.9	0.60 (0.08, 4.64)	0.6206	0.0	0.7824
Baseline HRCT pattern										
UIP-like	6/206 (2.9)	4/206 (1.9)	93.1	0/ 23 (0.0)	1/ 45 (2.2)	6.9	0.79 (0.25, 2.53)	0.6973	0.0	0.5020
Other fibrotic patterns	2/125 (1.6)	6/126 (4.8)	82.5	0/ 4 (0.0)	0/ 9 (0.0)	17.5	2.63 (0.61,11.28)	0.1931	0.0	0.6268
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	2/ 76 (2.6)	1/ 79 (1.3)	82.1	0/ 27 (0.0)	1/ 54 (1.9)	17.9	0.84 (0.13, 5.43)	0.8569	0.0	0.4620
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Oropharyngeal pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	8/331 (2.4)	10/332 (3.0)	90.0	0/ 27 (0.0)	1/ 54 (1.9)	10.0	0.72 (-1.59, 3.02)	0.0	0.7169
Age									
<65 years	3/121 (2.5)	5/139 (3.6)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	1.01 (-2.92, 4.94)	0.0	0.8647
>=65 years	5/210 (2.4)	5/193 (2.6)	89.7	0/ 18 (0.0)	1/ 29 (3.4)	10.3	0.53 (-2.40, 3.46)	0.0	0.5705
Sex									
Male	5/177 (2.8)	5/179 (2.8)	91.6	0/ 11 (0.0)	1/ 26 (3.8)	8.4	0.28 (-3.05, 3.60)	0.0	0.5869
Female	3/154 (1.9)	5/153 (3.3)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	1.16 (-2.15, 4.47)	0.0	0.7844
Baseline FVC percent predicted									
<=70%	6/193 (3.1)	9/196 (4.6)	93.5	0/ 10 (0.0)	1/ 17 (5.9)	6.5	1.74 (-2.00, 5.48)	0.0	0.6538
>70%	2/138 (1.4)	1/136 (0.7)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	-0.61 (-2.98, 1.76)	0.0	0.8587
Baseline HRCT pattern									
UIP-like	6/206 (2.9)	4/206 (1.9)	86.8	0/ 23 (0.0)	1/ 45 (2.2)	13.2	-0.56 (-3.30, 2.19)	0.0	0.4298
Other fibrotic patterns	2/125 (1.6)	6/126 (4.8)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	3.01 (-1.31, 7.33)	0.0	0.8229
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	2/ 76 (2.6)	1/ 79 (1.3)	67.7	0/ 27 (0.0)	1/ 54 (1.9)	32.3	-0.34 (-3.89, 3.20)	0.0	0.4053
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Oropharyngeal pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	8/331 (2.4)	10/332 (3.0)	94.7	0/ 27 (0.0)	1/ 54 (1.9)	5.3	1.32 (0.53, 3.28)	0.0	0.7193
Age									
<65 years	3/121 (2.5)	5/139 (3.6)	89.1	0/ 9 (0.0)	0/ 25 (0.0)	10.9	1.42 (0.35, 5.66)	0.0	0.8738
>=65 years	5/210 (2.4)	5/193 (2.6)	91.2	0/ 18 (0.0)	1/ 29 (3.4)	8.8	1.23 (0.38, 3.95)	0.0	0.6370
Sex									
Male	5/177 (2.8)	5/179 (2.8)	92.6	0/ 11 (0.0)	1/ 26 (3.8)	7.4	1.10 (0.34, 3.58)	0.0	0.6591
Female	3/154 (1.9)	5/153 (3.3)	86.5	0/ 16 (0.0)	0/ 28 (0.0)	13.5	1.61 (0.41, 6.30)	0.0	0.8117
Baseline FVC percent predicted									
<=70%	6/193 (3.1)	9/196 (4.6)	93.1	0/ 10 (0.0)	1/ 17 (5.9)	6.9	1.59 (0.58, 4.34)	0.0	0.7554
>70%	2/138 (1.4)	1/136 (0.7)	82.3	0/ 17 (0.0)	0/ 37 (0.0)	17.7	0.59 (0.08, 4.62)	0.0	0.7836
Baseline HRCT pattern									
UIP-like	6/206 (2.9)	4/206 (1.9)	93.2	0/ 23 (0.0)	1/ 45 (2.2)	6.8	0.79 (0.25, 2.55)	0.0	0.4997
Other fibrotic patterns	2/125 (1.6)	6/126 (4.8)	82.8	0/ 4 (0.0)	0/ 9 (0.0)	17.2	2.72 (0.60,12.34)	0.0	0.6384
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	2/ 76 (2.6)	1/ 79 (1.3)	82.4	0/ 27 (0.0)	1/ 54 (1.9)	17.6	0.84 (0.13, 5.32)	0.0	0.4603
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Productive cough

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	7/331 (2.1)	10/332 (3.0)	94.0	0/ 27 (0.0)	2/ 54 (3.7)	6.0	1.58 (0.63, 3.95)	0.3298	0.0	0.5840
Age										
<65 years	3/121 (2.5)	4/139 (2.9)	89.2	0/ 9 (0.0)	0/ 25 (0.0)	10.8	1.14 (0.28, 4.63)	0.8512	0.0	0.9496
>=65 years	4/210 (1.9)	6/193 (3.1)	89.0	0/ 18 (0.0)	2/ 29 (6.9)	11.0	1.92 (0.60, 6.13)	0.2718	0.0	0.5998
Sex										
Male										
Female										
Baseline FVC percent predicted										
<=70%	7/193 (3.6)	6/196 (3.1)	93.8	0/ 10 (0.0)	0/ 17 (0.0)	6.2	0.85 (0.30, 2.40)	0.7646	0.0	0.9359
>70%	0/138 (0.0)	4/136 (2.9)	53.7	0/ 17 (0.0)	2/ 37 (5.4)	46.3	6.68 (0.72,62.07)	0.0950	0.0	0.7247
Baseline HRCT pattern										
UIP-like	2/206 (1.0)	8/206 (3.9)	81.7	0/ 23 (0.0)	2/ 45 (4.4)	18.3	4.00 (0.97,16.46)	0.0544	0.0	0.9978
Other fibrotic patterns	5/125 (4.0)	2/126 (1.6)	92.2	0/ 4 (0.0)	0/ 9 (0.0)	7.8	0.44 (0.10, 1.97)	0.2863	0.0	0.6813
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Productive cough

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2 p-value
Overall	7/331 (2.1)	10/332 (3.0)	90.0	0/ 27 (0.0)	2/ 54 (3.7)	10.0	1.17 (-1.10, 3.44)	0.0 0.4693
Age								
<65 years	3/121 (2.5)	4/139 (2.9)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	0.36 (-3.38, 4.09)	0.0 0.9513
>=65 years	4/210 (1.9)	6/193 (3.1)	89.7	0/ 18 (0.0)	2/ 29 (6.9)	10.3	1.76 (-1.25, 4.78)	0.0 0.3878
Sex								
Male								
Female								
Baseline FVC percent predicted								
<=70%	7/193 (3.6)	6/196 (3.1)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-0.53 (-3.99, 2.93)	0.0 0.9378
>70%	0/138 (0.0)	4/136 (2.9)	85.1	0/ 17 (0.0)	2/ 37 (5.4)	14.9	3.26 (0.19, 6.34)	0.0 0.6729
Baseline HRCT pattern								
UIP-like	2/206 (1.0)	8/206 (3.9)	86.8	0/ 23 (0.0)	2/ 45 (4.4)	13.2	3.10 (0.31, 5.89)	0.0 0.7529
Other fibrotic patterns	5/125 (4.0)	2/126 (1.6)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-2.30 (-6.39, 1.80)	0.0 0.8642
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia								
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Productive cough

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	7/331 (2.1)	10/332 (3.0)	94.1	0/ 27 (0.0)	2/ 54 (3.7)	5.9	1.60 (0.63, 4.06)	0.0	0.5803
Age									
<65 years	3/121 (2.5)	4/139 (2.9)	89.2	0/ 9 (0.0)	0/ 25 (0.0)	10.8	1.15 (0.27, 4.84)	0.0	0.9497
>=65 years	4/210 (1.9)	6/193 (3.1)	89.6	0/ 18 (0.0)	2/ 29 (6.9)	10.4	1.95 (0.60, 6.36)	0.0	0.5889
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%	7/193 (3.6)	6/196 (3.1)	93.8	0/ 10 (0.0)	0/ 17 (0.0)	6.2	0.85 (0.29, 2.48)	0.0	0.9359
>70%	0/138 (0.0)	4/136 (2.9)	54.7	0/ 17 (0.0)	2/ 37 (5.4)	45.3	6.98 (0.70,69.16)	0.0	0.7369
Baseline HRCT pattern									
UIP-like	2/206 (1.0)	8/206 (3.9)	82.0	0/ 23 (0.0)	2/ 45 (4.4)	18.0	4.14 (0.98,17.40)	0.0	0.9919
Other fibrotic patterns	5/125 (4.0)	2/126 (1.6)	92.6	0/ 4 (0.0)	0/ 9 (0.0)	7.4	0.43 (0.09, 1.99)	0.0	0.6922
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Respiratory failure

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid					
Overall	10/331 (3.0)	11/332 (3.3)	79.0	2/ 27 (7.4)	2/ 54 (3.7)	21.0	0.97 (0.45, 2.08)	0.9402	0.0	0.4598
Age										
<65 years	2/121 (1.7)	6/139 (4.3)	53.5	1/ 9 (11.1)	0/ 25 (0.0)	46.5	1.49 (0.44, 5.05)	0.5184	58.3	0.1217
>=65 years	8/210 (3.8)	5/193 (2.6)	86.1	1/ 18 (5.6)	2/ 29 (6.9)	13.9	0.76 (0.28, 2.04)	0.5824	0.0	0.6468
Sex										
Male	8/177 (4.5)	6/179 (3.4)	85.1	1/ 11 (9.1)	2/ 26 (7.7)	14.9	0.76 (0.29, 1.95)	0.5644	0.0	0.9183
Female	2/154 (1.3)	5/153 (3.3)	53.5	1/ 16 (6.3)	0/ 28 (0.0)	46.5	1.47 (0.41, 5.26)	0.5542	42.5	0.1873
Baseline FVC percent predicted										
<=70%	9/193 (4.7)	8/196 (4.1)	84.0	1/ 10 (10.0)	0/ 17 (0.0)	16.0	0.78 (0.33, 1.86)	0.5742	0.0	0.4477
>70%	1/138 (0.7)	3/136 (2.2)	42.0	1/ 17 (5.9)	2/ 37 (5.4)	58.0	1.81 (0.38, 8.61)	0.4548	0.0	0.4687
Baseline HRCT pattern										
UIP-like	8/206 (3.9)	7/206 (3.4)	75.1	2/ 23 (8.7)	1/ 45 (2.2)	24.9	0.72 (0.29, 1.76)	0.4735	0.0	0.3441
Other fibrotic patterns	2/125 (1.6)	4/126 (3.2)	82.5	0/ 4 (0.0)	1/ 9 (11.1)	17.5	2.06 (0.45, 9.52)	0.3525	0.0	0.9195
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	3/ 76 (3.9)	0/ 79 (0.0)	57.2	2/ 27 (7.4)	2/ 54 (3.7)	42.8	0.29 (0.06, 1.41)	0.1267	0.0	0.4756
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Respiratory failure

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	10/331 (3.0)	11/332 (3.3)	90.2	2/ 27 (7.4)	2/ 54 (3.7)	9.8	-0.10 (-2.74, 2.54)	0.0	0.4923
Age									
<65 years	2/121 (1.7)	6/139 (4.3)	90.2	1/ 9 (11.1)	0/ 25 (0.0)	9.8	1.38 (-2.90, 5.66)	21.8	0.2580
>=65 years	8/210 (3.8)	5/193 (2.6)	90.1	1/ 18 (5.6)	2/ 29 (6.9)	9.9	-0.96 (-4.35, 2.42)	0.0	0.7284
Sex									
Male	8/177 (4.5)	6/179 (3.4)	92.0	1/ 11 (9.1)	2/ 26 (7.7)	8.0	-1.19 (-5.23, 2.85)	0.0	0.9822
Female	2/154 (1.3)	5/153 (3.3)	87.8	1/ 16 (6.3)	0/ 28 (0.0)	12.2	1.00 (-2.40, 4.40)	13.0	0.2836
Baseline FVC percent predicted									
<=70%	9/193 (4.7)	8/196 (4.1)	93.5	1/ 10 (10.0)	0/ 17 (0.0)	6.5	-1.15 (-5.20, 2.90)	0.0	0.4371
>70%	1/138 (0.7)	3/136 (2.2)	85.5	1/ 17 (5.9)	2/ 37 (5.4)	14.5	1.20 (-1.91, 4.31)	0.0	0.7786
Baseline HRCT pattern									
UIP-like	8/206 (3.9)	7/206 (3.4)	87.1	2/ 23 (8.7)	1/ 45 (2.2)	12.9	-1.26 (-4.78, 2.27)	0.0	0.3598
Other fibrotic patterns	2/125 (1.6)	4/126 (3.2)	95.2	0/ 4 (0.0)	1/ 9 (11.1)	4.8	1.96 (-1.94, 5.87)	0.0	0.6239
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	3/ 76 (3.9)	0/ 79 (0.0)	68.6	2/ 27 (7.4)	2/ 54 (3.7)	31.4	-3.84 (-8.71, 1.04)	0.0	0.9751
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Respiratory failure

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2 p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid			
Overall	10/331 (3.0)	11/332 (3.3)	79.0	2/ 27 (7.4)	2/ 54 (3.7)	21.0	0.97 (0.44, 2.15)	0.0 0.4603
Age								
<65 years	2/121 (1.7)	6/139 (4.3)	53.1	1/ 9 (11.1)	0/ 25 (0.0)	46.9	1.51 (0.41, 5.59)	57.9 0.1234
>=65 years	8/210 (3.8)	5/193 (2.6)	86.7	1/ 18 (5.6)	2/ 29 (6.9)	13.3	0.75 (0.27, 2.08)	0.0 0.6510
Sex								
Male	8/177 (4.5)	6/179 (3.4)	85.7	1/ 11 (9.1)	2/ 26 (7.7)	14.3	0.75 (0.28, 2.01)	0.0 0.9264
Female	2/154 (1.3)	5/153 (3.3)	53.2	1/ 16 (6.3)	0/ 28 (0.0)	46.8	1.48 (0.39, 5.66)	42.5 0.1874
Baseline FVC percent predicted								
<=70%	9/193 (4.7)	8/196 (4.1)	83.9	1/ 10 (10.0)	0/ 17 (0.0)	16.1	0.77 (0.31, 1.93)	0.0 0.4418
>70%	1/138 (0.7)	3/136 (2.2)	42.8	1/ 17 (5.9)	2/ 37 (5.4)	57.2	1.85 (0.36, 9.59)	0.0 0.4775
Baseline HRCT pattern								
UIP-like	8/206 (3.9)	7/206 (3.4)	74.9	2/ 23 (8.7)	1/ 45 (2.2)	25.1	0.71 (0.28, 1.82)	0.0 0.3411
Other fibrotic patterns	2/125 (1.6)	4/126 (3.2)	84.5	0/ 4 (0.0)	1/ 9 (11.1)	15.5	2.13 (0.44,10.26)	0.0 0.8923
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia	3/ 76 (3.9)	0/ 79 (0.0)	57.9	2/ 27 (7.4)	2/ 54 (3.7)	42.1	0.28 (0.06, 1.37)	0.0 0.4866
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Skin and subcutaneous tissue disorders
PT: Pruritus

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo			
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	18/331 (5.4)	12/332 (3.6)	97.6	0/ 27 (0.0)	2/ 54 (3.7)	2.4	0.74 (0.37, 1.48)	0.4015	0.0	0.3342
Age										
<65 years	2/121 (1.7)	5/139 (3.6)	84.6	0/ 9 (0.0)	0/ 25 (0.0)	15.4	2.00 (0.44, 9.03)	0.3701	0.0	0.7442
>=65 years	16/210 (7.6)	7/193 (3.6)	97.0	0/ 18 (0.0)	2/ 29 (6.9)	3.0	0.59 (0.26, 1.31)	0.1954	35.1	0.2143
Sex										
Male	10/177 (5.6)	6/179 (3.4)	96.0	0/ 11 (0.0)	1/ 26 (3.8)	4.0	0.67 (0.26, 1.71)	0.3991	0.0	0.4862
Female	8/154 (5.2)	6/153 (3.9)	94.5	0/ 16 (0.0)	1/ 28 (3.6)	5.5	0.85 (0.32, 2.27)	0.7530	0.0	0.5151
Baseline FVC percent predicted										
<=70%	11/193 (5.7)	7/196 (3.6)	96.0	0/ 10 (0.0)	0/ 17 (0.0)	4.0	0.64 (0.26, 1.58)	0.3347	0.0	0.8230
>70%	7/138 (5.1)	5/136 (3.7)	94.2	0/ 17 (0.0)	2/ 37 (5.4)	5.8	0.91 (0.32, 2.58)	0.8616	0.0	0.3863
Baseline HRCT pattern										
UIP-like	10/206 (4.9)	10/206 (4.9)	95.7	0/ 23 (0.0)	2/ 45 (4.4)	4.3	1.13 (0.50, 2.57)	0.7714	0.0	0.4542
Other fibrotic patterns	8/125 (6.4)	2/126 (1.6)	95.0	0/ 4 (0.0)	0/ 9 (0.0)	5.0	0.29 (0.07, 1.17)	0.0811	0.0	0.5325
Underlying ILD diagnosis										
iNSIP	4/ 61 (6.6)	4/ 64 (6.3)	89.6	0/ 7 (0.0)	0/ 11 (0.0)	10.4	0.96 (0.27, 3.41)	0.9471	0.0	0.9819
Unclassifiable IIP	3/ 50 (6.0)	2/ 64 (3.1)	87.5	0/ 3 (0.0)	0/ 2 (0.0)	12.5	0.58 (0.12, 2.80)	0.4981	0.0	0.7550
HP	7/ 89 (7.9)	3/ 84 (3.6)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	4/ 88 (4.5)	3/ 82 (3.7)	90.9	0/ 12 (0.0)	2/ 34 (5.9)	9.1	1.07 (0.28, 4.07)	0.9227	0.0	0.4789
Other ILD	0/ 43 (0.0)	0/ 38 (0.0)	50.1	0/ 5 (0.0)	0/ 6 (0.0)	49.9	1.00 (0.07,15.15)	1.0000	0.0	1.0000
Region										
Europe										
Asia	4/ 76 (5.3)	6/ 79 (7.6)	90.2	0/ 27 (0.0)	2/ 54 (3.7)	9.8	1.69 (0.53, 5.37)	0.3703	0.0	0.5967
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Skin and subcutaneous tissue disorders
PT: Pruritus

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk difference (95% CI)		Heterogeneity I^2 p-value
Overall	18/331 (5.4)	12/332 (3.6)	90.0	0/ 27 (0.0)	2/ 54 (3.7)	10.0	-1.28 (-4.21, 1.65)		48.6 0.1630
Age									
<65 years	2/121 (1.7)	5/139 (3.6)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	1.75 (-1.91, 5.42)		0.0 0.7652
>=65 years	16/210 (7.6)	7/193 (3.6)	89.7	0/ 18 (0.0)	2/ 29 (6.9)	10.3	-2.90 (-7.07, 1.28)		62.7 0.1016
Sex									
Male	10/177 (5.6)	6/179 (3.4)	91.6	0/ 11 (0.0)	1/ 26 (3.8)	8.4	-1.80 (-5.89, 2.29)		0.0 0.3889
Female	8/154 (5.2)	6/153 (3.9)	87.8	0/ 16 (0.0)	1/ 28 (3.6)	12.2	-0.70 (-5.01, 3.60)		0.0 0.4370
Baseline FVC percent predicted									
<=70%	11/193 (5.7)	7/196 (3.6)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-1.99 (-6.00, 2.02)		0.0 0.7717
>70%	7/138 (5.1)	5/136 (3.7)	85.0	0/ 17 (0.0)	2/ 37 (5.4)	15.0	-0.41 (-4.79, 3.98)		24.4 0.2500
Baseline HRCT pattern									
UIP-like	10/206 (4.9)	10/206 (4.9)	86.8	0/ 23 (0.0)	2/ 45 (4.4)	13.2	0.57 (-3.19, 4.33)		0.0 0.3587
Other fibrotic patterns	8/125 (6.4)	2/126 (1.6)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-4.58 (-9.35, 0.19)		0.0 0.7341
Underlying ILD diagnosis									
iNSIP	4/ 61 (6.6)	4/ 64 (6.3)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	-0.27 (-8.16, 7.62)		0.0 0.9775
Unclassifiable IIP	3/ 50 (6.0)	2/ 64 (3.1)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	-2.71 (-10.69, 5.27)		0.0 0.9161
HP	7/ 89 (7.9)	3/ 84 (3.6)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)		NC NC
Autoimmune ILD	4/ 88 (4.5)	3/ 82 (3.7)	82.1	0/ 12 (0.0)	2/ 34 (5.9)	17.9	0.28 (-5.05, 5.61)		0.0 0.3340
Other ILD	0/ 43 (0.0)	0/ 38 (0.0)	86.5	0/ 5 (0.0)	0/ 6 (0.0)	13.5	-0.00 (-5.65, 5.65)		0.0 1.0000
Region									
Europe									
Asia	4/ 76 (5.3)	6/ 79 (7.6)	67.7	0/ 27 (0.0)	2/ 54 (3.7)	32.3	2.75 (-2.93, 8.43)		0.0 0.8086
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Skin and subcutaneous tissue disorders
PT: Pruritus

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	18/331 (5.4)	12/332 (3.6)	97.6	0/ 27 (0.0)	2/ 54 (3.7)	2.4	0.74 (0.36, 1.50)	0.0	0.3276
Age									
<65 years	2/121 (1.7)	5/139 (3.6)	84.5	0/ 9 (0.0)	0/ 25 (0.0)	15.5	2.03 (0.43, 9.63)	0.0	0.7447
>=65 years	16/210 (7.6)	7/193 (3.6)	97.2	0/ 18 (0.0)	2/ 29 (6.9)	2.8	0.57 (0.25, 1.31)	37.6	0.2056
Sex									
Male	10/177 (5.6)	6/179 (3.4)	96.1	0/ 11 (0.0)	1/ 26 (3.8)	3.9	0.65 (0.25, 1.73)	0.0	0.4815
Female	8/154 (5.2)	6/153 (3.9)	94.6	0/ 16 (0.0)	1/ 28 (3.6)	5.4	0.85 (0.31, 2.34)	0.0	0.5112
Baseline FVC percent predicted									
<=70%	11/193 (5.7)	7/196 (3.6)	96.0	0/ 10 (0.0)	0/ 17 (0.0)	4.0	0.63 (0.25, 1.61)	0.0	0.8210
>70%	7/138 (5.1)	5/136 (3.7)	94.3	0/ 17 (0.0)	2/ 37 (5.4)	5.7	0.91 (0.31, 2.63)	0.0	0.3793
Baseline HRCT pattern									
UIP-like	10/206 (4.9)	10/206 (4.9)	95.8	0/ 23 (0.0)	2/ 45 (4.4)	4.2	1.14 (0.48, 2.67)	0.0	0.4495
Other fibrotic patterns	8/125 (6.4)	2/126 (1.6)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	0.27 (0.06, 1.14)	0.0	0.5442
Underlying ILD diagnosis									
iNSIP	4/ 61 (6.6)	4/ 64 (6.3)	89.5	0/ 7 (0.0)	0/ 11 (0.0)	10.5	0.96 (0.25, 3.70)	0.0	0.9816
Unclassifiable IIP	3/ 50 (6.0)	2/ 64 (3.1)	88.8	0/ 3 (0.0)	0/ 2 (0.0)	11.2	0.56 (0.10, 3.02)	0.0	0.7756
HP	7/ 89 (7.9)	3/ 84 (3.6)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	3/ 82 (3.7)	91.3	0/ 12 (0.0)	2/ 34 (5.9)	8.7	1.07 (0.28, 4.14)	0.0	0.4719
Other ILD	0/ 43 (0.0)	0/ 38 (0.0)	51.8	0/ 5 (0.0)	0/ 6 (0.0)	48.2	1.00 (0.06,17.19)	0.0	1.0000
Region									
Europe									
Asia	4/ 76 (5.3)	6/ 79 (7.6)	89.9	0/ 27 (0.0)	2/ 54 (3.7)	10.1	1.75 (0.52, 5.85)	0.0	0.6001
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Skin and subcutaneous tissue disorders
PT: Rash

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	10/331 (3.0)	12/332 (3.6)	84.9	1/ 27 (3.7)	0/ 54 (0.0)	15.1	1.05 (0.48, 2.29)	0.8949	3.2	0.3095
Age										
<65 years	6/121 (5.0)	6/139 (4.3)	77.5	1/ 9 (11.1)	0/ 25 (0.0)	22.5	0.72 (0.27, 1.96)	0.5226	0.0	0.3500
>=65 years	4/210 (1.9)	6/193 (3.1)	89.0	0/ 18 (0.0)	0/ 29 (0.0)	11.0	1.56 (0.48, 5.14)	0.4622	0.0	0.8184
Sex										
Male	3/177 (1.7)	8/179 (4.5)	62.3	1/ 11 (9.1)	0/ 26 (0.0)	37.7	1.73 (0.59, 5.09)	0.3200	57.8	0.1237
Female	7/154 (4.5)	4/153 (2.6)	93.8	0/ 16 (0.0)	0/ 28 (0.0)	6.2	0.60 (0.19, 1.91)	0.3880	0.0	0.7967
Baseline FVC percent predicted										
<=70%	7/193 (3.6)	5/196 (2.6)	80.3	1/ 10 (10.0)	0/ 17 (0.0)	19.7	0.62 (0.22, 1.75)	0.3642	0.0	0.5455
>70%	3/138 (2.2)	7/136 (5.1)	87.3	0/ 17 (0.0)	0/ 37 (0.0)	12.7	2.19 (0.62, 7.74)	0.2214	0.0	0.7003
Baseline HRCT pattern										
UIP-like	5/206 (2.4)	7/206 (3.4)	73.8	1/ 23 (4.3)	0/ 45 (0.0)	26.2	1.10 (0.40, 3.02)	0.8534	13.7	0.2816
Other fibrotic patterns	5/125 (4.0)	5/126 (4.0)	92.2	0/ 4 (0.0)	0/ 9 (0.0)	7.8	0.99 (0.31, 3.18)	0.9901	0.0	0.9971
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	2/ 64 (3.1)	68.3	0/ 7 (0.0)	0/ 11 (0.0)	31.7	1.62 (0.22,12.11)	0.6389	0.0	0.7826
Unclassifiable IIP	1/ 50 (2.0)	3/ 64 (4.7)	70.1	0/ 3 (0.0)	0/ 2 (0.0)	29.9	1.94 (0.29,12.90)	0.4924	0.0	0.6995
HP	4/ 89 (4.5)	6/ 84 (7.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	3/ 88 (3.4)	1/ 82 (1.2)	60.8	1/ 12 (8.3)	0/ 34 (0.0)	39.2	0.30 (0.05, 1.72)	0.1759	0.0	0.7647
Other ILD	1/ 43 (2.3)	0/ 38 (0.0)	74.3	0/ 5 (0.0)	0/ 6 (0.0)	25.7	0.51 (0.05, 5.65)	0.5868	0.0	0.6769
Region										
Europe										
Asia	1/ 76 (1.3)	2/ 79 (2.5)	36.4	1/ 27 (3.7)	0/ 54 (0.0)	63.6	0.86 (0.17, 4.41)	0.8566	11.9	0.2868
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Skin and subcutaneous tissue disorders
PT: Rash

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	10/331 (3.0)	12/332 (3.6)	90.0	1/ 27 (3.7)	0/ 54 (0.0)	10.0	0.17 (-2.42, 2.77)	0.0	0.3546
Age									
<65 years	6/121 (5.0)	6/139 (4.3)	90.2	1/ 9 (11.1)	0/ 25 (0.0)	9.8	-1.60 (-6.73, 3.52)	0.0	0.4014
>=65 years	4/210 (1.9)	6/193 (3.1)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	1.08 (-1.80, 3.96)	0.0	0.7863
Sex									
Male	3/177 (1.7)	8/179 (4.5)	91.6	1/ 11 (9.1)	0/ 26 (0.0)	8.4	1.82 (-1.83, 5.46)	24.5	0.2499
Female	7/154 (4.5)	4/153 (2.6)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	-1.70 (-5.49, 2.10)	0.0	0.6962
Baseline FVC percent predicted									
<=70%	7/193 (3.6)	5/196 (2.6)	93.5	1/ 10 (10.0)	0/ 17 (0.0)	6.5	-1.61 (-5.12, 1.90)	0.0	0.4613
>70%	3/138 (2.2)	7/136 (5.1)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	2.53 (-1.41, 6.46)	0.0	0.5024
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	7/206 (3.4)	86.8	1/ 23 (4.3)	0/ 45 (0.0)	13.2	0.29 (-2.82, 3.39)	0.0	0.3289
Other fibrotic patterns	5/125 (4.0)	5/126 (4.0)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-0.03 (-4.82, 4.76)	0.0	0.9982
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	2/ 64 (3.1)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	1.29 (-4.01, 6.58)	0.0	0.8860
Unclassifiable IIP	1/ 50 (2.0)	3/ 64 (4.7)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	2.54 (-4.26, 9.33)	0.0	0.9213
HP	4/ 89 (4.5)	6/ 84 (7.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	3/ 88 (3.4)	1/ 82 (1.2)	82.1	1/ 12 (8.3)	0/ 34 (0.0)	17.9	-3.23 (-8.03, 1.58)	0.0	0.5253
Other ILD	1/ 43 (2.3)	0/ 38 (0.0)	86.5	0/ 5 (0.0)	0/ 6 (0.0)	13.5	-1.96 (-8.75, 4.82)	0.0	0.8813
Region									
Europe									
Asia	1/ 76 (1.3)	2/ 79 (2.5)	67.7	1/ 27 (3.7)	0/ 54 (0.0)	32.3	-0.34 (-4.34, 3.66)	0.0	0.3197
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Skin and subcutaneous tissue disorders
PT: Rash

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	10/331 (3.0)	12/332 (3.6)	84.6	1/ 27 (3.7)	0/ 54 (0.0)	15.4	1.06 (0.47, 2.37)	3.6	0.3085
Age									
<65 years	6/121 (5.0)	6/139 (4.3)	77.2	1/ 9 (11.1)	0/ 25 (0.0)	22.8	0.71 (0.24, 2.06)	0.0	0.3473
>=65 years	4/210 (1.9)	6/193 (3.1)	88.9	0/ 18 (0.0)	0/ 29 (0.0)	11.1	1.58 (0.47, 5.36)	0.0	0.8177
Sex									
Male	3/177 (1.7)	8/179 (4.5)	61.9	1/ 11 (9.1)	0/ 26 (0.0)	38.1	1.76 (0.56, 5.55)	57.4	0.1253
Female	7/154 (4.5)	4/153 (2.6)	93.8	0/ 16 (0.0)	0/ 28 (0.0)	6.2	0.59 (0.18, 1.94)	0.0	0.7941
Baseline FVC percent predicted									
<=70%	7/193 (3.6)	5/196 (2.6)	80.5	1/ 10 (10.0)	0/ 17 (0.0)	19.5	0.61 (0.21, 1.79)	0.0	0.5342
>70%	3/138 (2.2)	7/136 (5.1)	87.0	0/ 17 (0.0)	0/ 37 (0.0)	13.0	2.25 (0.61, 8.33)	0.0	0.6957
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	7/206 (3.4)	73.5	1/ 23 (4.3)	0/ 45 (0.0)	26.5	1.10 (0.38, 3.17)	14.1	0.2806
Other fibrotic patterns	5/125 (4.0)	5/126 (4.0)	92.4	0/ 4 (0.0)	0/ 9 (0.0)	7.6	0.99 (0.29, 3.35)	0.0	0.9972
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	2/ 64 (3.1)	68.7	0/ 7 (0.0)	0/ 11 (0.0)	31.3	1.64 (0.20,13.19)	0.0	0.7868
Unclassifiable IIP	1/ 50 (2.0)	3/ 64 (4.7)	72.2	0/ 3 (0.0)	0/ 2 (0.0)	27.8	2.02 (0.28,14.65)	0.0	0.7246
HP	4/ 89 (4.5)	6/ 84 (7.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	3/ 88 (3.4)	1/ 82 (1.2)	61.0	1/ 12 (8.3)	0/ 34 (0.0)	39.0	0.29 (0.05, 1.80)	0.0	0.7485
Other ILD	1/ 43 (2.3)	0/ 38 (0.0)	75.6	0/ 5 (0.0)	0/ 6 (0.0)	24.4	0.50 (0.04, 5.95)	0.0	0.6868
Region									
Europe									
Asia	1/ 76 (1.3)	2/ 79 (2.5)	36.1	1/ 27 (3.7)	0/ 54 (0.0)	63.9	0.86 (0.15, 4.84)	12.3	0.2856
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Vascular disorders
PT: Hypertension

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo			
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	15/331 (4.5)	16/332 (4.8)	97.1	0/ 27 (0.0)	2/ 54 (3.7)	2.9	1.15 (0.59, 2.25)	0.6871	0.0	0.4753
Age										
<65 years	7/121 (5.8)	9/139 (6.5)	95.1	0/ 9 (0.0)	1/ 25 (4.0)	4.9	1.18 (0.47, 2.99)	0.7263	0.0	0.7236
>=65 years	8/210 (3.8)	7/193 (3.6)	94.2	0/ 18 (0.0)	1/ 29 (3.4)	5.8	1.05 (0.41, 2.71)	0.9212	0.0	0.5830
Sex										
Male	6/177 (3.4)	7/179 (3.9)	93.5	0/ 11 (0.0)	0/ 26 (0.0)	6.5	1.14 (0.41, 3.23)	0.7998	0.0	0.9488
Female	9/154 (5.8)	9/153 (5.9)	95.1	0/ 16 (0.0)	2/ 28 (7.1)	4.9	1.16 (0.49, 2.73)	0.7330	0.0	0.4322
Baseline FVC percent predicted										
<=70%	10/193 (5.2)	10/196 (5.1)	95.6	0/ 10 (0.0)	0/ 17 (0.0)	4.4	0.99 (0.43, 2.27)	0.9724	0.0	0.9941
>70%	5/138 (3.6)	6/136 (4.4)	92.0	0/ 17 (0.0)	2/ 37 (5.4)	8.0	1.43 (0.48, 4.30)	0.5201	0.0	0.5497
Baseline HRCT pattern										
UIP-like	8/206 (3.9)	7/206 (3.4)	94.7	0/ 23 (0.0)	2/ 45 (4.4)	5.3	1.04 (0.41, 2.67)	0.9320	0.0	0.4166
Other fibrotic patterns	7/125 (5.6)	9/126 (7.1)	94.3	0/ 4 (0.0)	0/ 9 (0.0)	5.7	1.26 (0.50, 3.20)	0.6268	0.0	0.9099
Underlying ILD diagnosis										
iNSIP	4/ 61 (6.6)	4/ 64 (6.3)	89.6	0/ 7 (0.0)	1/ 11 (9.1)	10.4	1.13 (0.33, 3.85)	0.8474	0.0	0.5838
Unclassifiable IIP	1/ 50 (2.0)	1/ 64 (1.6)	70.1	0/ 3 (0.0)	0/ 2 (0.0)	29.9	0.85 (0.09, 7.69)	0.8826	0.0	0.9164
HP	2/ 89 (2.2)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	5/ 88 (5.7)	5/ 82 (6.1)	92.6	0/ 12 (0.0)	1/ 34 (2.9)	7.4	1.17 (0.37, 3.69)	0.7913	0.0	0.7166
Other ILD	3/ 43 (7.0)	1/ 38 (2.6)	85.0	0/ 5 (0.0)	0/ 6 (0.0)	15.0	0.47 (0.07, 3.09)	0.4322	0.0	0.6630
Region										
Europe										
Asia	1/ 76 (1.3)	4/ 79 (5.1)	69.6	0/ 27 (0.0)	2/ 54 (3.7)	30.4	3.89 (0.61,25.03)	0.1521	0.0	0.9855
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Vascular disorders
PT: Hypertension

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	15/331 (4.5)	16/332 (4.8)	90.0	0/ 27 (0.0)	2/ 54 (3.7)	10.0	0.62 (-2.35, 3.60)	0.0	0.3947
Age									
<65 years	7/121 (5.8)	9/139 (6.5)	90.2	0/ 9 (0.0)	1/ 25 (4.0)	9.8	0.99 (-4.45, 6.43)	0.0	0.6910
>=65 years	8/210 (3.8)	7/193 (3.6)	89.7	0/ 18 (0.0)	1/ 29 (3.4)	10.3	0.18 (-3.30, 3.66)	0.0	0.5305
Sex									
Male	6/177 (3.4)	7/179 (3.9)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	0.48 (-3.21, 4.16)	0.0	0.9295
Female	9/154 (5.8)	9/153 (5.9)	87.8	0/ 16 (0.0)	2/ 28 (7.1)	12.2	0.87 (-3.99, 5.73)	0.0	0.3263
Baseline FVC percent predicted									
<=70%	10/193 (5.2)	10/196 (5.1)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-0.07 (-4.27, 4.13)	0.0	0.9914
>70%	5/138 (3.6)	6/136 (4.4)	85.0	0/ 17 (0.0)	2/ 37 (5.4)	15.0	1.45 (-2.79, 5.69)	0.0	0.4381
Baseline HRCT pattern									
UIP-like	8/206 (3.9)	7/206 (3.4)	86.8	0/ 23 (0.0)	2/ 45 (4.4)	13.2	0.15 (-3.17, 3.47)	8.8	0.2951
Other fibrotic patterns	7/125 (5.6)	9/126 (7.1)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	1.47 (-4.43, 7.37)	0.0	0.9140
Underlying ILD diagnosis									
iNSIP	4/ 61 (6.6)	4/ 64 (6.3)	86.8	0/ 7 (0.0)	1/ 11 (9.1)	13.2	0.81 (-7.31, 8.93)	0.0	0.5197
Unclassifiable IIP	1/ 50 (2.0)	1/ 64 (1.6)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	-0.41 (-5.94, 5.11)	0.0	0.9871
HP	2/ 89 (2.2)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	5/ 88 (5.7)	5/ 82 (6.1)	82.1	0/ 12 (0.0)	1/ 34 (2.9)	17.9	0.85 (-5.28, 6.97)	0.0	0.7124
Other ILD	3/ 43 (7.0)	1/ 38 (2.6)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	-3.75 (-12.60, 5.11)	0.0	0.7801
Region									
Europe									
Asia	1/ 76 (1.3)	4/ 79 (5.1)	67.7	0/ 27 (0.0)	2/ 54 (3.7)	32.3	3.70 (-0.63, 8.04)	0.0	0.9765
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

SOC: Vascular disorders
PT: Hypertension

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)		I^2	p-value
Overall	15/331 (4.5)	16/332 (4.8)	97.1	0/ 27 (0.0)	2/ 54 (3.7)	2.9	1.16 (0.57, 2.32)		0.0	0.4717
Age										
<65 years	7/121 (5.8)	9/139 (6.5)	95.1	0/ 9 (0.0)	1/ 25 (4.0)	4.9	1.19 (0.45, 3.19)		0.0	0.7216
>=65 years	8/210 (3.8)	7/193 (3.6)	94.3	0/ 18 (0.0)	1/ 29 (3.4)	5.7	1.05 (0.40, 2.80)		0.0	0.5803
Sex										
Male	6/177 (3.4)	7/179 (3.9)	93.4	0/ 11 (0.0)	0/ 26 (0.0)	6.6	1.15 (0.39, 3.37)		0.0	0.9483
Female	9/154 (5.8)	9/153 (5.9)	95.2	0/ 16 (0.0)	2/ 28 (7.1)	4.8	1.17 (0.48, 2.87)		0.0	0.4244
Baseline FVC percent predicted										
<=70%	10/193 (5.2)	10/196 (5.1)	95.5	0/ 10 (0.0)	0/ 17 (0.0)	4.5	0.98 (0.41, 2.37)		0.0	0.9940
>70%	5/138 (3.6)	6/136 (4.4)	92.2	0/ 17 (0.0)	2/ 37 (5.4)	7.8	1.45 (0.47, 4.48)		0.0	0.5443
Baseline HRCT pattern										
UIP-like	8/206 (3.9)	7/206 (3.4)	94.8	0/ 23 (0.0)	2/ 45 (4.4)	5.2	1.04 (0.40, 2.73)		0.0	0.4113
Other fibrotic patterns	7/125 (5.6)	9/126 (7.1)	94.3	0/ 4 (0.0)	0/ 9 (0.0)	5.7	1.28 (0.47, 3.46)		0.0	0.9101
Underlying ILD diagnosis										
iNSIP	4/ 61 (6.6)	4/ 64 (6.3)	90.3	0/ 7 (0.0)	1/ 11 (9.1)	9.7	1.14 (0.31, 4.19)		0.0	0.5765
Unclassifiable IIP	1/ 50 (2.0)	1/ 64 (1.6)	72.9	0/ 3 (0.0)	0/ 2 (0.0)	27.1	0.84 (0.08, 8.81)		0.0	0.9238
HP	2/ 89 (2.2)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)		NC	NC
Autoimmune ILD	5/ 88 (5.7)	5/ 82 (6.1)	92.5	0/ 12 (0.0)	1/ 34 (2.9)	7.5	1.18 (0.35, 3.93)		0.0	0.7157
Other ILD	3/ 43 (7.0)	1/ 38 (2.6)	85.7	0/ 5 (0.0)	0/ 6 (0.0)	14.3	0.45 (0.06, 3.21)		0.0	0.6705
Region										
Europe										
Asia	1/ 76 (1.3)	4/ 79 (5.1)	69.6	0/ 27 (0.0)	2/ 54 (3.7)	30.4	4.05 (0.61,26.94)		0.0	0.9863
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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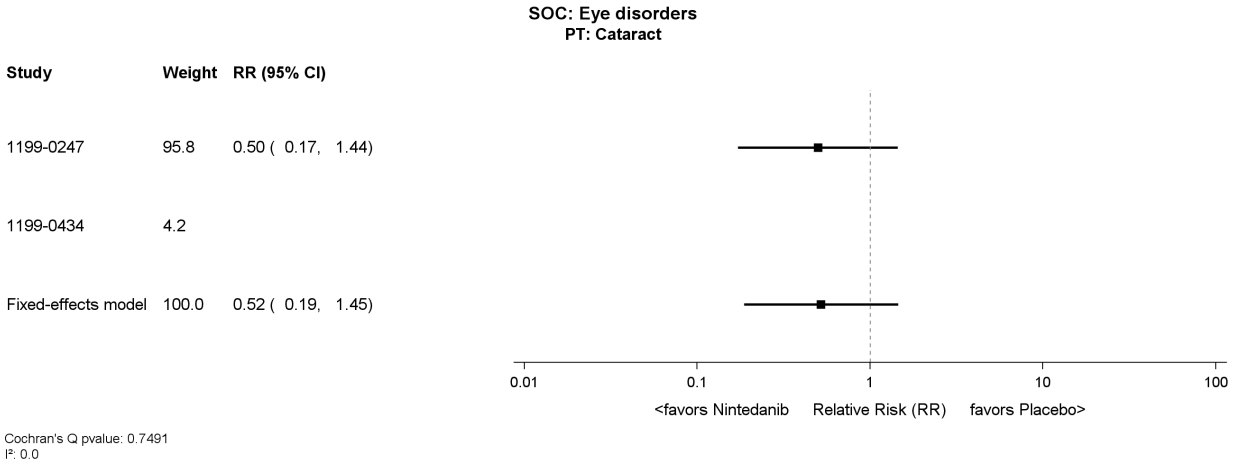

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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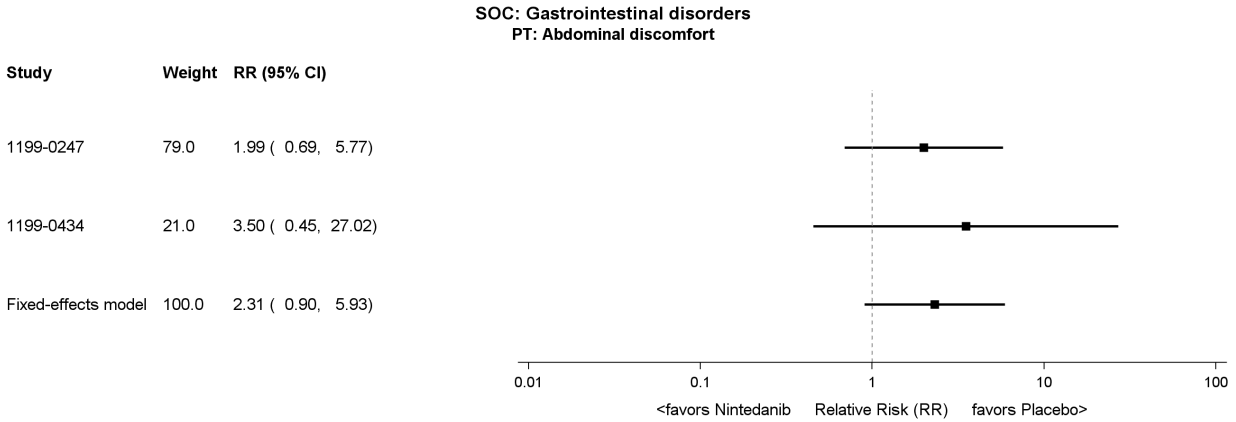

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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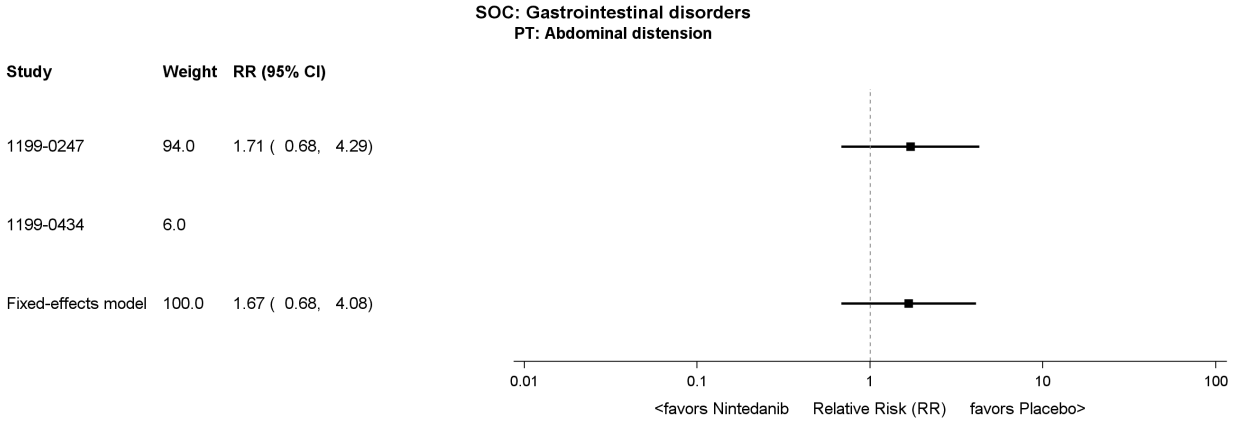

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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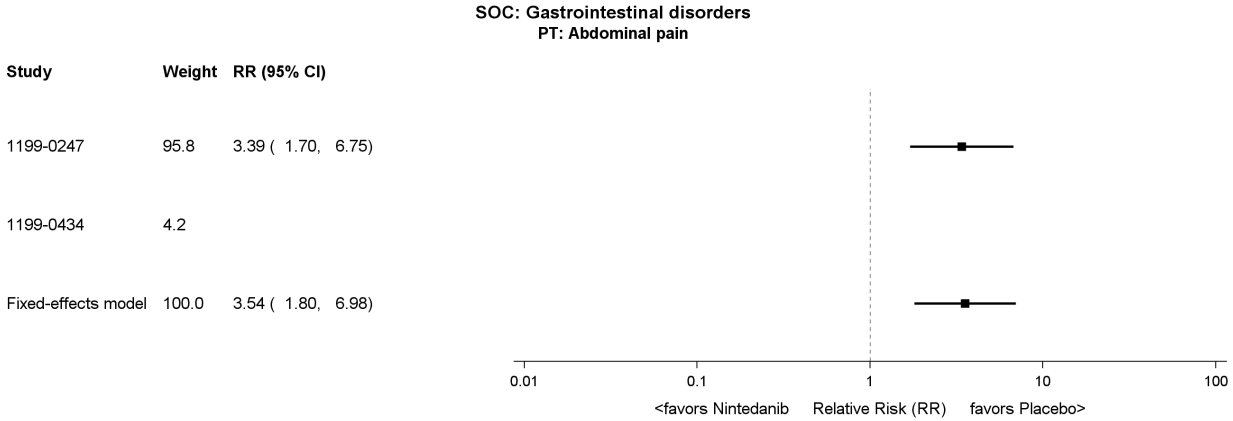

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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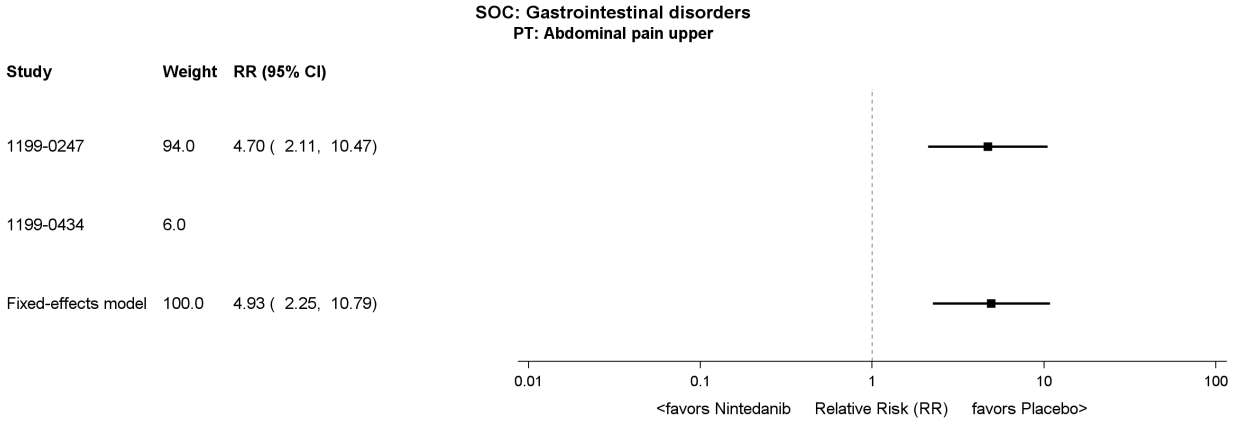

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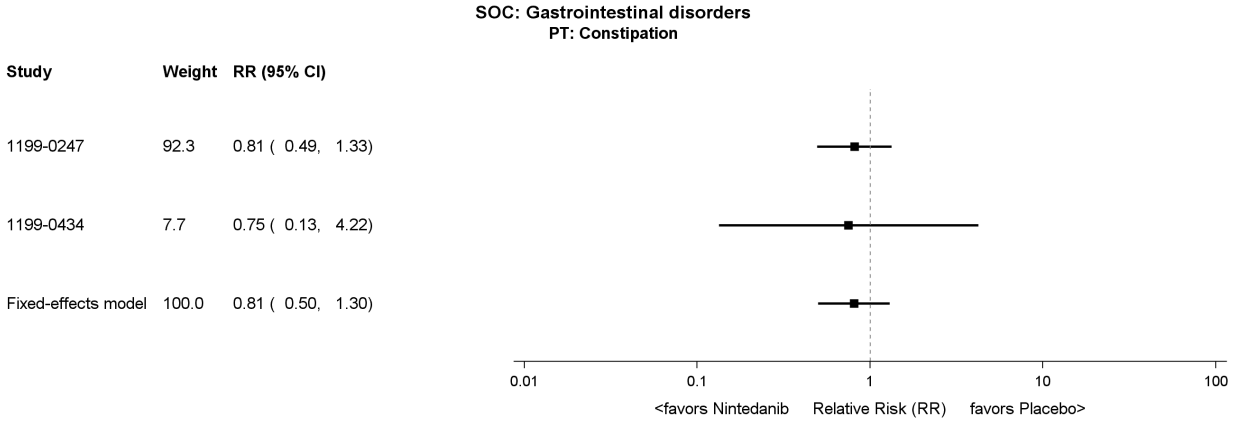

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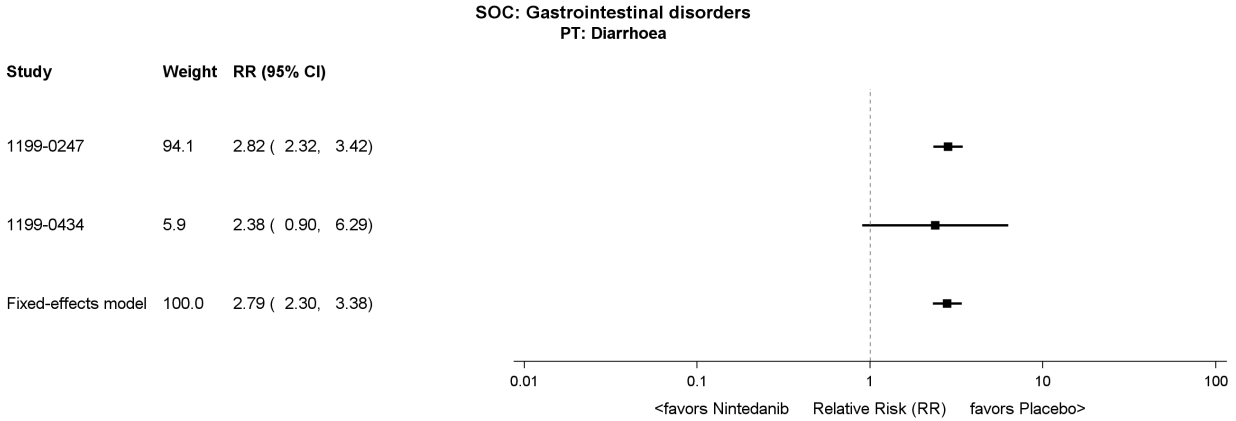

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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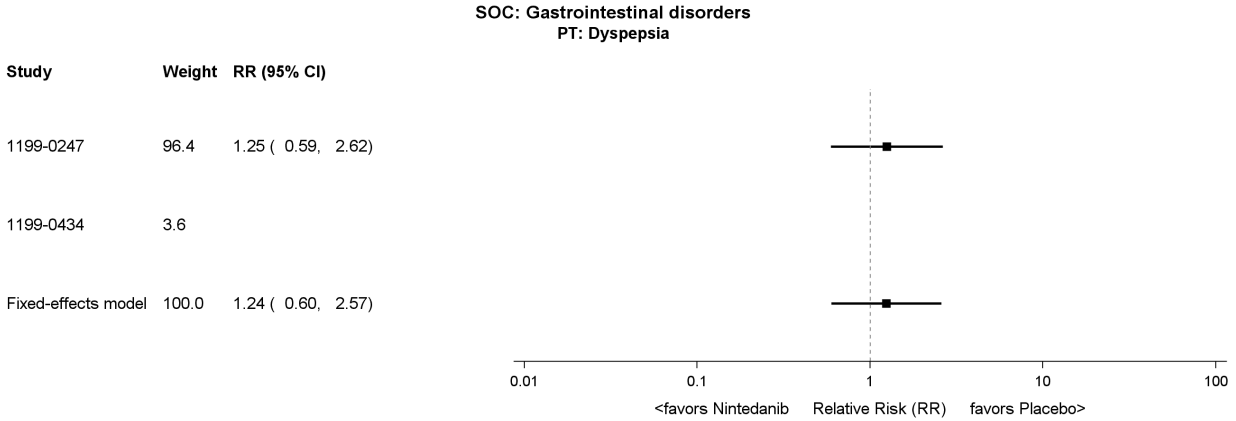

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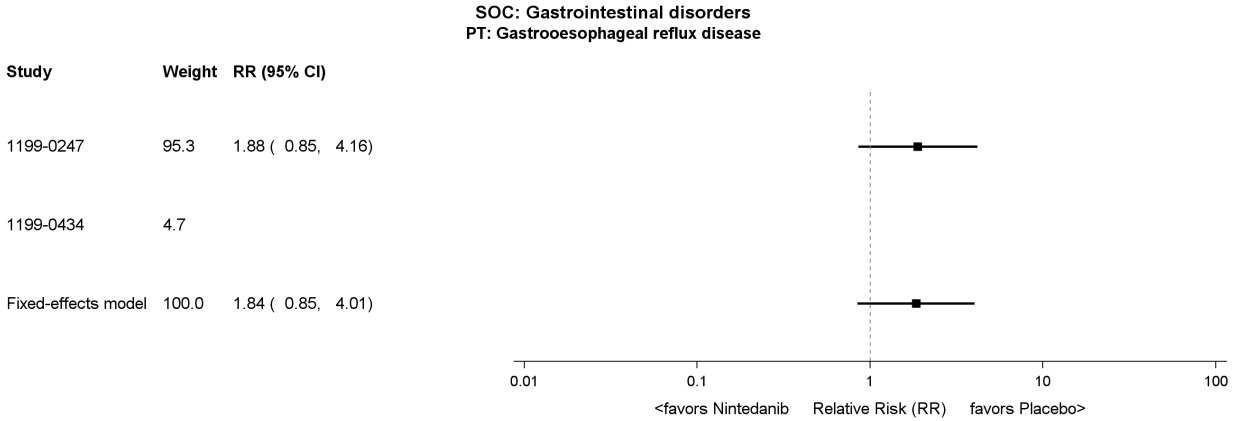

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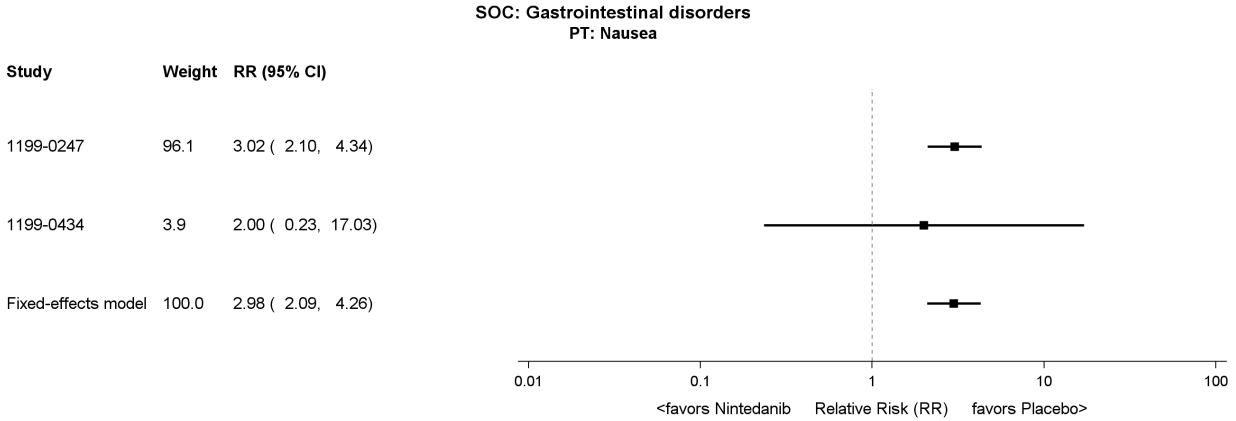

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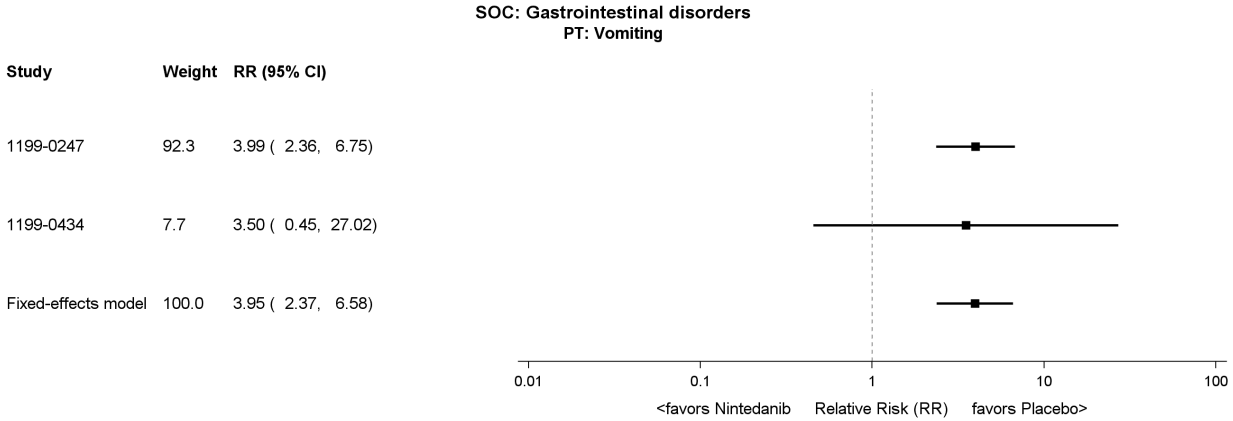

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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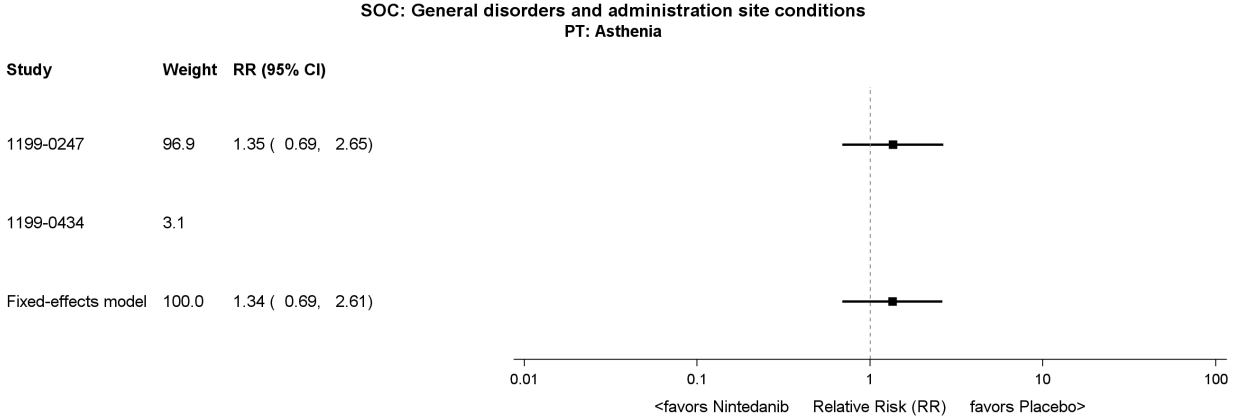

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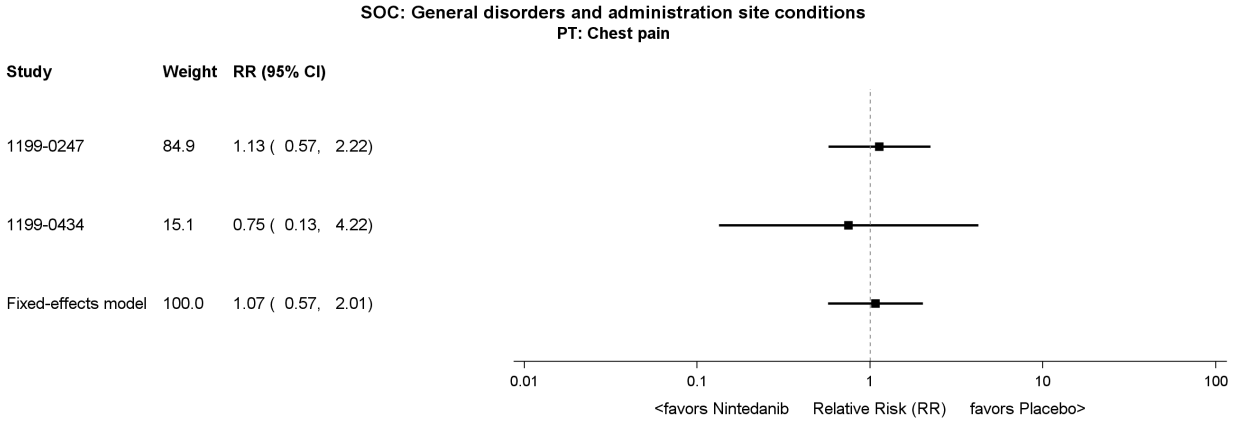

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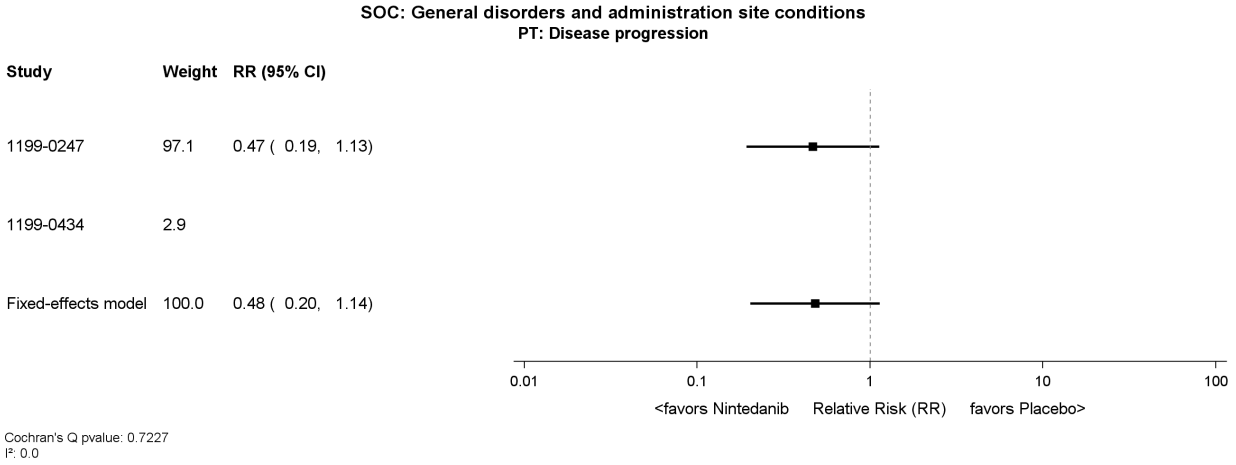

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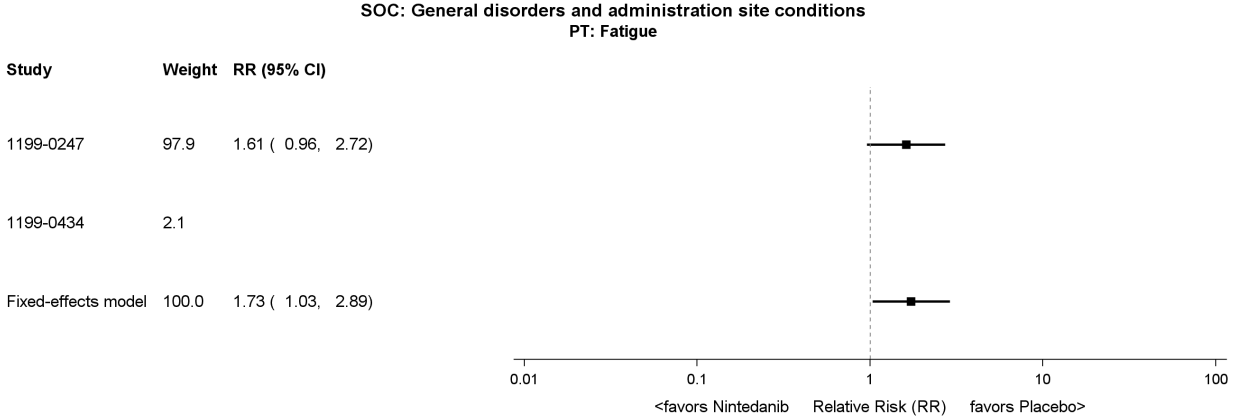

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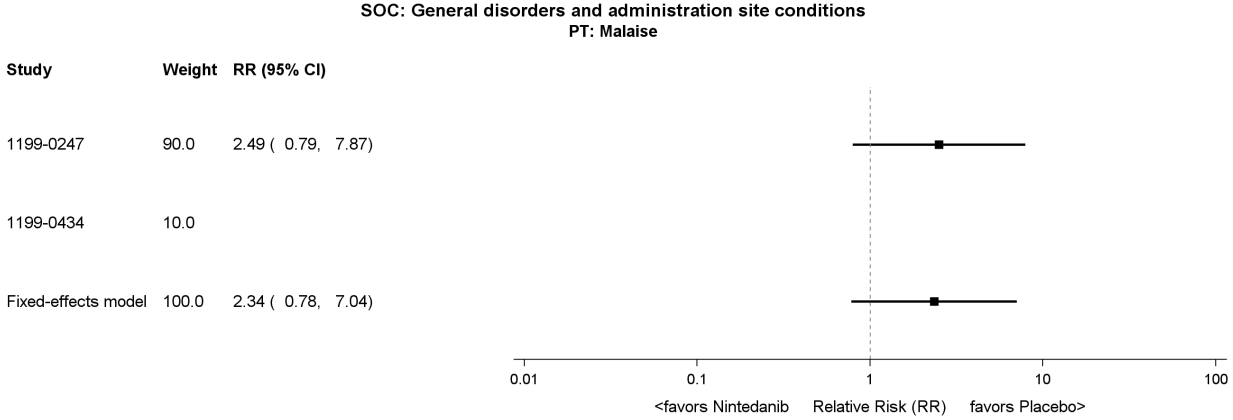

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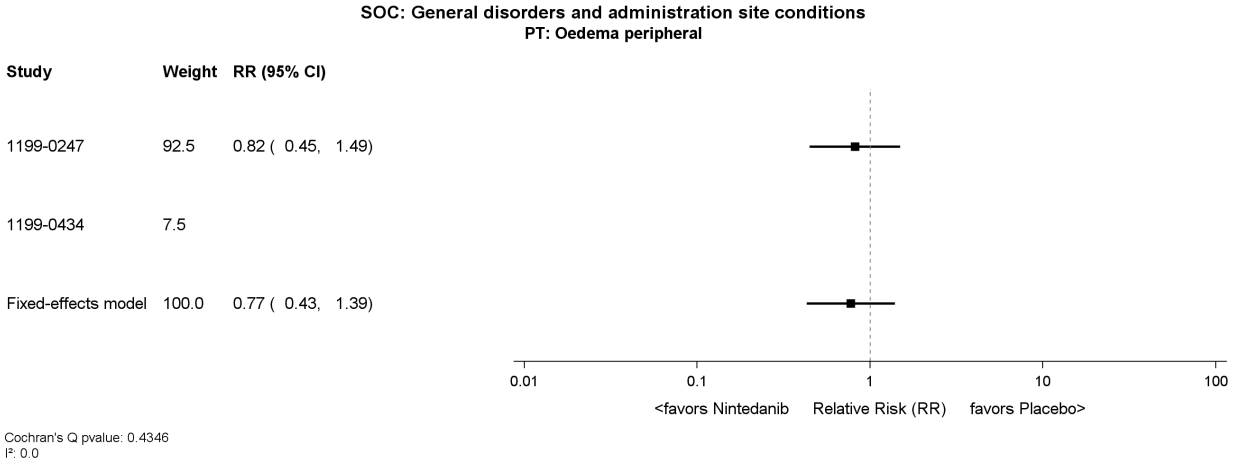

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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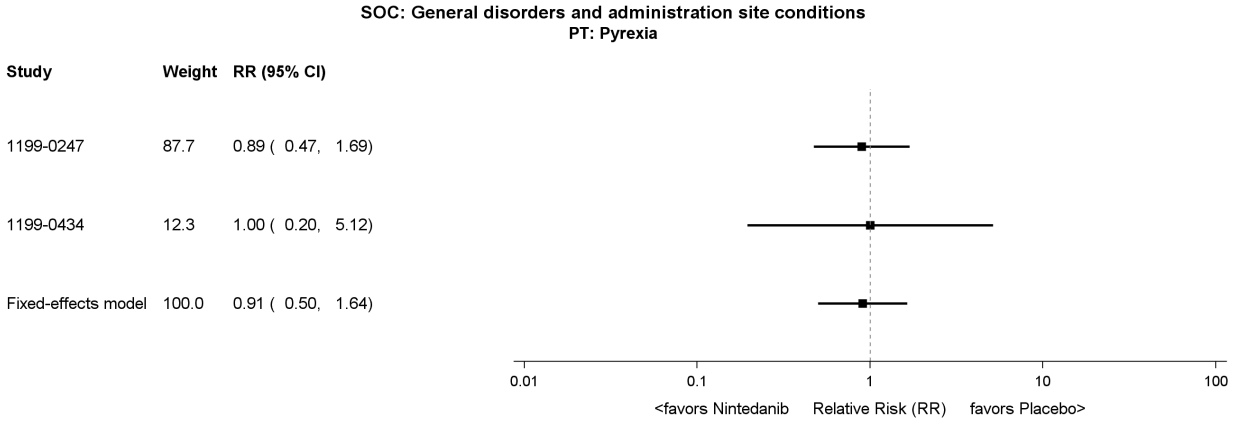

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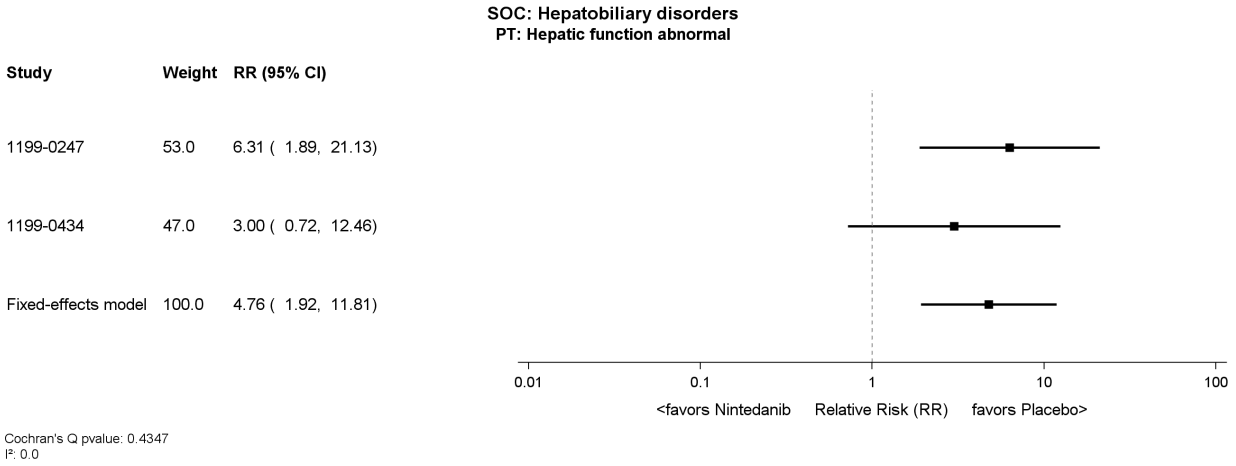

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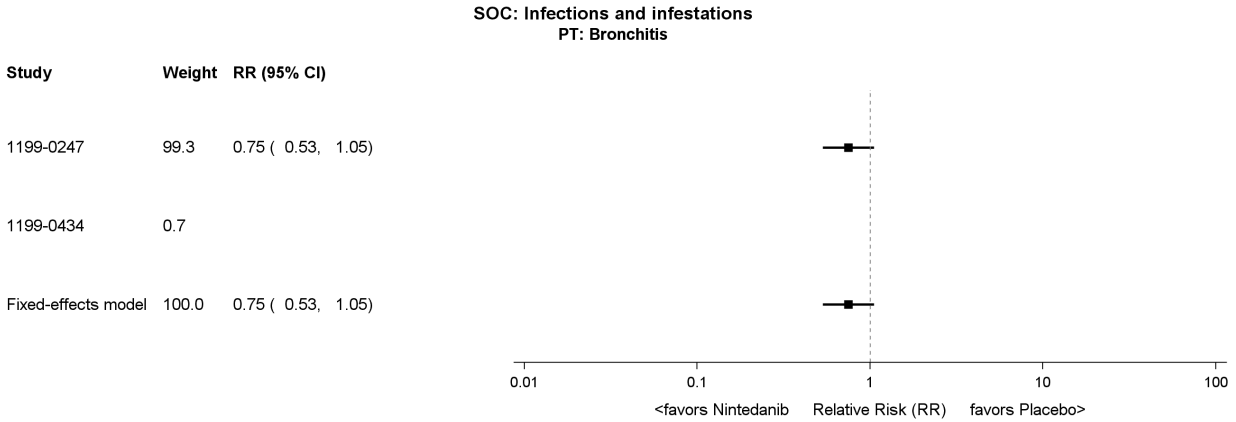

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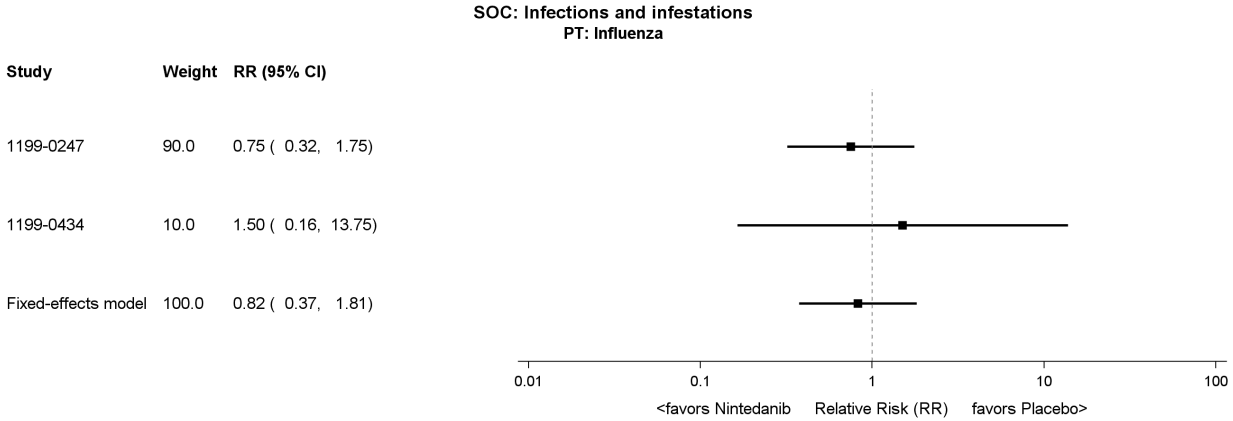

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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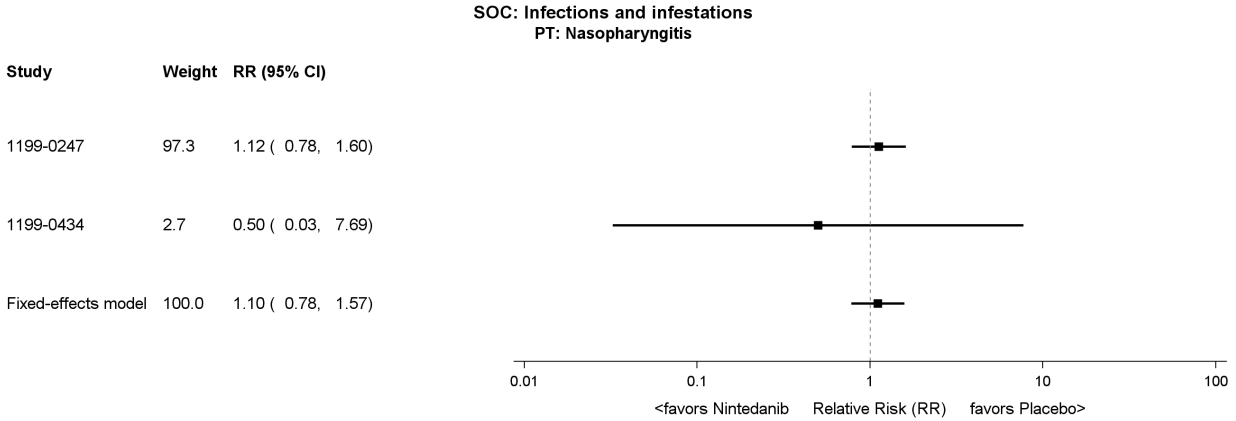

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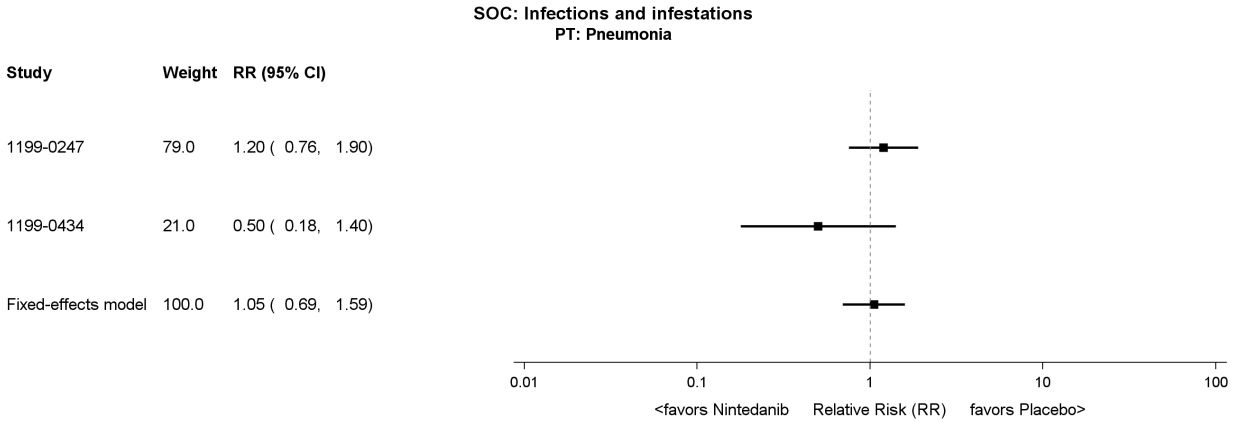

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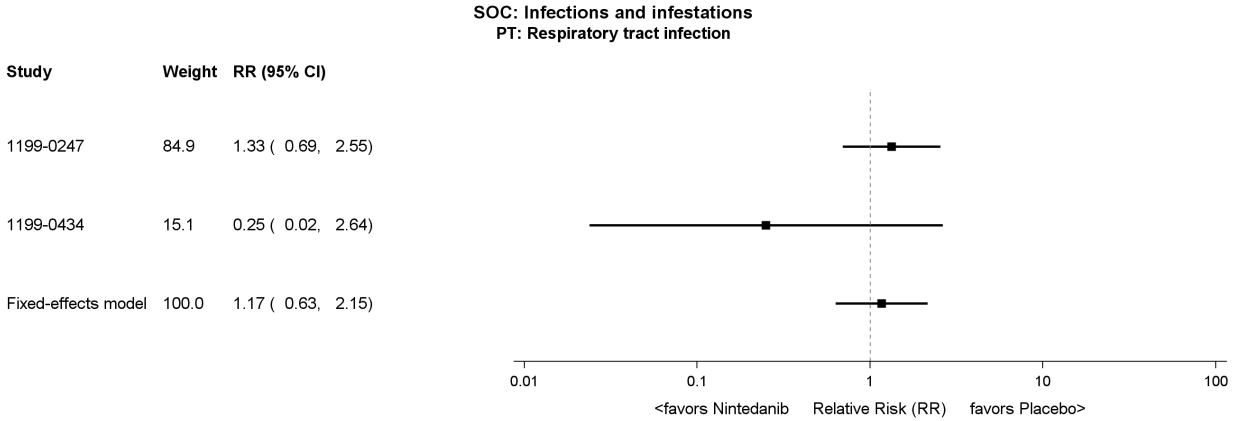

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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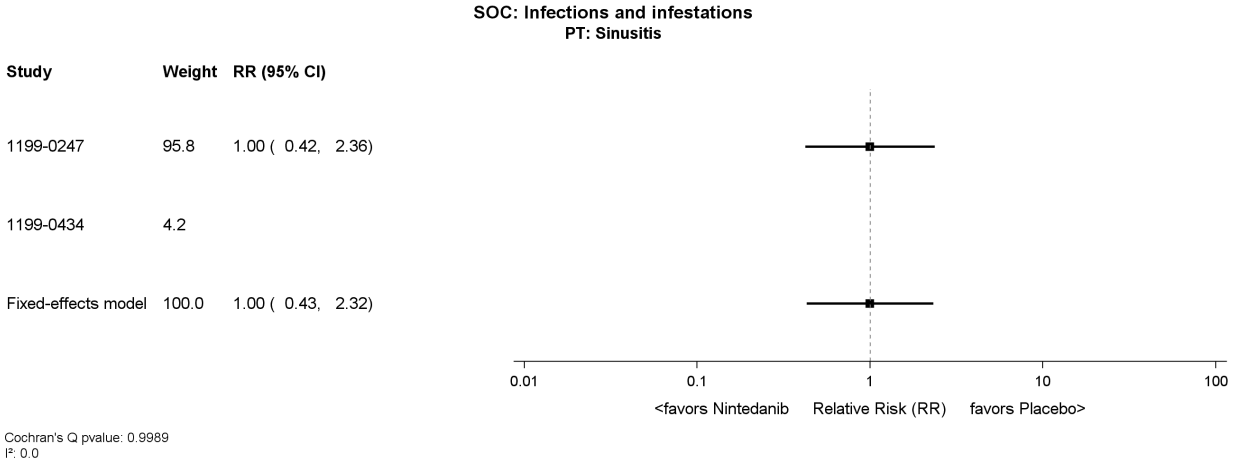

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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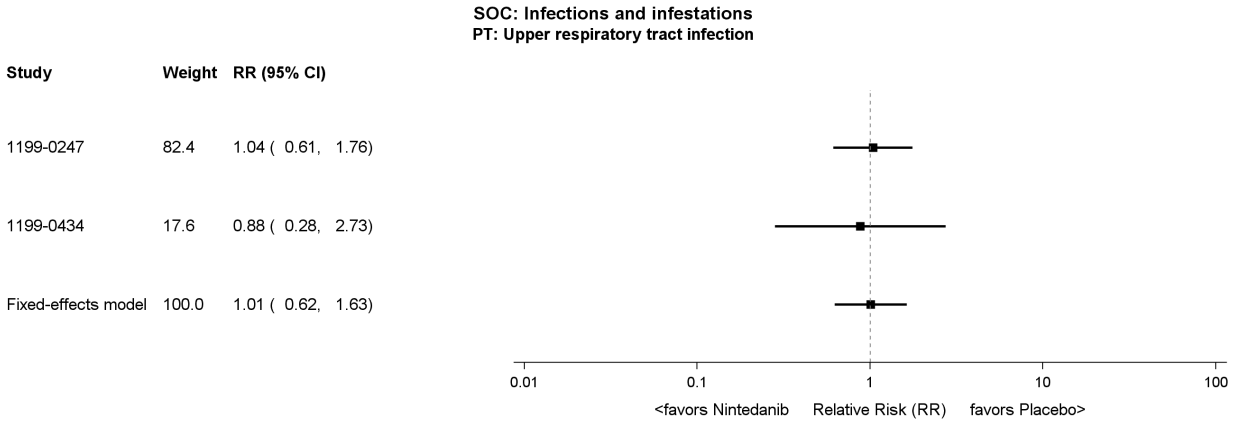

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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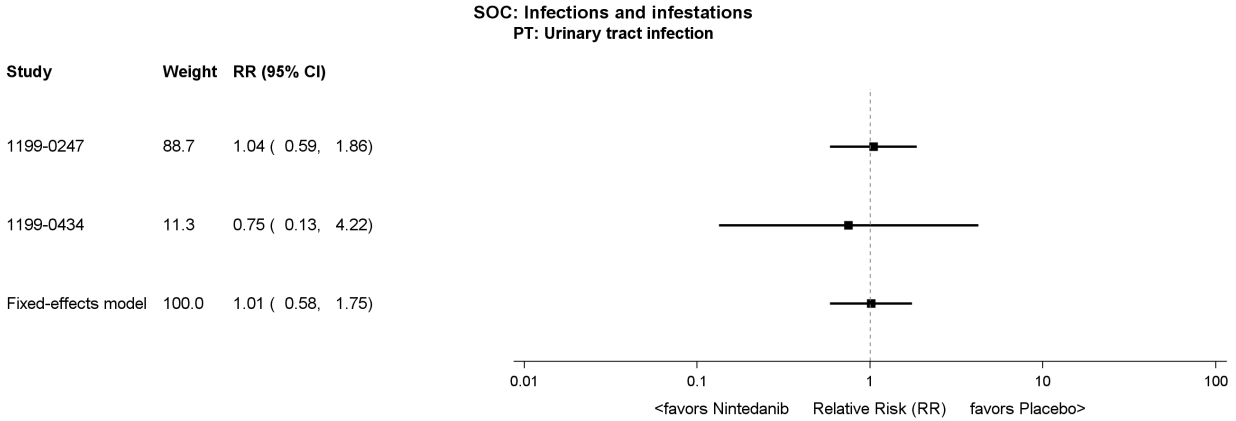

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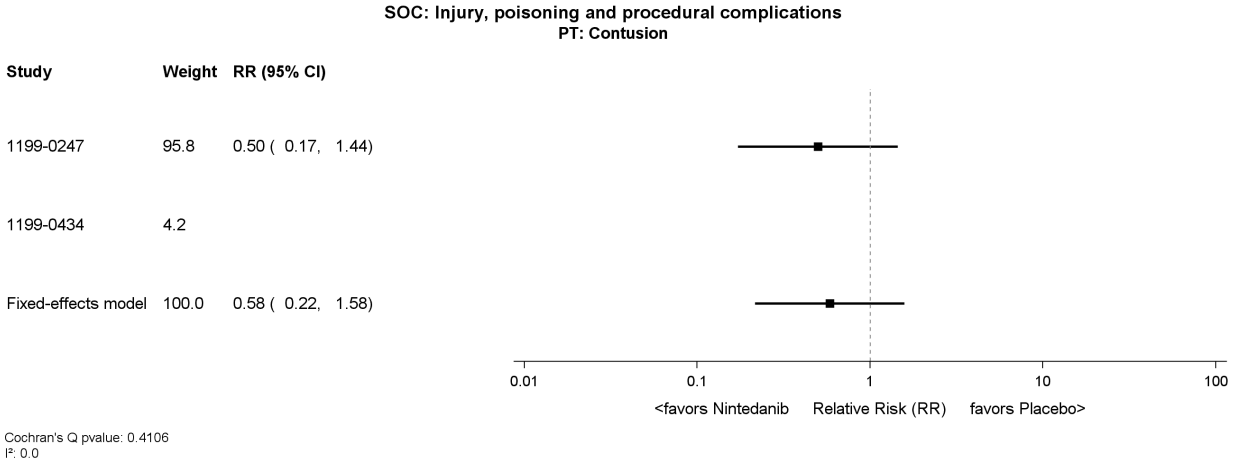

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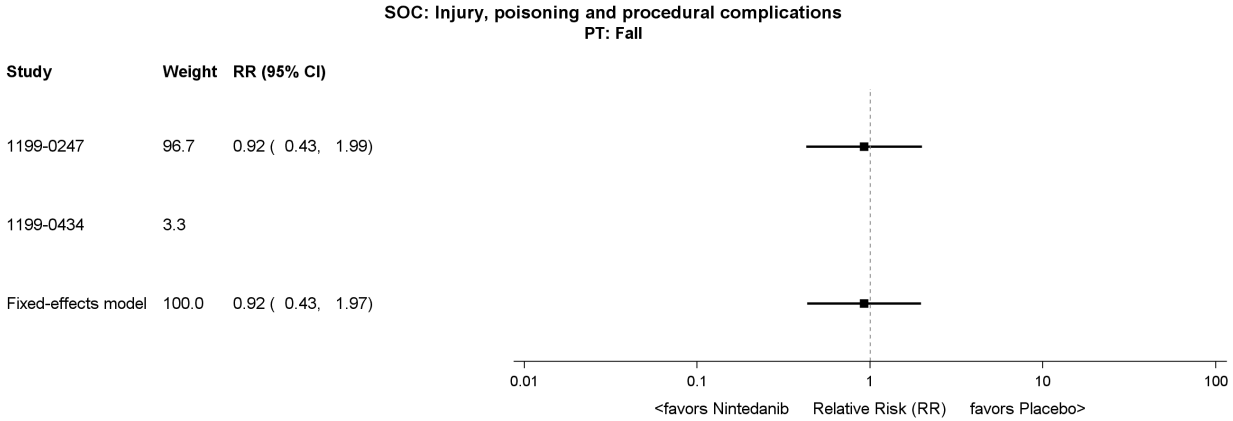

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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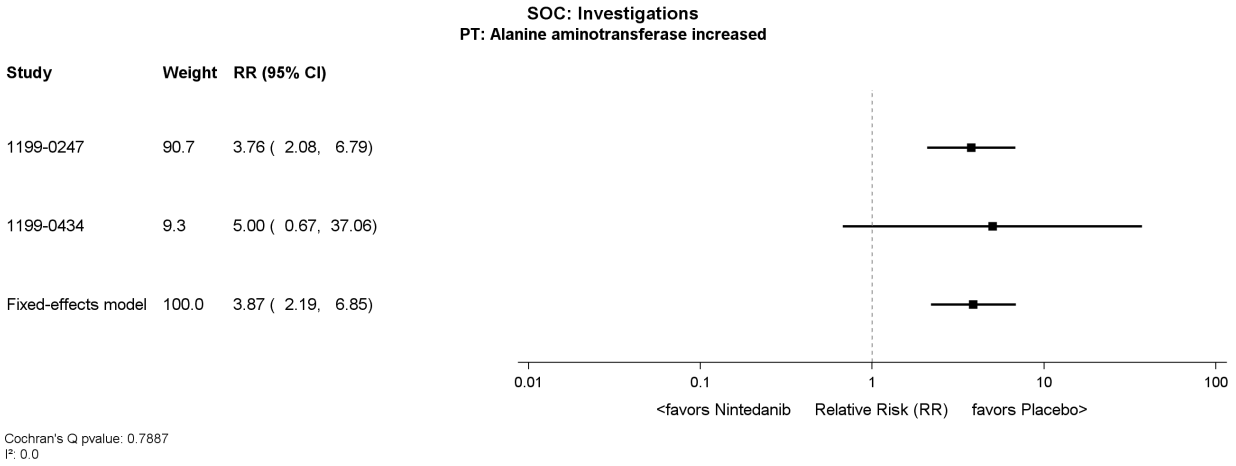

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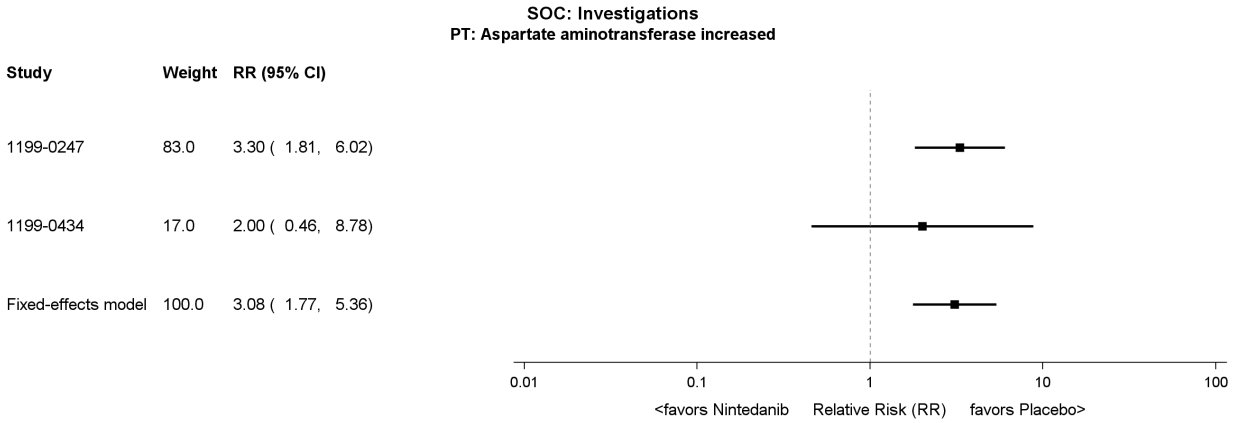

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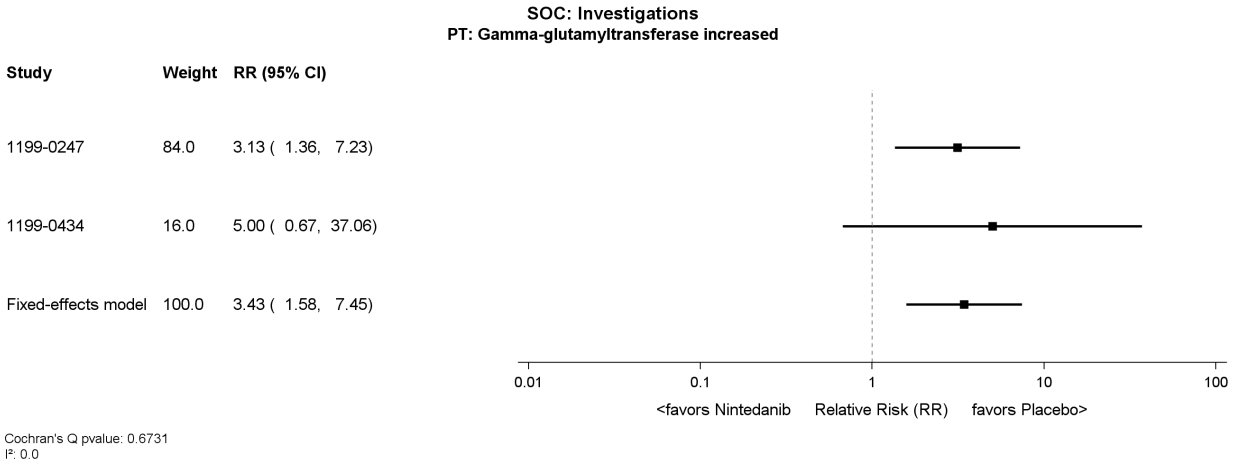

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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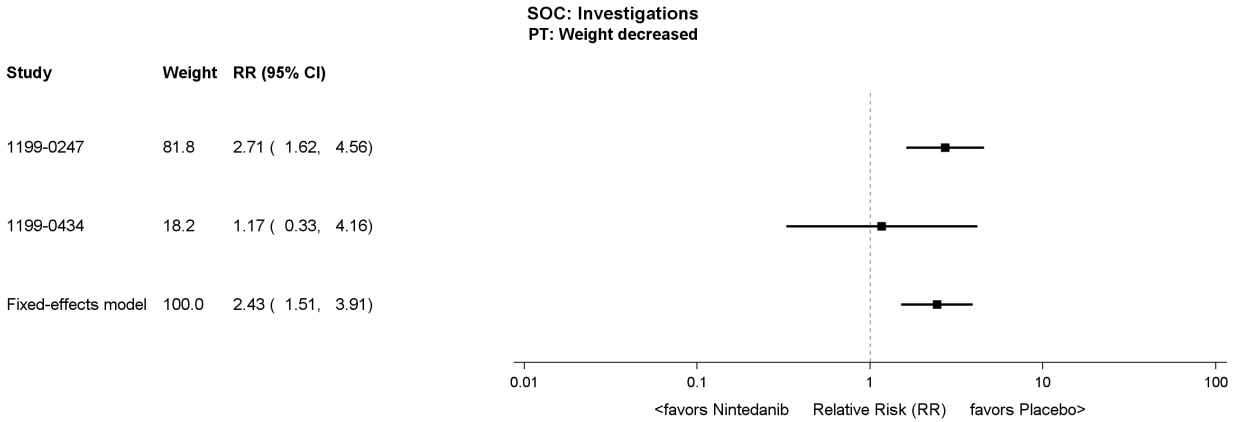

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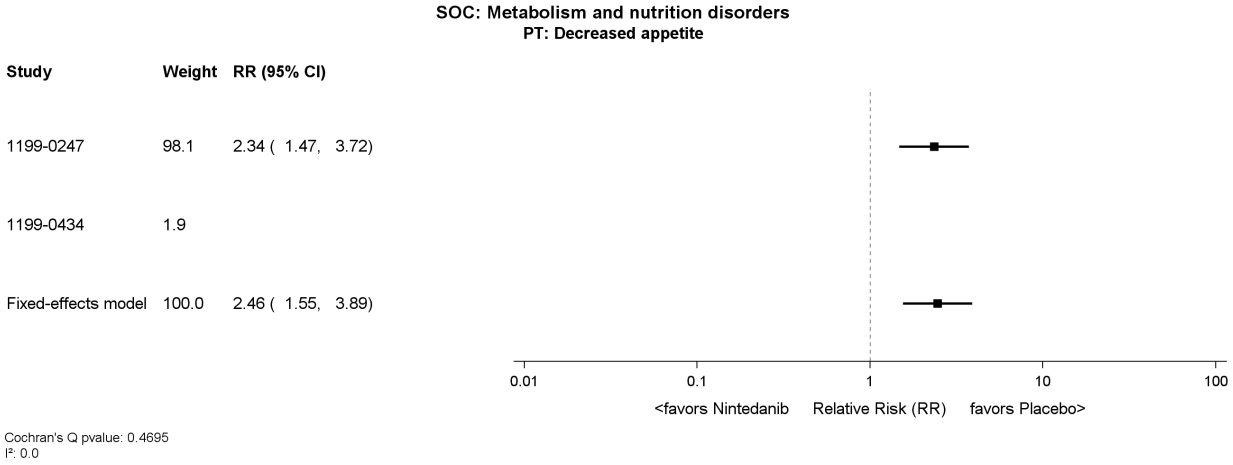

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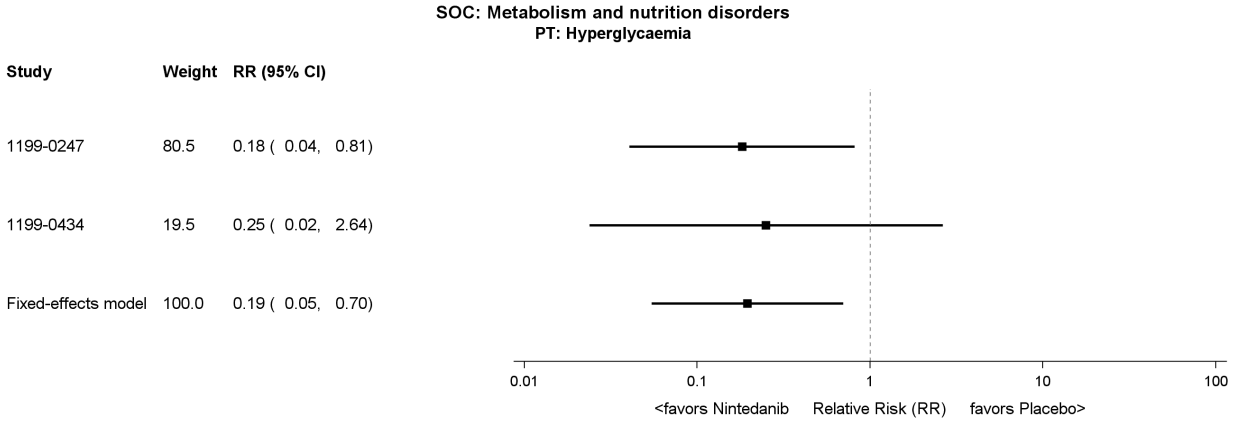

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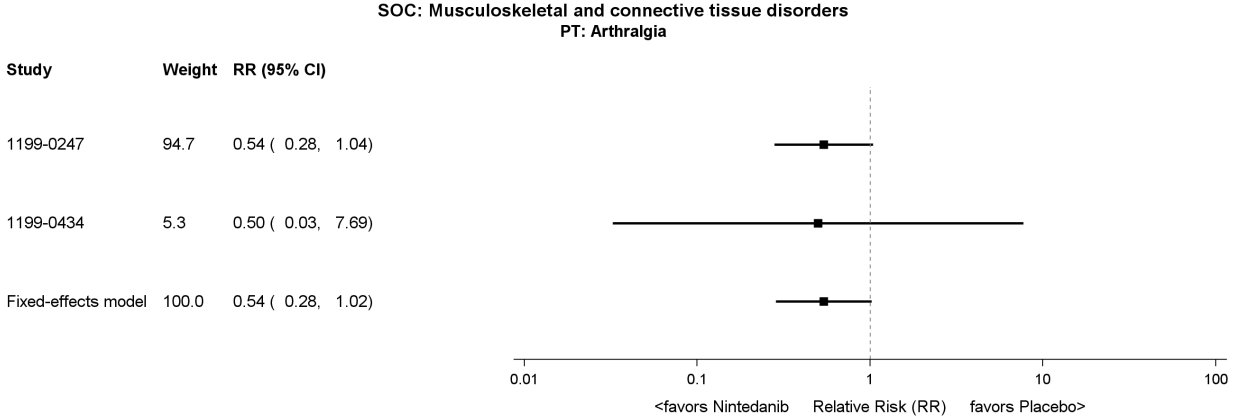

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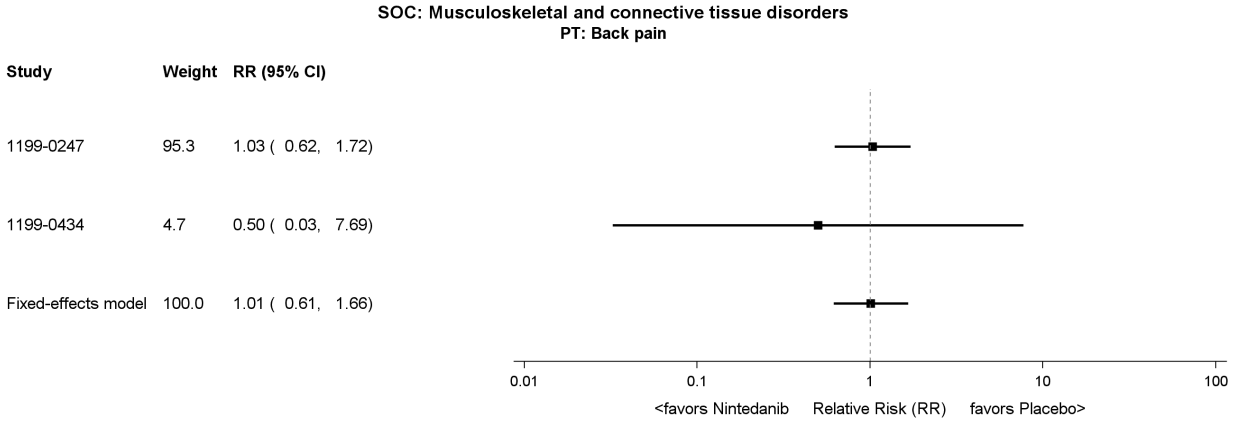

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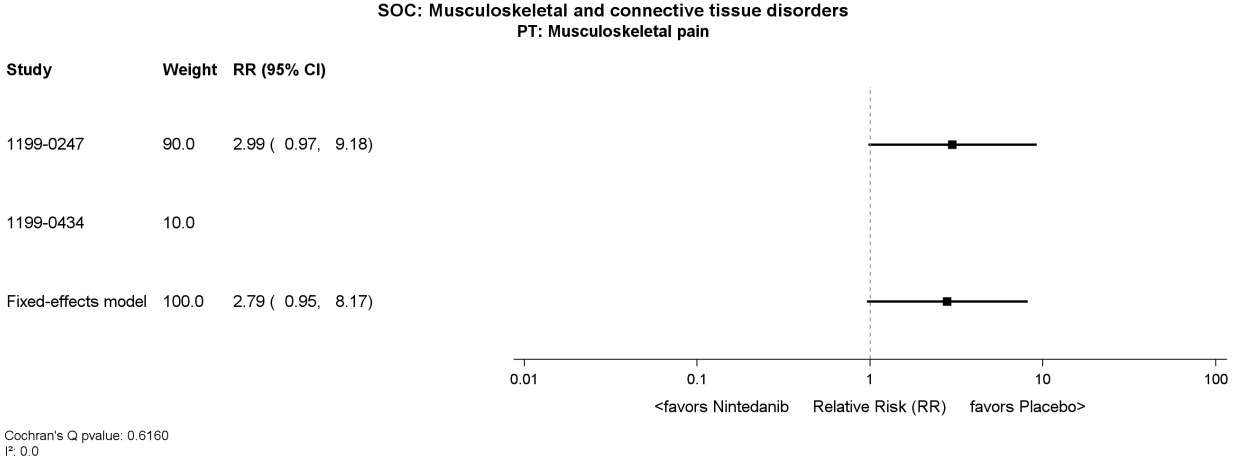

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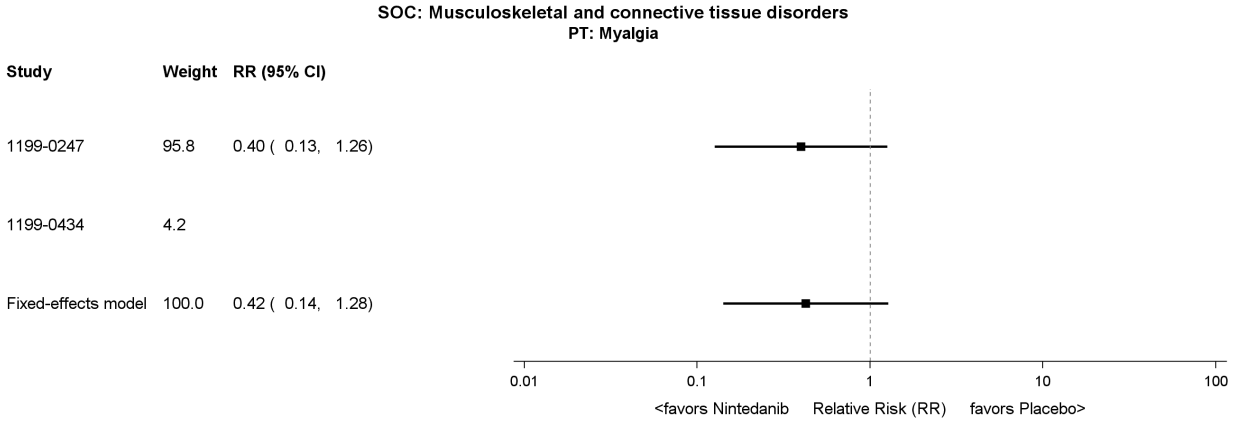

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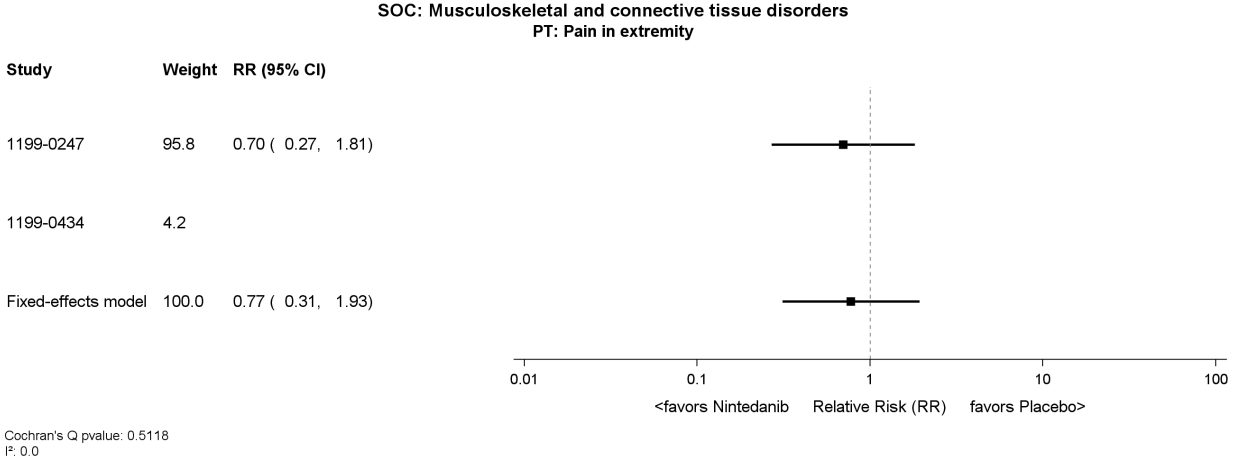

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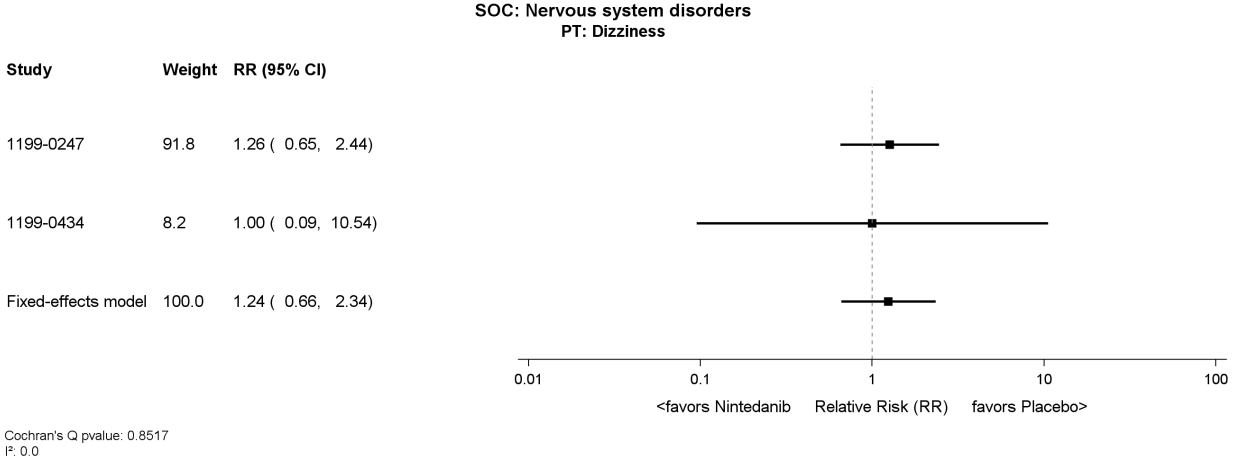

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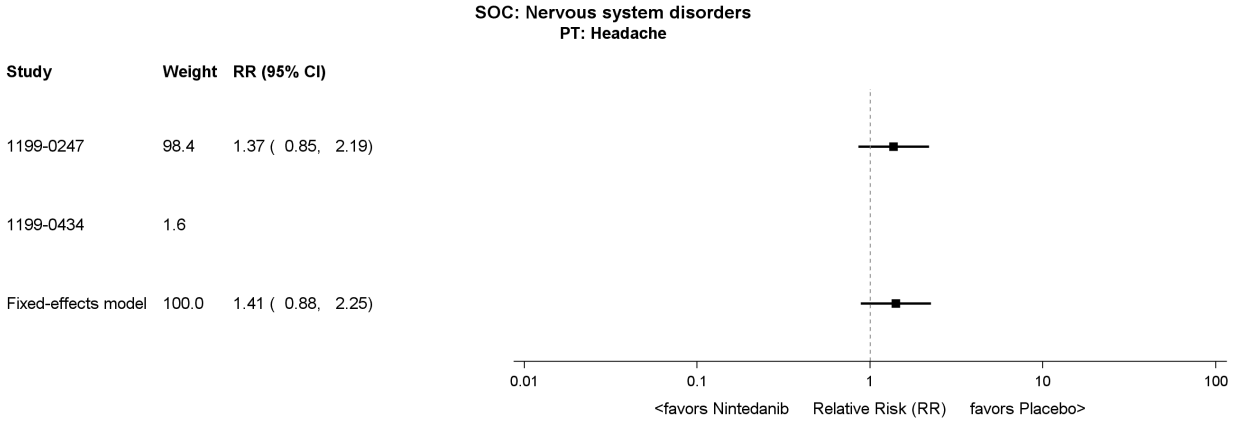

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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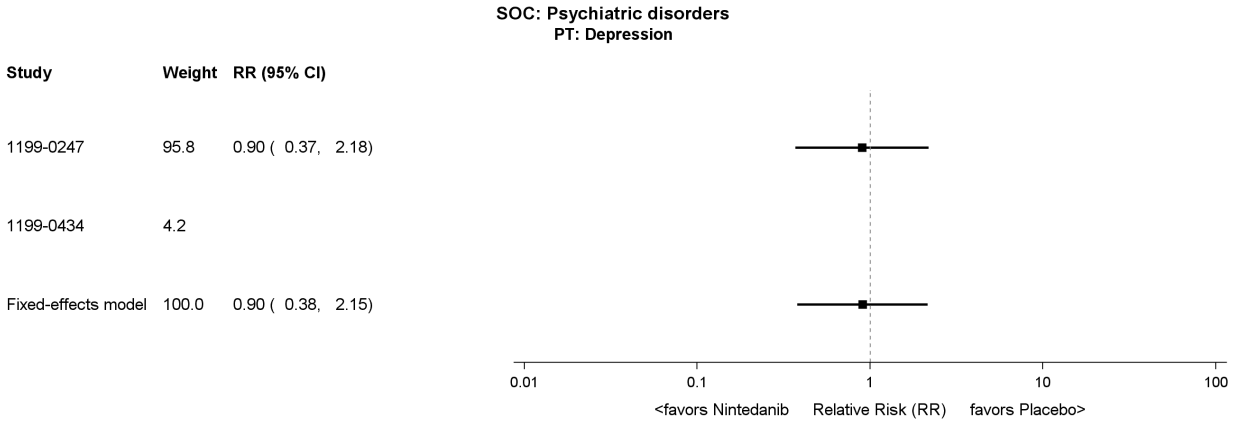

Cochran's Q pvalue: 0.9599
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Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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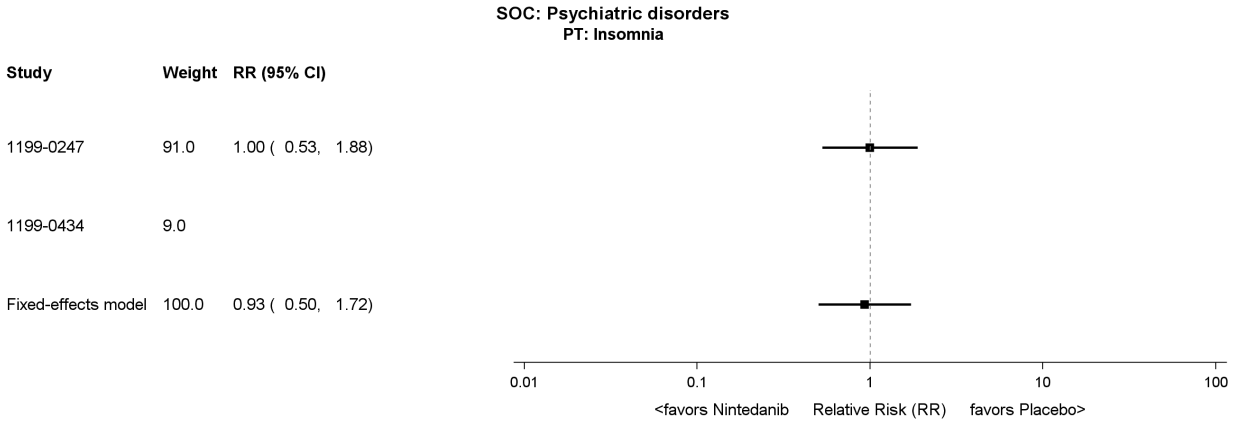

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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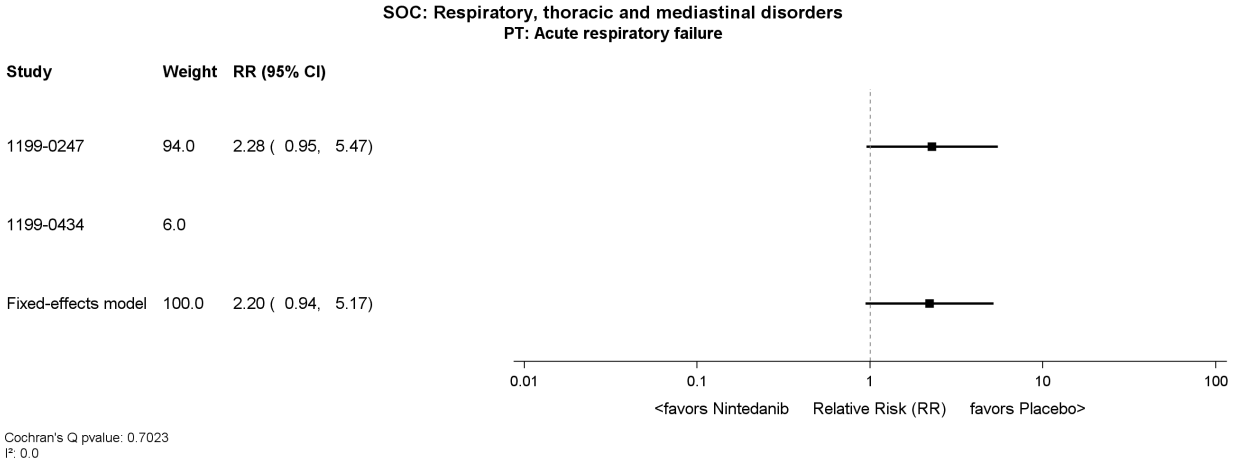

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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Boehringer Ingelheim
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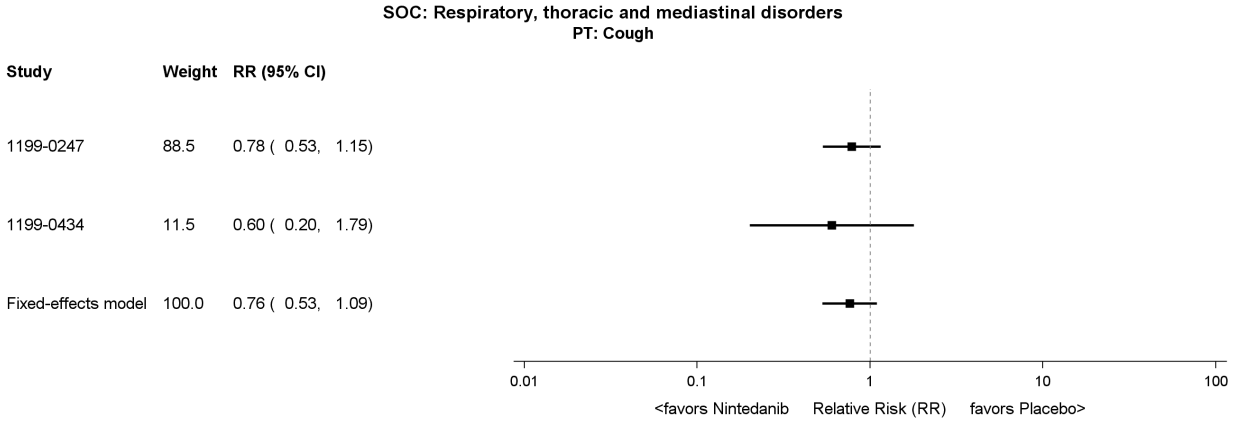

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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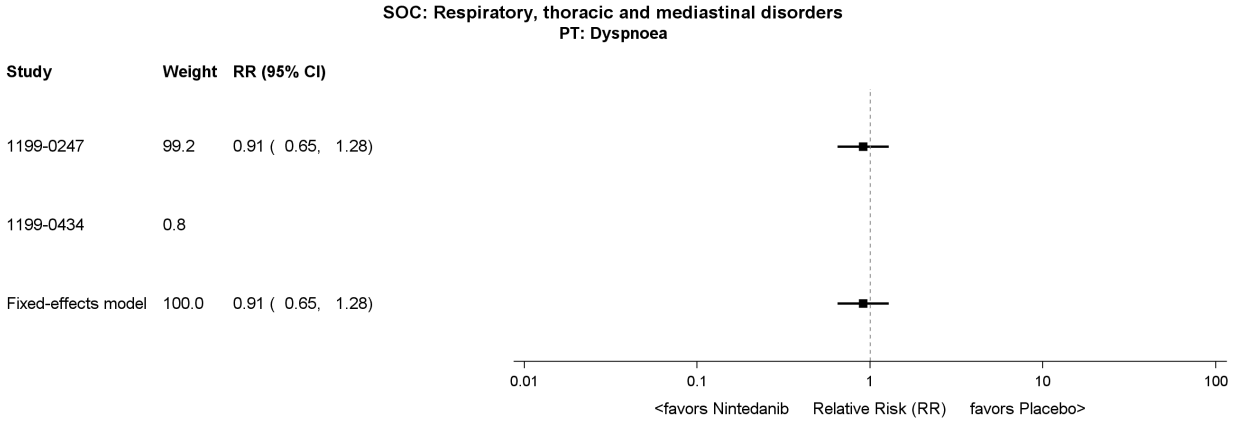

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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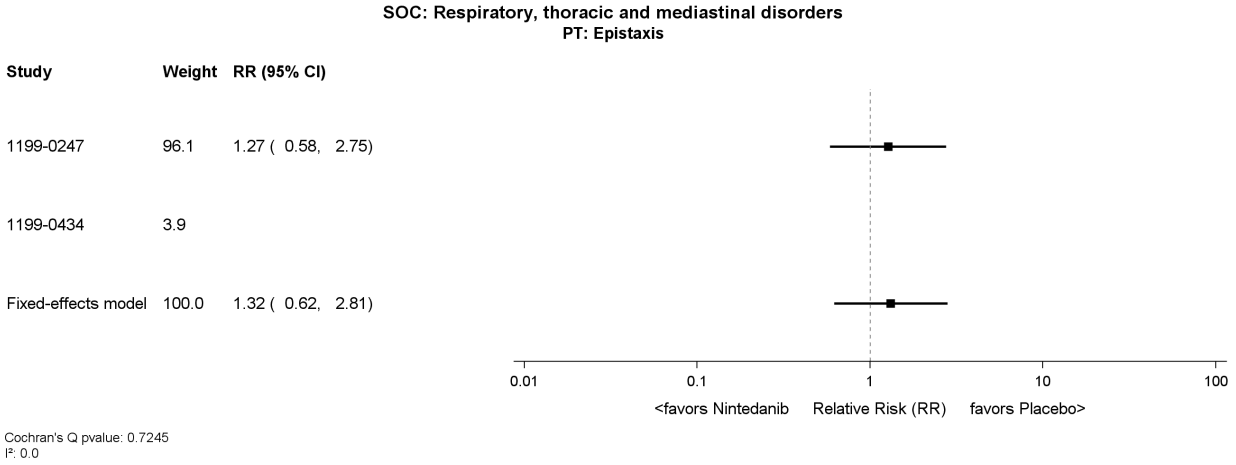

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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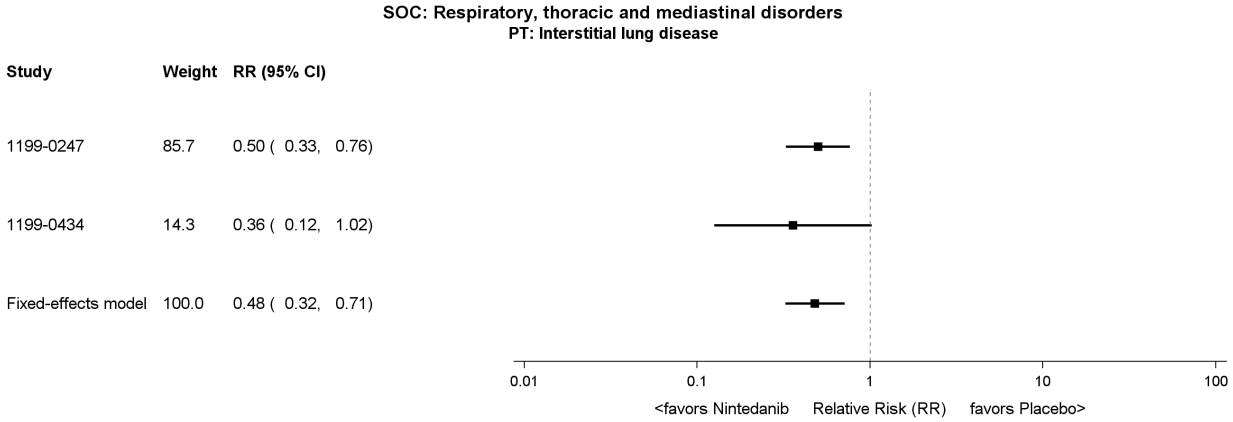

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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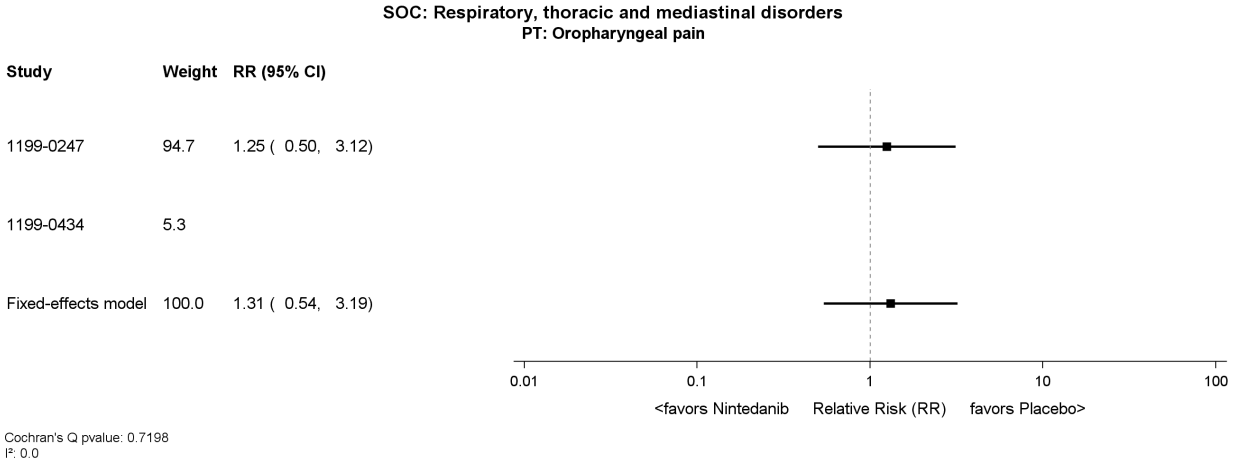

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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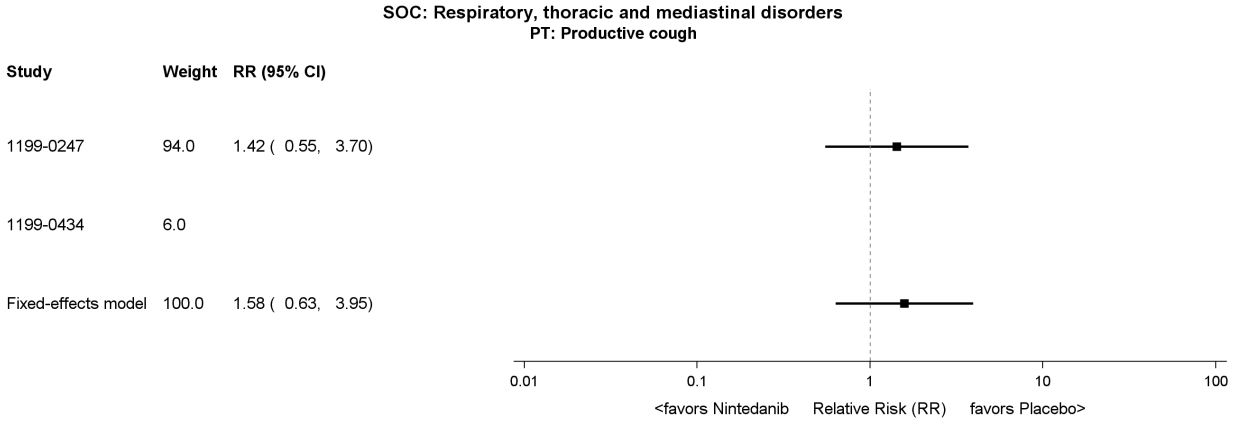

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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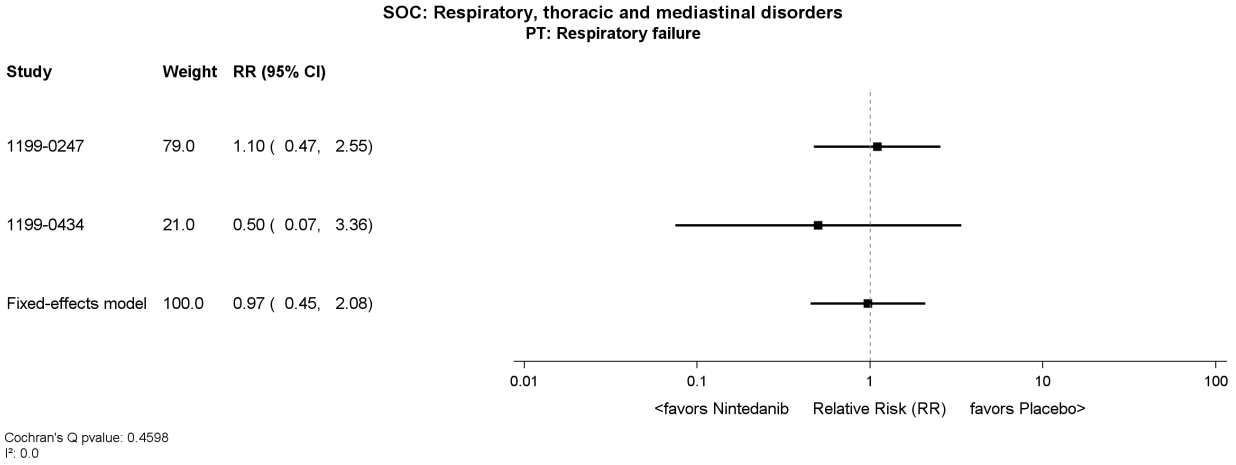

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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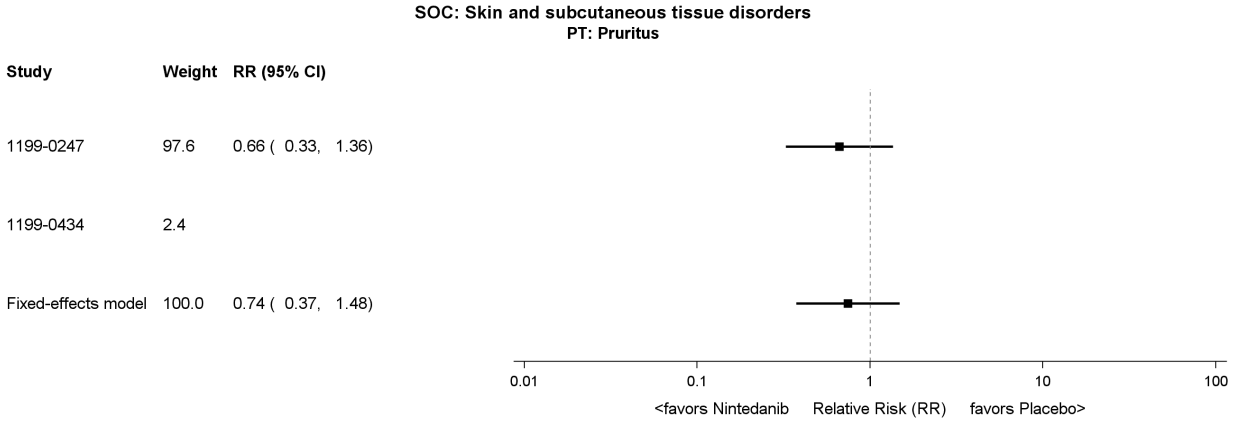

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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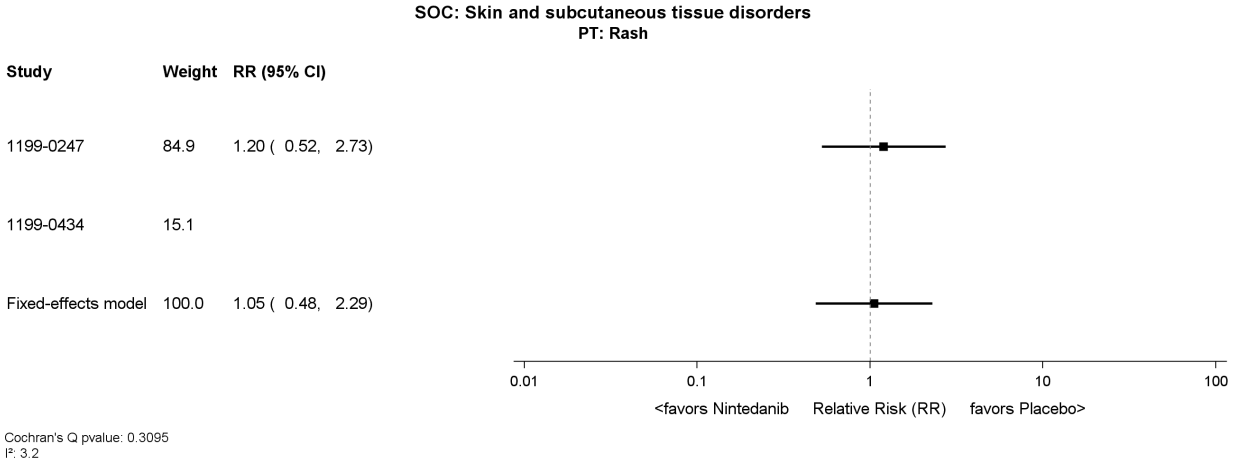

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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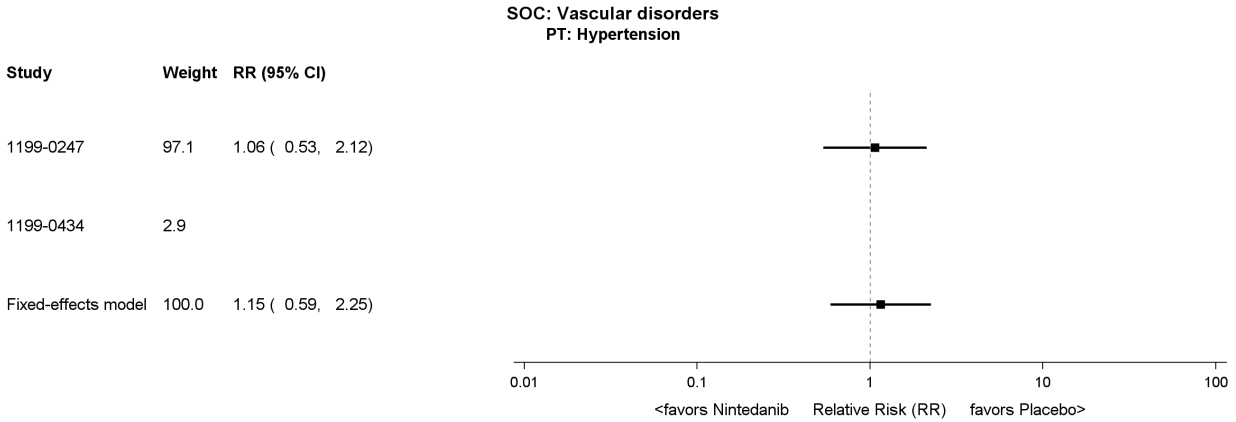

Figure M.2.2.1.4: 1 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC and PT over the whole trial

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Table M.2.2.1.4: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo: Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	16/331 (4.8)	24/332 (7.2)	75.0	4/ 27 (14.8)	5/ 54 (9.3)	25.0	1.28 (0.74, 2.20)	0.3755	35.3	0.2138
Age										
<65 years	4/121 (3.3)	10/139 (7.2)	74.4	1/ 9 (11.1)	1/ 25 (4.0)	25.6	1.71 (0.63, 4.66)	0.2929	32.6	0.2234
>=65 years	12/210 (5.7)	14/193 (7.3)	75.6	3/ 18 (16.7)	4/ 29 (13.8)	24.4	1.16 (0.60, 2.23)	0.6532	0.0	0.5923
Sex										
Male	8/177 (4.5)	15/179 (8.4)	65.6	3/ 11 (27.3)	5/ 26 (19.2)	34.4	1.46 (0.74, 2.89)	0.2791	37.5	0.2060
Female	8/154 (5.2)	9/153 (5.9)	82.1	1/ 16 (6.3)	0/ 28 (0.0)	17.9	0.98 (0.41, 2.32)	0.9590	0.0	0.3540
Baseline FVC percent predicted										
<=70%	15/193 (7.8)	17/196 (8.7)	92.3	1/ 10 (10.0)	2/ 17 (11.8)	7.7	1.12 (0.59, 2.12)	0.7266	0.0	0.9651
>70%	1/138 (0.7)	7/136 (5.1)	19.5	3/ 17 (17.6)	3/ 37 (8.1)	80.5	1.75 (0.63, 4.87)	0.2824	77.2	0.0362
Baseline HRCT pattern										
UIP-like	11/206 (5.3)	15/206 (7.3)	67.5	4/ 23 (17.4)	5/ 45 (11.1)	32.5	1.13 (0.60, 2.13)	0.7090	7.4	0.2987
Other fibrotic patterns	5/125 (4.0)	9/126 (7.1)	92.2	0/ 4 (0.0)	0/ 9 (0.0)	7.8	1.72 (0.62, 4.82)	0.2991	0.0	0.7886
Underlying ILD diagnosis										
iNSIP	6/ 61 (9.8)	3/ 64 (4.7)	92.8	0/ 7 (0.0)	1/ 11 (9.1)	7.2	0.63 (0.19, 2.08)	0.4491	0.0	0.3571
Unclassifiable IIP	0/ 50 (0.0)	5/ 64 (7.8)	50.6	0/ 3 (0.0)	0/ 2 (0.0)	49.4	5.51 (0.60,50.42)	0.1308	0.0	0.3490
HP	3/ 89 (3.4)	4/ 84 (4.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	6/ 88 (6.8)	10/ 82 (12.2)	66.2	2/ 12 (16.7)	4/ 34 (11.8)	33.8	1.42 (0.63, 3.19)	0.3927	0.0	0.3217
Other ILD	1/ 43 (2.3)	2/ 38 (5.3)	25.9	2/ 5 (40.0)	0/ 6 (0.0)	74.1	0.72 (0.16, 3.21)	0.6709	46.0	0.1734
Region										
Europe										
Asia	5/ 76 (6.6)	6/ 79 (7.6)	48.9	4/ 27 (14.8)	5/ 54 (9.3)	51.1	0.88 (0.39, 2.03)	0.7703	0.0	0.4742
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	16/331 (4.8)	24/332 (7.2)	90.2	4/ 27 (14.8)	5/ 54 (9.3)	9.8	1.62 (-1.98, 5.22)	0.0	0.3267
Age									
<65 years	4/121 (3.3)	10/139 (7.2)	90.7	1/ 9 (11.1)	1/ 25 (4.0)	9.3	2.87 (-2.39, 8.13)	0.0	0.3394
>=65 years	12/210 (5.7)	14/193 (7.3)	90.1	3/ 18 (16.7)	4/ 29 (13.8)	9.9	1.10 (-3.73, 5.93)	0.0	0.6921
Sex									
Male	8/177 (4.5)	15/179 (8.4)	92.0	3/ 11 (27.3)	5/ 26 (19.2)	8.0	2.91 (-2.36, 8.18)	0.0	0.4487
Female	8/154 (5.2)	9/153 (5.9)	87.8	1/ 16 (6.3)	0/ 28 (0.0)	12.2	-0.12 (-4.94, 4.69)	0.0	0.3849
Baseline FVC percent predicted									
<=70%	15/193 (7.8)	17/196 (8.7)	93.9	1/ 10 (10.0)	2/ 17 (11.8)	6.1	0.95 (-4.38, 6.29)	0.0	0.9454
>70%	1/138 (0.7)	7/136 (5.1)	85.5	3/ 17 (17.6)	3/ 37 (8.1)	14.5	2.39 (-2.09, 6.88)	43.7	0.1826
Baseline HRCT pattern									
UIP-like	11/206 (5.3)	15/206 (7.3)	87.1	4/ 23 (17.4)	5/ 45 (11.1)	12.9	0.88 (-3.82, 5.58)	0.0	0.3865
Other fibrotic patterns	5/125 (4.0)	9/126 (7.1)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	2.99 (-2.55, 8.54)	0.0	0.8254
Underlying ILD diagnosis									
iNSIP	6/ 61 (9.8)	3/ 64 (4.7)	86.8	0/ 7 (0.0)	1/ 11 (9.1)	13.2	-3.39 (-11.91, 5.14)	0.8	0.3153
Unclassifiable IIP	0/ 50 (0.0)	5/ 64 (7.8)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	7.25 (-0.20, 14.70)	0.0	0.7781
HP	3/ 89 (3.4)	4/ 84 (4.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	6/ 88 (6.8)	10/ 82 (12.2)	82.7	2/ 12 (16.7)	4/ 34 (11.8)	17.3	3.60 (-4.77, 11.97)	0.0	0.4258
Other ILD	1/ 43 (2.3)	2/ 38 (5.3)	86.2	2/ 5 (40.0)	0/ 6 (0.0)	13.8	-2.13 (-11.61, 7.35)	60.9	0.1099
Region									
Europe									
Asia	5/ 76 (6.6)	6/ 79 (7.6)	68.3	4/ 27 (14.8)	5/ 54 (9.3)	31.7	-1.07 (-8.45, 6.31)	0.0	0.4605
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	16/331 (4.8)	24/332 (7.2)	75.4	4/ 27 (14.8)	5/ 54 (9.3)	24.6	1.30 (0.72, 2.34)	32.4	0.2239
Age									
<65 years	4/121 (3.3)	10/139 (7.2)	73.8	1/ 9 (11.1)	1/ 25 (4.0)	26.2	1.76 (0.60, 5.14)	31.1	0.2283
>=65 years	12/210 (5.7)	14/193 (7.3)	77.0	3/ 18 (16.7)	4/ 29 (13.8)	23.0	1.18 (0.58, 2.41)	0.0	0.6051
Sex									
Male	8/177 (4.5)	15/179 (8.4)	68.4	3/ 11 (27.3)	5/ 26 (19.2)	31.6	1.52 (0.70, 3.29)	26.6	0.2433
Female	8/154 (5.2)	9/153 (5.9)	81.6	1/ 16 (6.3)	0/ 28 (0.0)	18.4	0.98 (0.39, 2.45)	0.0	0.3520
Baseline FVC percent predicted									
<=70%	15/193 (7.8)	17/196 (8.7)	92.6	1/ 10 (10.0)	2/ 17 (11.8)	7.4	1.13 (0.56, 2.27)	0.0	0.9628
>70%	1/138 (0.7)	7/136 (5.1)	20.0	3/ 17 (17.6)	3/ 37 (8.1)	80.0	1.81 (0.57, 5.72)	77.0	0.0371
Baseline HRCT pattern									
UIP-like	11/206 (5.3)	15/206 (7.3)	68.4	4/ 23 (17.4)	5/ 45 (11.1)	31.6	1.14 (0.57, 2.29)	4.2	0.3069
Other fibrotic patterns	5/125 (4.0)	9/126 (7.1)	92.1	0/ 4 (0.0)	0/ 9 (0.0)	7.9	1.78 (0.60, 5.28)	0.0	0.7911
Underlying ILD diagnosis									
iNSIP	6/ 61 (9.8)	3/ 64 (4.7)	93.4	0/ 7 (0.0)	1/ 11 (9.1)	6.6	0.61 (0.17, 2.15)	0.0	0.3507
Unclassifiable IIP	0/ 50 (0.0)	5/ 64 (7.8)	52.3	0/ 3 (0.0)	0/ 2 (0.0)	47.7	6.09 (0.63,58.70)	0.0	0.3815
HP	3/ 89 (3.4)	4/ 84 (4.8)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	6/ 88 (6.8)	10/ 82 (12.2)	66.1	2/ 12 (16.7)	4/ 34 (11.8)	33.9	1.48 (0.59, 3.71)	0.0	0.3346
Other ILD	1/ 43 (2.3)	2/ 38 (5.3)	26.5	2/ 5 (40.0)	0/ 6 (0.0)	73.5	0.70 (0.14, 3.65)	52.6	0.1462
Region									
Europe									
Asia	5/ 76 (6.6)	6/ 79 (7.6)	49.3	4/ 27 (14.8)	5/ 54 (9.3)	50.7	0.87 (0.35, 2.20)	0.0	0.4705
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Acute respiratory failure

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	7/331 (2.1)	16/332 (4.8)	94.0	0/ 27 (0.0)	0/ 54 (0.0)	6.0	2.20 (0.94, 5.17)	0.0697	0.0	0.7023
Age										
<65 years	3/121 (2.5)	3/139 (2.2)	89.2	0/ 9 (0.0)	0/ 25 (0.0)	10.8	0.88 (0.20, 3.91)	0.8715	0.0	0.9535
>=65 years	4/210 (1.9)	13/193 (6.7)	89.0	0/ 18 (0.0)	0/ 29 (0.0)	11.0	3.26 (1.14, 9.33)	0.0278	0.0	0.5499
Sex										
Male	4/177 (2.3)	9/179 (5.0)	90.6	0/ 11 (0.0)	0/ 26 (0.0)	9.4	2.11 (0.69, 6.42)	0.1886	0.0	0.7210
Female	3/154 (1.9)	7/153 (4.6)	86.6	0/ 16 (0.0)	0/ 28 (0.0)	13.4	2.17 (0.62, 7.62)	0.2277	0.0	0.6934
Baseline FVC percent predicted										
<=70%	7/193 (3.6)	10/196 (5.1)	93.8	0/ 10 (0.0)	0/ 17 (0.0)	6.2	1.38 (0.55, 3.46)	0.4907	0.0	0.8704
>70%	0/138 (0.0)	6/136 (4.4)	53.7	0/ 17 (0.0)	0/ 37 (0.0)	46.3	7.49 (0.87,64.13)	0.0661	0.0	0.3197
Baseline HRCT pattern										
UIP-like	5/206 (2.4)	11/206 (5.3)	91.8	0/ 23 (0.0)	0/ 45 (0.0)	8.2	2.10 (0.77, 5.73)	0.1470	0.0	0.7157
Other fibrotic patterns	2/125 (1.6)	5/126 (4.0)	82.5	0/ 4 (0.0)	0/ 9 (0.0)	17.5	2.22 (0.50, 9.89)	0.2948	0.0	0.6865
Underlying ILD diagnosis										
iNSIP	0/ 61 (0.0)	2/ 64 (3.1)	51.3	0/ 7 (0.0)	0/ 11 (0.0)	48.7	3.00 (0.31,29.36)	0.3447	0.0	0.5300
Unclassifiable IIP	0/ 50 (0.0)	3/ 64 (4.7)	50.6	0/ 3 (0.0)	0/ 2 (0.0)	49.4	3.71 (0.38,35.94)	0.2584	0.0	0.4543
HP	3/ 89 (3.4)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	2/ 88 (2.3)	1/ 82 (1.2)	83.3	0/ 12 (0.0)	0/ 34 (0.0)	16.7	0.61 (0.08, 4.91)	0.6455	0.0	0.8079
Other ILD	2/ 43 (4.7)	3/ 38 (7.9)	79.1	0/ 5 (0.0)	0/ 6 (0.0)	20.9	1.55 (0.32, 7.45)	0.5833	0.0	0.8032
Region										
Europe										
Asia	0/ 76 (0.0)	0/ 79 (0.0)	52.9	0/ 27 (0.0)	0/ 54 (0.0)	47.1	1.00 (0.06,17.11)	1.0000	0.0	1.0000
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Acute respiratory failure

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	7/331 (2.1)	16/332 (4.8)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	2.43 (-0.11, 4.98)	0.0	0.3525
Age									
<65 years	3/121 (2.5)	3/139 (2.2)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	-0.29 (-3.81, 3.23)	0.0	0.9605
>=65 years	4/210 (1.9)	13/193 (6.7)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	4.33 (0.66, 8.01)	8.3	0.2965
Sex									
Male	4/177 (2.3)	9/179 (5.0)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	2.54 (-1.13, 6.20)	0.0	0.6378
Female	3/154 (1.9)	7/153 (4.6)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	2.31 (-1.34, 5.95)	0.0	0.5923
Baseline FVC percent predicted									
<=70%	7/193 (3.6)	10/196 (5.1)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	1.38 (-2.52, 5.27)	0.0	0.8402
>70%	0/138 (0.0)	6/136 (4.4)	85.1	0/ 17 (0.0)	0/ 37 (0.0)	14.9	3.73 (0.39, 7.06)	5.8	0.3029
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	11/206 (5.3)	86.8	0/ 23 (0.0)	0/ 45 (0.0)	13.2	2.53 (-0.79, 5.85)	0.0	0.4117
Other fibrotic patterns	2/125 (1.6)	5/126 (4.0)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	2.25 (-1.83, 6.33)	0.0	0.8667
Underlying ILD diagnosis									
iNSIP	0/ 61 (0.0)	2/ 64 (3.1)	87.0	0/ 7 (0.0)	0/ 11 (0.0)	13.0	2.68 (-2.50, 7.85)	0.0	0.7661
Unclassifiable IIP	0/ 50 (0.0)	3/ 64 (4.7)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	4.35 (-2.10, 10.80)	0.0	0.8654
HP	3/ 89 (3.4)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	2/ 88 (2.3)	1/ 82 (1.2)	82.1	0/ 12 (0.0)	0/ 34 (0.0)	17.9	-0.86 (-4.48, 2.75)	0.0	0.8365
Other ILD	2/ 43 (4.7)	3/ 38 (7.9)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	2.80 (-7.21, 12.81)	0.0	0.8374
Region									
Europe									
Asia	0/ 76 (0.0)	0/ 79 (0.0)	68.0	0/ 27 (0.0)	0/ 54 (0.0)	32.0	0.00 (-2.32, 2.32)	0.0	1.0000
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Acute respiratory failure

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2 p-value
Overall	7/331 (2.1)	16/332 (4.8)	93.8	0/ 27 (0.0)	0/ 54 (0.0)	6.2	2.26 (0.94, 5.46)	0.0 0.6965
Age								
<65 years	3/121 (2.5)	3/139 (2.2)	89.2	0/ 9 (0.0)	0/ 25 (0.0)	10.8	0.88 (0.19, 4.04)	0.0 0.9537
>=65 years	4/210 (1.9)	13/193 (6.7)	88.5	0/ 18 (0.0)	0/ 29 (0.0)	11.5	3.41 (1.15,10.14)	0.0 0.5427
Sex								
Male	4/177 (2.3)	9/179 (5.0)	90.4	0/ 11 (0.0)	0/ 26 (0.0)	9.6	2.17 (0.68, 6.87)	0.0 0.7186
Female	3/154 (1.9)	7/153 (4.6)	86.3	0/ 16 (0.0)	0/ 28 (0.0)	13.7	2.22 (0.61, 8.13)	0.0 0.6909
Baseline FVC percent predicted								
<=70%	7/193 (3.6)	10/196 (5.1)	93.7	0/ 10 (0.0)	0/ 17 (0.0)	6.3	1.40 (0.54, 3.66)	0.0 0.8693
>70%	0/138 (0.0)	6/136 (4.4)	52.9	0/ 17 (0.0)	0/ 37 (0.0)	47.1	7.72 (0.82,72.77)	0.0 0.3183
Baseline HRCT pattern								
UIP-like	5/206 (2.4)	11/206 (5.3)	91.5	0/ 23 (0.0)	0/ 45 (0.0)	8.5	2.16 (0.76, 6.11)	0.0 0.7096
Other fibrotic patterns	2/125 (1.6)	5/126 (4.0)	82.9	0/ 4 (0.0)	0/ 9 (0.0)	17.1	2.28 (0.48,10.72)	0.0 0.6972
Underlying ILD diagnosis								
iNSIP	0/ 61 (0.0)	2/ 64 (3.1)	51.5	0/ 7 (0.0)	0/ 11 (0.0)	48.5	3.09 (0.29,33.11)	0.0 0.5372
Unclassifiable IIP	0/ 50 (0.0)	3/ 64 (4.7)	53.1	0/ 3 (0.0)	0/ 2 (0.0)	46.9	4.00 (0.38,41.73)	0.0 0.4877
HP	3/ 89 (3.4)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC NC
Autoimmune ILD	2/ 88 (2.3)	1/ 82 (1.2)	83.5	0/ 12 (0.0)	0/ 34 (0.0)	16.5	0.61 (0.08, 4.91)	0.0 0.8084
Other ILD	2/ 43 (4.7)	3/ 38 (7.9)	79.1	0/ 5 (0.0)	0/ 6 (0.0)	20.9	1.60 (0.30, 8.57)	0.0 0.8058
Region								
Europe								
Asia	0/ 76 (0.0)	0/ 79 (0.0)	53.1	0/ 27 (0.0)	0/ 54 (0.0)	46.9	1.00 (0.06,17.56)	0.0 1.0000
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	13/331 (3.9)	6/332 (1.8)	96.7	0/ 27 (0.0)	0/ 54 (0.0)	3.3	0.48 (0.19, 1.21)	0.1188	0.0	0.7198
Age										
<65 years	1/121 (0.8)	2/139 (1.4)	73.3	0/ 9 (0.0)	0/ 25 (0.0)	26.7	1.54 (0.19,12.40)	0.6832	0.0	0.8276
>=65 years	12/210 (5.7)	4/193 (2.1)	96.1	0/ 18 (0.0)	0/ 29 (0.0)	3.9	0.39 (0.13, 1.13)	0.0815	0.0	0.6314
Sex										
Male	8/177 (4.5)	3/179 (1.7)	95.1	0/ 11 (0.0)	0/ 26 (0.0)	4.9	0.40 (0.12, 1.39)	0.1500	0.0	0.6608
Female	5/154 (3.2)	3/153 (2.0)	91.5	0/ 16 (0.0)	0/ 28 (0.0)	8.5	0.64 (0.17, 2.41)	0.5072	0.0	0.8170
Baseline FVC percent predicted										
<=70%	10/193 (5.2)	3/196 (1.5)	95.6	0/ 10 (0.0)	0/ 17 (0.0)	4.4	0.33 (0.10, 1.08)	0.0674	0.0	0.5681
>70%	3/138 (2.2)	3/136 (2.2)	87.3	0/ 17 (0.0)	0/ 37 (0.0)	12.7	1.01 (0.23, 4.45)	0.9865	0.0	0.9949
Baseline HRCT pattern										
UIP-like	10/206 (4.9)	2/206 (1.0)	95.7	0/ 23 (0.0)	0/ 45 (0.0)	4.3	0.23 (0.06, 0.93)	0.0394	0.0	0.4714
Other fibrotic patterns	3/125 (2.4)	4/126 (3.2)	87.6	0/ 4 (0.0)	0/ 9 (0.0)	12.4	1.28 (0.32, 5.14)	0.7251	0.0	0.8999
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	1/ 76 (1.3)	0/ 79 (0.0)	77.4	0/ 27 (0.0)	0/ 54 (0.0)	22.6	0.48 (0.04, 5.48)	0.5554	0.0	0.6755
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk difference (95% CI)		I^2	p-value
Overall	13/331 (3.9)	6/332 (1.8)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	-1.91 (-4.24, 0.43)		0.0	0.4571
Age										
<65 years	1/121 (0.8)	2/139 (1.4)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	0.55 (-2.04, 3.15)		0.0	0.9231
>=65 years	12/210 (5.7)	4/193 (2.1)	89.7	0/ 18 (0.0)	0/ 29 (0.0)	10.3	-3.27 (-6.71, 0.18)		0.0	0.4255
Sex										
Male	8/177 (4.5)	3/179 (1.7)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-2.61 (-6.02, 0.81)		0.0	0.6259
Female	5/154 (3.2)	3/153 (2.0)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	-1.13 (-4.43, 2.17)		0.0	0.7898
Baseline FVC percent predicted										
<=70%	10/193 (5.2)	3/196 (1.5)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	-3.41 (-6.87, 0.04)		0.0	0.6145
>70%	3/138 (2.2)	3/136 (2.2)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	0.03 (-3.12, 3.18)		0.0	0.9939
Baseline HRCT pattern										
UIP-like	10/206 (4.9)	2/206 (1.0)	86.8	0/ 23 (0.0)	0/ 45 (0.0)	13.2	-3.37 (-6.28, -0.47)		22.4	0.2562
Other fibrotic patterns	3/125 (2.4)	4/126 (3.2)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	0.74 (-3.36, 4.83)		0.0	0.9562
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	1/ 76 (1.3)	0/ 79 (0.0)	68.0	0/ 27 (0.0)	0/ 54 (0.0)	32.0	-0.88 (-3.77, 2.00)		0.0	0.6768
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo	Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	I^2	p-value
Overall	13/331 (3.9)	6/332 (1.8)	96.7	0/ 27 (0.0)	0/ 54 (0.0)	3.3	0.47 (0.18, 1.21)	0.0	0.7158
Age									
<65 years	1/121 (0.8)	2/139 (1.4)	73.6	0/ 9 (0.0)	0/ 25 (0.0)	26.4	1.55 (0.18,13.10)	0.0	0.8298
>=65 years	12/210 (5.7)	4/193 (2.1)	96.0	0/ 18 (0.0)	0/ 29 (0.0)	4.0	0.37 (0.13, 1.12)	0.0	0.6261
Sex									
Male	8/177 (4.5)	3/179 (1.7)	95.1	0/ 11 (0.0)	0/ 26 (0.0)	4.9	0.39 (0.11, 1.38)	0.0	0.6598
Female	5/154 (3.2)	3/153 (2.0)	91.5	0/ 16 (0.0)	0/ 28 (0.0)	8.5	0.63 (0.16, 2.45)	0.0	0.8163
Baseline FVC percent predicted									
<=70%	10/193 (5.2)	3/196 (1.5)	95.7	0/ 10 (0.0)	0/ 17 (0.0)	4.3	0.32 (0.09, 1.07)	0.0	0.5695
>70%	3/138 (2.2)	3/136 (2.2)	87.3	0/ 17 (0.0)	0/ 37 (0.0)	12.7	1.01 (0.22, 4.60)	0.0	0.9949
Baseline HRCT pattern									
UIP-like	10/206 (4.9)	2/206 (1.0)	95.7	0/ 23 (0.0)	0/ 45 (0.0)	4.3	0.23 (0.06, 0.91)	0.0	0.4670
Other fibrotic patterns	3/125 (2.4)	4/126 (3.2)	88.0	0/ 4 (0.0)	0/ 9 (0.0)	12.0	1.29 (0.31, 5.44)	0.0	0.9035
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	1/ 76 (1.3)	0/ 79 (0.0)	77.5	0/ 27 (0.0)	0/ 54 (0.0)	22.5	0.48 (0.04, 5.32)	0.0	0.6754
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Interstitial lung disease

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo			
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	45/331 (13.6)	19/332 (5.7)	91.0	3/ 27 (11.1)	0/ 54 (0.0)	9.0	0.39 (0.24, 0.65)	0.0002	12.2	0.2860
Age										
<65 years	13/121 (10.7)	2/139 (1.4)	88.2	1/ 9 (11.1)	0/ 25 (0.0)	11.8	0.14 (0.04, 0.53)	0.0037	0.0	0.7806
>=65 years	32/210 (15.2)	17/193 (8.8)	91.2	2/ 18 (11.1)	0/ 29 (0.0)	8.8	0.54 (0.32, 0.93)	0.0257	0.0	0.3695
Sex										
Male	26/177 (14.7)	12/179 (6.7)	98.4	0/ 11 (0.0)	0/ 26 (0.0)	1.6	0.46 (0.24, 0.88)	0.0196	0.0	0.7196
Female	19/154 (12.3)	7/153 (4.6)	81.6	3/ 16 (18.8)	0/ 28 (0.0)	18.4	0.32 (0.15, 0.71)	0.0046	0.0	0.3783
Baseline FVC percent predicted										
<=70%	28/193 (14.5)	17/196 (8.7)	90.4	2/ 10 (20.0)	0/ 17 (0.0)	9.6	0.56 (0.32, 0.96)	0.0365	0.0	0.3361
>70%	17/138 (12.3)	2/136 (1.5)	90.4	1/ 17 (5.9)	0/ 37 (0.0)	9.6	0.13 (0.04, 0.48)	0.0022	0.0	0.6708
Baseline HRCT pattern										
UIP-like	35/206 (17.0)	15/206 (7.3)	88.8	3/ 23 (13.0)	0/ 45 (0.0)	11.2	0.39 (0.23, 0.68)	0.0009	11.9	0.2867
Other fibrotic patterns	10/125 (8.0)	4/126 (3.2)	95.9	0/ 4 (0.0)	0/ 9 (0.0)	4.1	0.42 (0.14, 1.25)	0.1187	0.0	0.6704
Underlying ILD diagnosis										
iNSIP	9/ 61 (14.8)	4/ 64 (6.3)	84.4	1/ 7 (14.3)	0/ 11 (0.0)	15.6	0.40 (0.14, 1.14)	0.0866	0.0	0.7924
Unclassifiable IIP	16/ 50 (32.0)	9/ 64 (14.1)	93.3	1/ 3 (33.3)	0/ 2 (0.0)	6.7	0.44 (0.21, 0.88)	0.0216	0.0	0.9226
HP	8/ 89 (9.0)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	8/ 88 (9.1)	1/ 82 (1.2)	80.5	1/ 12 (8.3)	0/ 34 (0.0)	19.5	0.15 (0.03, 0.81)	0.0280	0.0	0.8068
Other ILD	4/ 43 (9.3)	0/ 38 (0.0)	89.6	0/ 5 (0.0)	0/ 6 (0.0)	10.4	0.21 (0.02, 1.84)	0.1582	0.0	0.3825
Region										
Europe										
Asia	27/ 76 (35.5)	10/ 79 (12.7)	86.1	3/ 27 (11.1)	0/ 54 (0.0)	13.9	0.32 (0.17, 0.60)	0.0004	0.0	0.3511
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Interstitial lung disease

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	45/331 (13.6)	19/332 (5.7)	90.0	3/ 27 (11.1)	0/ 54 (0.0)	10.0	-8.17 (-12.37, -3.97)	0.0	0.6600
Age									
<65 years	13/121 (10.7)	2/139 (1.4)	90.2	1/ 9 (11.1)	0/ 25 (0.0)	9.8	-9.42 (-15.15, -3.70)	0.0	0.9199
>=65 years	32/210 (15.2)	17/193 (8.8)	89.7	2/ 18 (11.1)	0/ 29 (0.0)	10.3	-6.87 (-12.74, -0.99)	0.0	0.6277
Sex									
Male	26/177 (14.7)	12/179 (6.7)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	-7.32 (-13.22, -1.41)	35.3	0.2137
Female	19/154 (12.3)	7/153 (4.6)	87.8	3/ 16 (18.8)	0/ 28 (0.0)	12.2	-9.00 (-14.93, -3.07)	0.0	0.3390
Baseline FVC percent predicted									
<=70%	28/193 (14.5)	17/196 (8.7)	93.5	2/ 10 (20.0)	0/ 17 (0.0)	6.5	-6.67 (-12.83, -0.50)	0.0	0.3521
>70%	17/138 (12.3)	2/136 (1.5)	85.0	1/ 17 (5.9)	0/ 37 (0.0)	15.0	-10.07 (-15.41, -4.74)	0.0	0.4755
Baseline HRCT pattern									
UIP-like	35/206 (17.0)	15/206 (7.3)	86.8	3/ 23 (13.0)	0/ 45 (0.0)	13.2	-10.10 (-15.84, -4.36)	0.0	0.7119
Other fibrotic patterns	10/125 (8.0)	4/126 (3.2)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	-4.59 (-10.13, 0.95)	0.0	0.7349
Underlying ILD diagnosis									
iNSIP	9/ 61 (14.8)	4/ 64 (6.3)	86.8	1/ 7 (14.3)	0/ 11 (0.0)	13.2	-9.08 (-19.15, 0.99)	0.0	0.7861
Unclassifiable IIP	16/ 50 (32.0)	9/ 64 (14.1)	94.4	1/ 3 (33.3)	0/ 2 (0.0)	5.6	-18.27 (-33.29, -3.25)	0.0	0.8570
HP	8/ 89 (9.0)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	8/ 88 (9.1)	1/ 82 (1.2)	82.1	1/ 12 (8.3)	0/ 34 (0.0)	17.9	-7.89 (-14.03, -1.75)	0.0	0.9903
Other ILD	4/ 43 (9.3)	0/ 38 (0.0)	86.5	0/ 5 (0.0)	0/ 6 (0.0)	13.5	-7.85 (-17.04, 1.33)	0.0	0.5614
Region									
Europe									
Asia	27/ 76 (35.5)	10/ 79 (12.7)	67.7	3/ 27 (11.1)	0/ 54 (0.0)	32.3	-18.99 (-28.68, -9.30)	41.5	0.1911
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Interstitial lung disease

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	45/331 (13.6)	19/332 (5.7)	90.6	3/ 27 (11.1)	0/ 54 (0.0)	9.4	0.36 (0.21, 0.62)	9.7	0.2925
Age									
<65 years	13/121 (10.7)	2/139 (1.4)	88.3	1/ 9 (11.1)	0/ 25 (0.0)	11.7	0.13 (0.03, 0.50)	0.0	0.8001
>=65 years	32/210 (15.2)	17/193 (8.8)	90.7	2/ 18 (11.1)	0/ 29 (0.0)	9.3	0.50 (0.27, 0.92)	0.0	0.3767
Sex									
Male	26/177 (14.7)	12/179 (6.7)	98.4	0/ 11 (0.0)	0/ 26 (0.0)	1.6	0.43 (0.21, 0.86)	0.0	0.6973
Female	19/154 (12.3)	7/153 (4.6)	81.2	3/ 16 (18.8)	0/ 28 (0.0)	18.8	0.29 (0.13, 0.68)	0.0	0.3613
Baseline FVC percent predicted									
<=70%	28/193 (14.5)	17/196 (8.7)	89.9	2/ 10 (20.0)	0/ 17 (0.0)	10.1	0.52 (0.28, 0.96)	0.0	0.3250
>70%	17/138 (12.3)	2/136 (1.5)	90.4	1/ 17 (5.9)	0/ 37 (0.0)	9.6	0.12 (0.03, 0.44)	0.0	0.6573
Baseline HRCT pattern									
UIP-like	35/206 (17.0)	15/206 (7.3)	88.2	3/ 23 (13.0)	0/ 45 (0.0)	11.8	0.35 (0.19, 0.65)	7.9	0.2974
Other fibrotic patterns	10/125 (8.0)	4/126 (3.2)	96.1	0/ 4 (0.0)	0/ 9 (0.0)	3.9	0.40 (0.13, 1.25)	0.0	0.6746
Underlying ILD diagnosis									
iNSIP	9/ 61 (14.8)	4/ 64 (6.3)	84.3	1/ 7 (14.3)	0/ 11 (0.0)	15.7	0.36 (0.11, 1.15)	0.0	0.7885
Unclassifiable IIP	16/ 50 (32.0)	9/ 64 (14.1)	93.4	1/ 3 (33.3)	0/ 2 (0.0)	6.6	0.34 (0.14, 0.84)	0.0	0.9023
HP	8/ 89 (9.0)	5/ 84 (6.0)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	8/ 88 (9.1)	1/ 82 (1.2)	80.7	1/ 12 (8.3)	0/ 34 (0.0)	19.3	0.14 (0.02, 0.77)	0.0	0.8154
Other ILD	4/ 43 (9.3)	0/ 38 (0.0)	90.2	0/ 5 (0.0)	0/ 6 (0.0)	9.8	0.19 (0.02, 1.78)	0.0	0.3893
Region									
Europe									
Asia	27/ 76 (35.5)	10/ 79 (12.7)	84.6	3/ 27 (11.1)	0/ 54 (0.0)	15.4	0.24 (0.11, 0.51)	0.0	0.4472
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Respiratory failure

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid					
Overall	10/331 (3.0)	11/332 (3.3)	79.0	2/ 27 (7.4)	2/ 54 (3.7)	21.0	0.97 (0.45, 2.08)	0.9402	0.0	0.4598
Age										
<65 years	2/121 (1.7)	6/139 (4.3)	53.5	1/ 9 (11.1)	0/ 25 (0.0)	46.5	1.49 (0.44, 5.05)	0.5184	58.3	0.1217
>=65 years	8/210 (3.8)	5/193 (2.6)	86.1	1/ 18 (5.6)	2/ 29 (6.9)	13.9	0.76 (0.28, 2.04)	0.5824	0.0	0.6468
Sex										
Male	8/177 (4.5)	6/179 (3.4)	85.1	1/ 11 (9.1)	2/ 26 (7.7)	14.9	0.76 (0.29, 1.95)	0.5644	0.0	0.9183
Female	2/154 (1.3)	5/153 (3.3)	53.5	1/ 16 (6.3)	0/ 28 (0.0)	46.5	1.47 (0.41, 5.26)	0.5542	42.5	0.1873
Baseline FVC percent predicted										
<=70%	9/193 (4.7)	8/196 (4.1)	84.0	1/ 10 (10.0)	0/ 17 (0.0)	16.0	0.78 (0.33, 1.86)	0.5742	0.0	0.4477
>70%	1/138 (0.7)	3/136 (2.2)	42.0	1/ 17 (5.9)	2/ 37 (5.4)	58.0	1.81 (0.38, 8.61)	0.4548	0.0	0.4687
Baseline HRCT pattern										
UIP-like	8/206 (3.9)	7/206 (3.4)	75.1	2/ 23 (8.7)	1/ 45 (2.2)	24.9	0.72 (0.29, 1.76)	0.4735	0.0	0.3441
Other fibrotic patterns	2/125 (1.6)	4/126 (3.2)	82.5	0/ 4 (0.0)	1/ 9 (11.1)	17.5	2.06 (0.45, 9.52)	0.3525	0.0	0.9195
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	3/ 76 (3.9)	0/ 79 (0.0)	57.2	2/ 27 (7.4)	2/ 54 (3.7)	42.8	0.29 (0.06, 1.41)	0.1267	0.0	0.4756
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Respiratory failure

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2 p-value
Overall	10/331 (3.0)	11/332 (3.3)	90.2	2/ 27 (7.4)	2/ 54 (3.7)	9.8	-0.10 (-2.74, 2.54)	0.0 0.4923
Age								
<65 years	2/121 (1.7)	6/139 (4.3)	90.2	1/ 9 (11.1)	0/ 25 (0.0)	9.8	1.38 (-2.90, 5.66)	21.8 0.2580
>=65 years	8/210 (3.8)	5/193 (2.6)	90.1	1/ 18 (5.6)	2/ 29 (6.9)	9.9	-0.96 (-4.35, 2.42)	0.0 0.7284
Sex								
Male	8/177 (4.5)	6/179 (3.4)	92.0	1/ 11 (9.1)	2/ 26 (7.7)	8.0	-1.19 (-5.23, 2.85)	0.0 0.9822
Female	2/154 (1.3)	5/153 (3.3)	87.8	1/ 16 (6.3)	0/ 28 (0.0)	12.2	1.00 (-2.40, 4.40)	13.0 0.2836
Baseline FVC percent predicted								
<=70%	9/193 (4.7)	8/196 (4.1)	93.5	1/ 10 (10.0)	0/ 17 (0.0)	6.5	-1.15 (-5.20, 2.90)	0.0 0.4371
>70%	1/138 (0.7)	3/136 (2.2)	85.5	1/ 17 (5.9)	2/ 37 (5.4)	14.5	1.20 (-1.91, 4.31)	0.0 0.7786
Baseline HRCT pattern								
UIP-like	8/206 (3.9)	7/206 (3.4)	87.1	2/ 23 (8.7)	1/ 45 (2.2)	12.9	-1.26 (-4.78, 2.27)	0.0 0.3598
Other fibrotic patterns	2/125 (1.6)	4/126 (3.2)	95.2	0/ 4 (0.0)	1/ 9 (11.1)	4.8	1.96 (-1.94, 5.87)	0.0 0.6239
Underlying ILD diagnosis								
iNSIP								
Unclassifiable IIP								
HP								
Autoimmune ILD								
Other ILD								
Region								
Europe								
Asia	3/ 76 (3.9)	0/ 79 (0.0)	68.6	2/ 27 (7.4)	2/ 54 (3.7)	31.4	-3.84 (-8.71, 1.04)	0.0 0.9751
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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Table M.2.2.1.4: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

SOC: Respiratory, thoracic and mediastinal disorders
PT: Respiratory failure

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo	Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	I^2	p-value
Overall	10/331 (3.0)	11/332 (3.3)	79.0	2/ 27 (7.4)	2/ 54 (3.7)	21.0	0.97 (0.44, 2.15)	0.0	0.4603
Age									
<65 years	2/121 (1.7)	6/139 (4.3)	53.1	1/ 9 (11.1)	0/ 25 (0.0)	46.9	1.51 (0.41, 5.59)	57.9	0.1234
>=65 years	8/210 (3.8)	5/193 (2.6)	86.7	1/ 18 (5.6)	2/ 29 (6.9)	13.3	0.75 (0.27, 2.08)	0.0	0.6510
Sex									
Male	8/177 (4.5)	6/179 (3.4)	85.7	1/ 11 (9.1)	2/ 26 (7.7)	14.3	0.75 (0.28, 2.01)	0.0	0.9264
Female	2/154 (1.3)	5/153 (3.3)	53.2	1/ 16 (6.3)	0/ 28 (0.0)	46.8	1.48 (0.39, 5.66)	42.5	0.1874
Baseline FVC percent predicted									
<=70%	9/193 (4.7)	8/196 (4.1)	83.9	1/ 10 (10.0)	0/ 17 (0.0)	16.1	0.77 (0.31, 1.93)	0.0	0.4418
>70%	1/138 (0.7)	3/136 (2.2)	42.8	1/ 17 (5.9)	2/ 37 (5.4)	57.2	1.85 (0.36, 9.59)	0.0	0.4775
Baseline HRCT pattern									
UIP-like	8/206 (3.9)	7/206 (3.4)	74.9	2/ 23 (8.7)	1/ 45 (2.2)	25.1	0.71 (0.28, 1.82)	0.0	0.3411
Other fibrotic patterns	2/125 (1.6)	4/126 (3.2)	84.5	0/ 4 (0.0)	1/ 9 (11.1)	15.5	2.13 (0.44,10.26)	0.0	0.8923
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	3/ 76 (3.9)	0/ 79 (0.0)	57.9	2/ 27 (7.4)	2/ 54 (3.7)	42.1	0.28 (0.06, 1.37)	0.0	0.4866
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.
Only adverse events reported in study 1199-0247 that met the minimum occurrence threshold
(incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.

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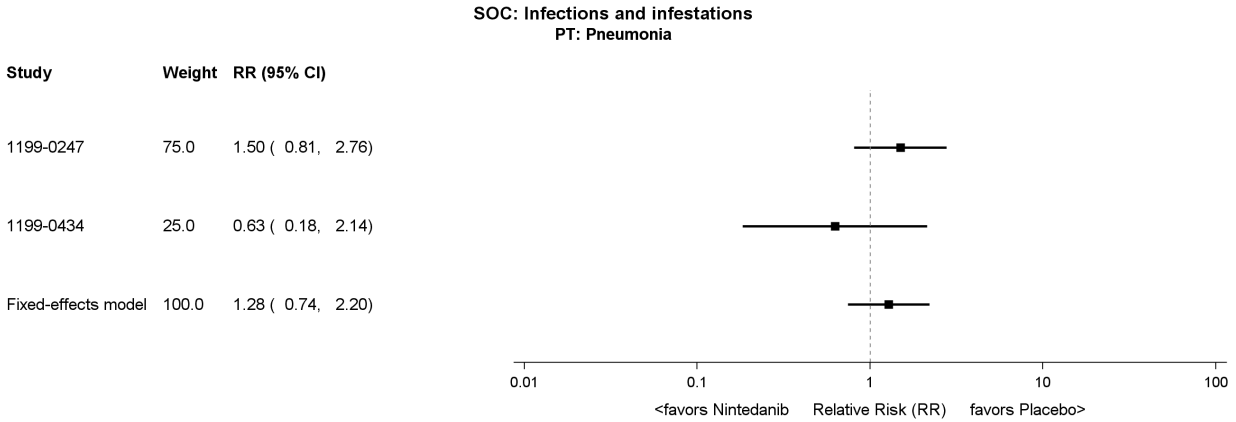

Figure M.2.2.1.4: 2 Forest Plot comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

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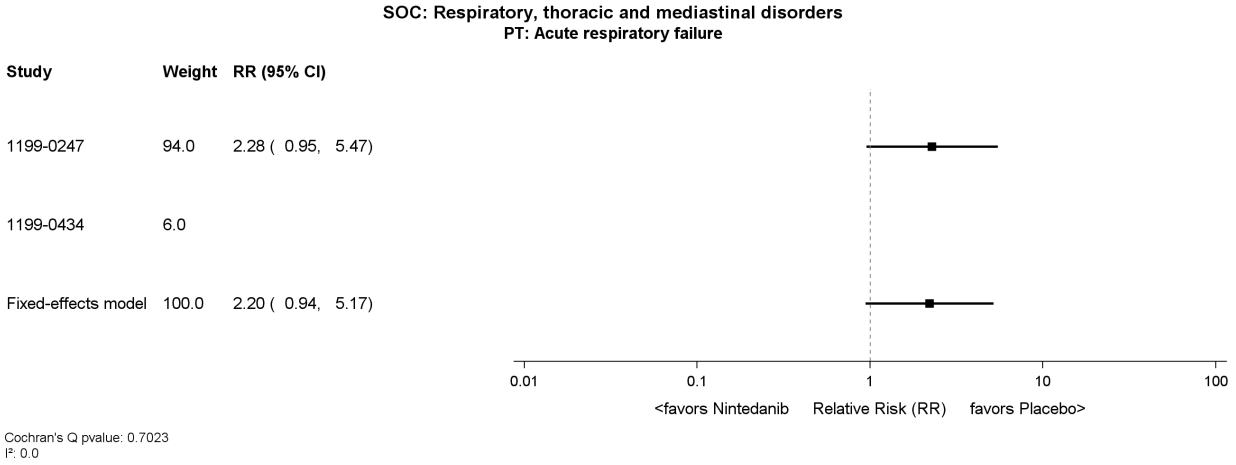

Figure M.2.2.1.4: 2 Forest Plot comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

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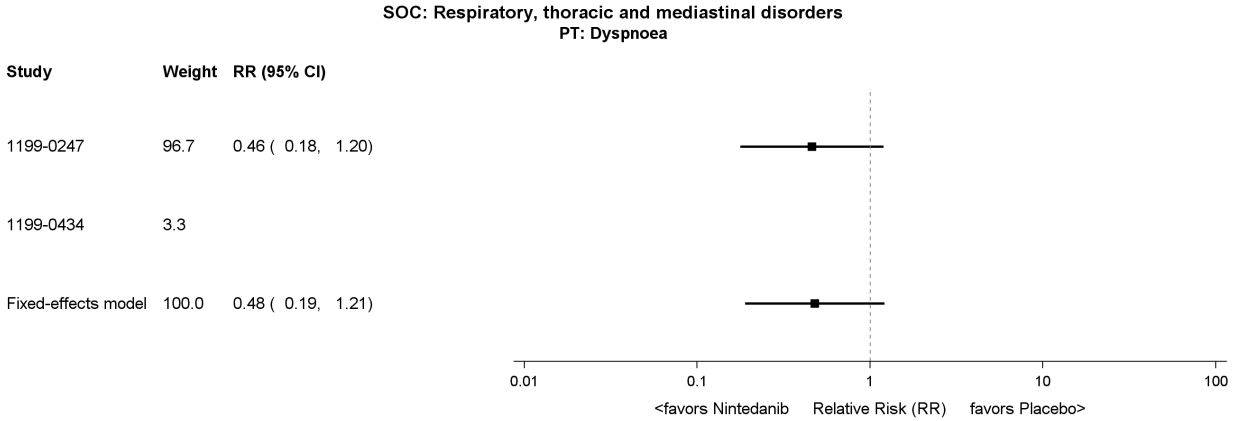

Figure M.2.2.1.4: 2 Forest Plot comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

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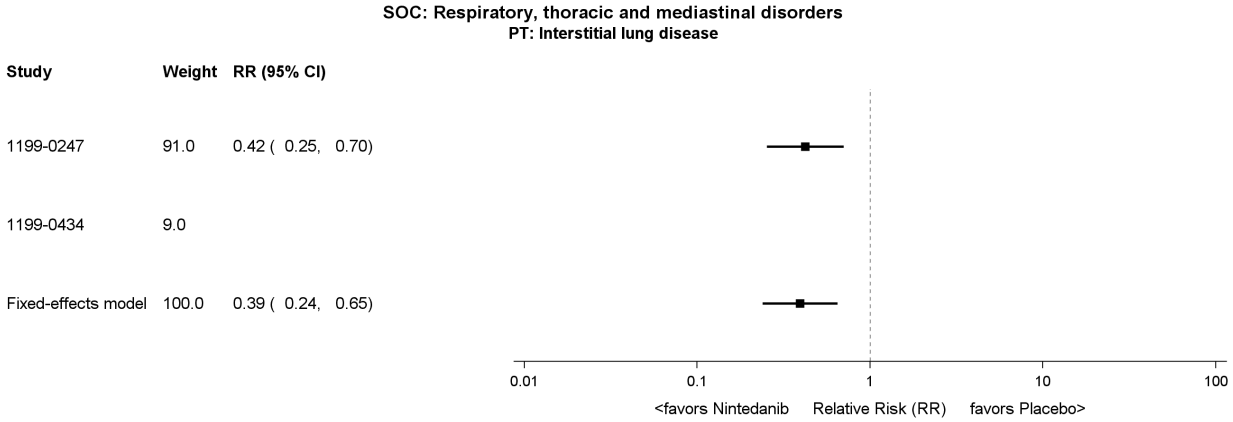

Figure M.2.2.1.4: 2 Forest Plot comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

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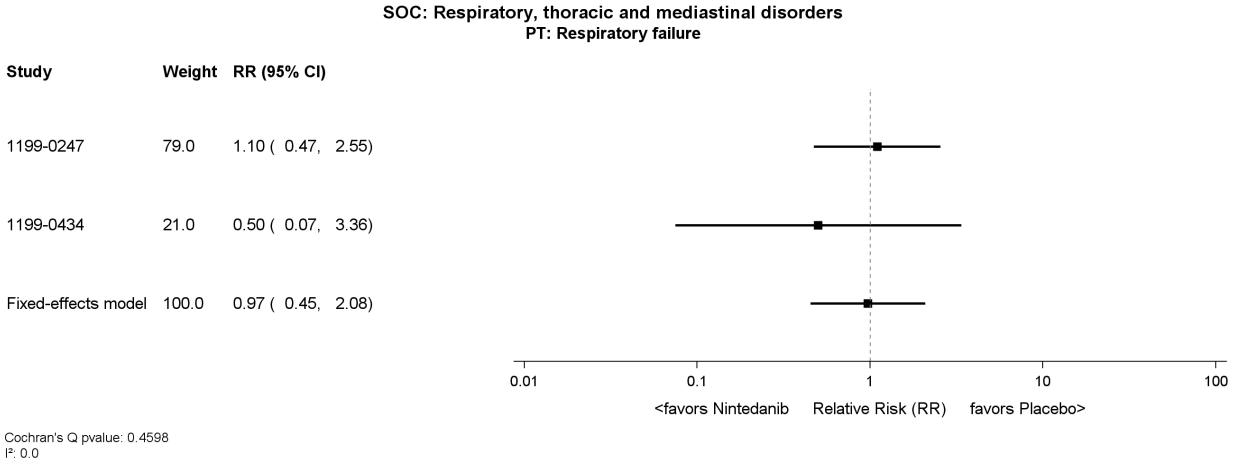

Figure M.2.2.1.4: 2 Forest Plot comparing Nintedanib versus Placebo for patients with frequent serious AEs by SOC and PT over the whole trial

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M.2.2.1.5 Further safety analysis

Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	164/331 (49.5)	279/332 (84.0)	93.9	8/ 27 (29.6)	35/ 54 (64.8)	6.1	1.73 (1.53, 1.94)	<.0001	0.0	0.4249
Age										
<65 years	52/121 (43.0)	114/139 (82.0)	92.6	3/ 9 (33.3)	14/ 25 (56.0)	7.4	1.89 (1.53, 2.35)	<.0001	0.0	0.8048
>=65 years	112/210 (53.3)	165/193 (85.5)	94.6	5/ 18 (27.8)	21/ 29 (72.4)	5.4	1.66 (1.44, 1.91)	<.0001	31.2	0.2279
Sex										
Male	89/177 (50.3)	151/179 (84.4)	95.5	3/ 11 (27.3)	13/ 26 (50.0)	4.5	1.68 (1.44, 1.98)	<.0001	0.0	0.8686
Female	75/154 (48.7)	128/153 (83.7)	92.2	5/ 16 (31.3)	22/ 28 (78.6)	7.8	1.78 (1.50, 2.12)	<.0001	0.0	0.3338
Baseline FVC percent predicted										
<=70%	103/193 (53.4)	165/196 (84.2)	95.4	4/ 10 (40.0)	8/ 17 (47.1)	4.6	1.56 (1.35, 1.80)	<.0001	0.0	0.5333
>70%	61/138 (44.2)	114/136 (83.8)	91.7	4/ 17 (23.5)	27/ 37 (73.0)	8.3	2.00 (1.63, 2.44)	<.0001	12.5	0.2851
Baseline HRCT pattern										
UIP-like	107/206 (51.9)	175/206 (85.0)	93.1	6/ 23 (26.1)	29/ 45 (64.4)	6.9	1.69 (1.47, 1.96)	<.0001	17.2	0.2717
Other fibrotic patterns	57/125 (45.6)	104/126 (82.5)	95.4	2/ 4 (50.0)	6/ 9 (66.7)	4.6	1.79 (1.46, 2.19)	<.0001	0.0	0.5870
Underlying ILD diagnosis										
iNSIP	18/ 61 (29.5)	48/ 64 (75.0)	88.3	2/ 7 (28.6)	8/ 11 (72.7)	11.7	2.54 (1.72, 3.76)	<.0001	0.0	0.9982
Unclassifiable IIP	21/ 50 (42.0)	59/ 64 (92.2)	98.0	0/ 3 (0.0)	2/ 2 (100.0)	2.0	2.27 (1.63, 3.16)	<.0001	0.0	0.4142
HP	54/ 89 (60.7)	71/ 84 (84.5)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	48/ 88 (54.5)	69/ 82 (84.1)	94.0	2/ 12 (16.7)	20/ 34 (58.8)	6.0	1.66 (1.33, 2.08)	<.0001	34.4	0.2168
Other ILD	23/ 43 (53.5)	32/ 38 (84.2)	83.2	4/ 5 (80.0)	4/ 6 (66.7)	16.8	1.45 (1.09, 1.93)	0.0105	60.8	0.1100
Region										
Europe										
Asia	44/ 76 (57.9)	75/ 79 (94.9)	80.8	8/ 27 (29.6)	35/ 54 (64.8)	19.2	1.75 (1.42, 2.14)	<.0001	0.0	0.3811
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	164/331 (49.5)	279/332 (84.0)	90.2	8/ 27 (29.6)	35/ 54 (64.8)	9.8	34.56 (28.18, 40.93)	0.0	0.9515
Age									
<65 years	52/121 (43.0)	114/139 (82.0)	90.7	3/ 9 (33.3)	14/ 25 (56.0)	9.3	37.52 (27.08, 47.96)	0.0	0.3987
>=65 years	112/210 (53.3)	165/193 (85.5)	90.1	5/ 18 (27.8)	21/ 29 (72.4)	9.9	33.40 (25.41, 41.39)	0.0	0.3760
Sex									
Male	89/177 (50.3)	151/179 (84.4)	92.0	3/ 11 (27.3)	13/ 26 (50.0)	8.0	33.17 (24.41, 41.93)	0.0	0.5109
Female	75/154 (48.7)	128/153 (83.7)	88.3	5/ 16 (31.3)	22/ 28 (78.6)	11.7	36.41 (27.16, 45.66)	0.0	0.4041
Baseline FVC percent predicted									
<=70%	103/193 (53.4)	165/196 (84.2)	93.9	4/ 10 (40.0)	8/ 17 (47.1)	6.1	29.37 (20.87, 37.87)	28.0	0.2385
>70%	61/138 (44.2)	114/136 (83.8)	85.5	4/ 17 (23.5)	27/ 37 (73.0)	14.5	41.05 (31.51, 50.59)	0.0	0.4725
Baseline HRCT pattern									
UIP-like	107/206 (51.9)	175/206 (85.0)	87.1	6/ 23 (26.1)	29/ 45 (64.4)	12.9	33.70 (25.82, 41.57)	0.0	0.6656
Other fibrotic patterns	57/125 (45.6)	104/126 (82.5)	95.8	2/ 4 (50.0)	6/ 9 (66.7)	4.2	36.08 (25.30, 46.86)	0.0	0.4999
Underlying ILD diagnosis									
iNSIP	18/ 61 (29.5)	48/ 64 (75.0)	88.0	2/ 7 (28.6)	8/ 11 (72.7)	12.0	45.33 (30.68, 59.98)	0.0	0.9540
Unclassifiable IIP	21/ 50 (42.0)	59/ 64 (92.2)	94.4	0/ 3 (0.0)	2/ 2 (100.0)	5.6	51.39 (36.76, 66.02)	0.0	0.4495
HP	54/ 89 (60.7)	71/ 84 (84.5)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	48/ 88 (54.5)	69/ 82 (84.1)	82.7	2/ 12 (16.7)	20/ 34 (58.8)	17.3	31.77 (20.01, 43.53)	0.0	0.4092
Other ILD	23/ 43 (53.5)	32/ 38 (84.2)	88.1	4/ 5 (80.0)	4/ 6 (66.7)	11.9	25.48 (7.74, 43.21)	59.6	0.1154
Region									
Europe									
Asia	44/ 76 (57.9)	75/ 79 (94.9)	68.3	8/ 27 (29.6)	35/ 54 (64.8)	31.7	36.45 (25.75, 47.15)	0.0	0.8824
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	164/331 (49.5)	279/332 (84.0)	87.5	8/ 27 (29.6)	35/ 54 (64.8)	12.5	5.24 (3.72, 7.37)	0.0	0.7076
Age									
<65 years	52/121 (43.0)	114/139 (82.0)	83.7	3/ 9 (33.3)	14/ 25 (56.0)	16.3	5.48 (3.23, 9.31)	0.7	0.3157
>=65 years	112/210 (53.3)	165/193 (85.5)	90.1	5/ 18 (27.8)	21/ 29 (72.4)	9.9	5.32 (3.38, 8.38)	0.0	0.6947
Sex									
Male	89/177 (50.3)	151/179 (84.4)	86.9	3/ 11 (27.3)	13/ 26 (50.0)	13.1	4.98 (3.10, 8.01)	0.0	0.3997
Female	75/154 (48.7)	128/153 (83.7)	90.0	5/ 16 (31.3)	22/ 28 (78.6)	10.0	5.66 (3.44, 9.31)	0.0	0.5960
Baseline FVC percent predicted									
<=70%	103/193 (53.4)	165/196 (84.2)	86.0	4/ 10 (40.0)	8/ 17 (47.1)	14.0	4.19 (2.66, 6.59)	54.4	0.1387
>70%	61/138 (44.2)	114/136 (83.8)	86.9	4/ 17 (23.5)	27/ 37 (73.0)	13.1	6.83 (4.06,11.51)	0.0	0.6913
Baseline HRCT pattern									
UIP-like	107/206 (51.9)	175/206 (85.0)	85.1	6/ 23 (26.1)	29/ 45 (64.4)	14.9	5.21 (3.38, 8.03)	0.0	0.9781
Other fibrotic patterns	57/125 (45.6)	104/126 (82.5)	91.5	2/ 4 (50.0)	6/ 9 (66.7)	8.5	5.33 (3.04, 9.34)	0.0	0.4106
Underlying ILD diagnosis									
iNSIP	18/ 61 (29.5)	48/ 64 (75.0)	87.4	2/ 7 (28.6)	8/ 11 (72.7)	12.6	7.10 (3.39,14.88)	0.0	0.9498
Unclassifiable IIP	21/ 50 (42.0)	59/ 64 (92.2)	96.4	0/ 3 (0.0)	2/ 2 (100.0)	3.6	17.00 (6.01,48.10)	0.0	0.7271
HP	54/ 89 (60.7)	71/ 84 (84.5)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	48/ 88 (54.5)	69/ 82 (84.1)	85.8	2/ 12 (16.7)	20/ 34 (58.8)	14.2	4.81 (2.48, 9.34)	0.0	0.6050
Other ILD	23/ 43 (53.5)	32/ 38 (84.2)	70.1	4/ 5 (80.0)	4/ 6 (66.7)	29.9	3.40 (1.32, 8.78)	53.8	0.1412
Region									
Europe									
Asia	44/ 76 (57.9)	75/ 79 (94.9)	37.7	8/ 27 (29.6)	35/ 54 (64.8)	62.3	7.87 (3.83,16.17)	55.4	0.1342
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	11/331 (3.3)	41/332 (12.3)	80.5	2/ 27 (7.4)	18/ 54 (33.3)	19.5	3.87 (2.15, 6.97)	<.0001	0.0	0.8063
Age										
<65 years	2/121 (1.7)	17/139 (12.2)	84.6	0/ 9 (0.0)	9/ 25 (36.0)	15.4	8.30 (2.11,32.64)	0.0025	0.0	0.7785
>=65 years	9/210 (4.3)	24/193 (12.4)	77.7	2/ 18 (11.1)	9/ 29 (31.0)	22.3	2.88 (1.49, 5.55)	0.0016	0.0	0.9627
Sex										
Male	6/177 (3.4)	25/179 (14.0)	68.2	2/ 11 (18.2)	7/ 26 (26.9)	31.8	3.28 (1.59, 6.79)	0.0014	32.3	0.2242
Female	5/154 (3.2)	16/153 (10.5)	91.5	0/ 16 (0.0)	11/ 28 (39.3)	8.5	4.50 (1.76,11.52)	0.0017	0.8	0.3154
Baseline FVC percent predicted										
<=70%	8/193 (4.1)	27/196 (13.8)	94.5	0/ 10 (0.0)	7/ 17 (41.2)	5.5	3.80 (1.81, 8.00)	0.0004	0.0	0.4423
>70%	3/138 (2.2)	14/136 (10.3)	52.1	2/ 17 (11.8)	11/ 37 (29.7)	47.9	3.68 (1.48, 9.14)	0.0051	0.0	0.5069
Baseline HRCT pattern										
UIP-like	8/206 (3.9)	24/206 (11.7)	75.1	2/ 23 (8.7)	15/ 45 (33.3)	24.9	3.21 (1.63, 6.32)	0.0008	0.0	0.7625
Other fibrotic patterns	3/125 (2.4)	17/126 (13.5)	87.6	0/ 4 (0.0)	3/ 9 (33.3)	12.4	5.59 (1.79,17.45)	0.0031	0.0	0.9778
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	9/ 64 (14.1)	45.6	1/ 7 (14.3)	4/ 11 (36.4)	54.4	5.30 (1.31,21.41)	0.0193	0.0	0.4013
Unclassifiable IIP	1/ 50 (2.0)	16/ 64 (25.0)	70.1	0/ 3 (0.0)	0/ 2 (0.0)	29.9	9.06 (1.70,48.38)	0.0100	27.9	0.2389
HP	5/ 89 (5.6)	6/ 84 (7.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	3/ 88 (3.4)	7/ 82 (8.5)	88.2	0/ 12 (0.0)	14/ 34 (41.2)	11.8	4.55 (1.27,16.30)	0.0198	1.4	0.3140
Other ILD	1/ 43 (2.3)	3/ 38 (7.9)	37.2	1/ 5 (20.0)	0/ 6 (0.0)	62.8	1.46 (0.32, 6.65)	0.6265	38.6	0.2019
Region										
Europe										
Asia	3/ 76 (3.9)	27/ 79 (34.2)	53.4	2/ 27 (7.4)	18/ 54 (33.3)	46.6	6.72 (2.80,16.12)	<.0001	0.0	0.4764
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	11/331 (3.3)	41/332 (12.3)	90.2	2/ 27 (7.4)	18/ 54 (33.3)	9.8	10.68 (6.72, 14.64)	75.2	0.0446
Age									
<65 years	2/121 (1.7)	17/139 (12.2)	90.2	0/ 9 (0.0)	9/ 25 (36.0)	9.8	12.87 (7.16, 18.58)	77.2	0.0364
>=65 years	9/210 (4.3)	24/193 (12.4)	90.1	2/ 18 (11.1)	9/ 29 (31.0)	9.9	9.32 (3.98, 14.66)	1.7	0.3132
Sex									
Male	6/177 (3.4)	25/179 (14.0)	92.0	2/ 11 (18.2)	7/ 26 (26.9)	8.0	10.43 (4.68, 16.18)	0.0	0.9014
Female	5/154 (3.2)	16/153 (10.5)	87.8	0/ 16 (0.0)	11/ 28 (39.3)	12.2	10.91 (5.47, 16.35)	88.9	0.0027
Baseline FVC percent predicted									
<=70%	8/193 (4.1)	27/196 (13.8)	93.5	0/ 10 (0.0)	7/ 17 (41.2)	6.5	11.50 (6.03, 16.97)	79.1	0.0288
>70%	3/138 (2.2)	14/136 (10.3)	85.5	2/ 17 (11.8)	11/ 37 (29.7)	14.5	9.55 (3.81, 15.29)	0.0	0.3802
Baseline HRCT pattern									
UIP-like	8/206 (3.9)	24/206 (11.7)	87.1	2/ 23 (8.7)	15/ 45 (33.3)	12.9	9.94 (4.92, 14.96)	68.1	0.0765
Other fibrotic patterns	3/125 (2.4)	17/126 (13.5)	95.2	0/ 4 (0.0)	3/ 9 (33.3)	4.8	11.95 (5.48, 18.43)	0.0	0.3526
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	9/ 64 (14.1)	88.0	1/ 7 (14.3)	4/ 11 (36.4)	12.0	13.59 (4.34, 22.83)	0.0	0.6322
Unclassifiable IIP	1/ 50 (2.0)	16/ 64 (25.0)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	21.70 (10.63, 32.77)	0.0	0.4048
HP	5/ 89 (5.6)	6/ 84 (7.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	3/ 88 (3.4)	7/ 82 (8.5)	82.1	0/ 12 (0.0)	14/ 34 (41.2)	17.9	11.27 (4.58, 17.96)	91.7	0.0005
Other ILD	1/ 43 (2.3)	3/ 38 (7.9)	86.2	1/ 5 (20.0)	0/ 6 (0.0)	13.8	2.47 (-7.53, 12.47)	13.3	0.2828
Region									
Europe									
Asia	3/ 76 (3.9)	27/ 79 (34.2)	68.3	2/ 27 (7.4)	18/ 54 (33.3)	31.7	28.86 (19.61, 38.12)	0.0	0.6669
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	11/331 (3.3)	41/332 (12.3)	84.5	2/ 27 (7.4)	18/ 54 (33.3)	15.5	4.43 (2.37, 8.28)	0.0	0.6250
Age									
<65 years	2/121 (1.7)	17/139 (12.2)	88.4	0/ 9 (0.0)	9/ 25 (36.0)	11.6	9.69 (2.43,38.71)	0.0	0.6761
>=65 years	9/210 (4.3)	24/193 (12.4)	81.6	2/ 18 (11.1)	9/ 29 (31.0)	18.4	3.25 (1.59, 6.65)	0.0	0.8930
Sex									
Male	6/177 (3.4)	25/179 (14.0)	71.6	2/ 11 (18.2)	7/ 26 (26.9)	28.4	3.78 (1.69, 8.47)	2.6	0.3109
Female	5/154 (3.2)	16/153 (10.5)	94.1	0/ 16 (0.0)	11/ 28 (39.3)	5.9	5.02 (1.94,13.00)	29.7	0.2330
Baseline FVC percent predicted									
<=70%	8/193 (4.1)	27/196 (13.8)	96.2	0/ 10 (0.0)	7/ 17 (41.2)	3.8	4.31 (1.97, 9.43)	0.0	0.3433
>70%	3/138 (2.2)	14/136 (10.3)	58.1	2/ 17 (11.8)	11/ 37 (29.7)	41.9	4.33 (1.59,11.78)	0.0	0.6449
Baseline HRCT pattern									
UIP-like	8/206 (3.9)	24/206 (11.7)	80.0	2/ 23 (8.7)	15/ 45 (33.3)	20.0	3.66 (1.77, 7.58)	0.0	0.6007
Other fibrotic patterns	3/125 (2.4)	17/126 (13.5)	90.5	0/ 4 (0.0)	3/ 9 (33.3)	9.5	6.47 (1.96,21.35)	0.0	0.9244
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	9/ 64 (14.1)	53.1	1/ 7 (14.3)	4/ 11 (36.4)	46.9	6.82 (1.43,32.59)	0.0	0.5224
Unclassifiable IIP	1/ 50 (2.0)	16/ 64 (25.0)	67.2	0/ 3 (0.0)	0/ 2 (0.0)	32.8	11.30 (2.03,62.82)	23.5	0.2528
HP	5/ 89 (5.6)	6/ 84 (7.1)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	3/ 88 (3.4)	7/ 82 (8.5)	92.2	0/ 12 (0.0)	14/ 34 (41.2)	7.8	5.06 (1.49,17.21)	29.5	0.2335
Other ILD	1/ 43 (2.3)	3/ 38 (7.9)	37.1	1/ 5 (20.0)	0/ 6 (0.0)	62.9	1.50 (0.28, 7.88)	38.8	0.2010
Region									
Europe									
Asia	3/ 76 (3.9)	27/ 79 (34.2)	53.1	2/ 27 (7.4)	18/ 54 (33.3)	46.9	9.64 (3.67,25.35)	0.0	0.4873
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo: Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	10/331 (3.0)	34/332 (10.2)	95.8	0/ 27 (0.0)	4/ 54 (7.4)	4.2	3.54 (1.80, 6.98)	0.0003	0.0	0.6890
Age										
<65 years	3/121 (2.5)	14/139 (10.1)	89.2	0/ 9 (0.0)	2/ 25 (8.0)	10.8	4.03 (1.25,12.96)	0.0196	0.0	0.9665
>=65 years	7/210 (3.3)	20/193 (10.4)	93.4	0/ 18 (0.0)	2/ 29 (6.9)	6.6	3.18 (1.41, 7.19)	0.0053	0.0	0.8597
Sex										
Male	4/177 (2.3)	19/179 (10.6)	90.6	0/ 11 (0.0)	2/ 26 (7.7)	9.4	4.62 (1.67,12.78)	0.0032	0.0	0.9194
Female	6/154 (3.9)	15/153 (9.8)	92.8	0/ 16 (0.0)	2/ 28 (7.1)	7.2	2.63 (1.08, 6.41)	0.0329	0.0	0.7823
Baseline FVC percent predicted										
<=70%	5/193 (2.6)	19/196 (9.7)	91.5	0/ 10 (0.0)	0/ 17 (0.0)	8.5	3.51 (1.39, 8.89)	0.0081	0.0	0.5285
>70%	5/138 (3.6)	15/136 (11.0)	92.0	0/ 17 (0.0)	4/ 37 (10.8)	8.0	3.35 (1.29, 8.70)	0.0131	0.0	0.6680
Baseline HRCT pattern										
UIP-like	3/206 (1.5)	20/206 (9.7)	87.0	0/ 23 (0.0)	3/ 45 (6.7)	13.0	6.52 (2.10,20.26)	0.0012	0.0	0.9211
Other fibrotic patterns	7/125 (5.6)	14/126 (11.1)	94.3	0/ 4 (0.0)	1/ 9 (11.1)	5.7	2.01 (0.86, 4.70)	0.1073	0.0	0.9139
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	2/ 64 (3.1)	68.3	0/ 7 (0.0)	3/ 11 (27.3)	31.7	3.18 (0.49,20.48)	0.2244	0.0	0.5766
Unclassifiable IIP	0/ 50 (0.0)	9/ 64 (14.1)	50.6	0/ 3 (0.0)	0/ 2 (0.0)	49.4	9.12 (1.05,79.51)	0.0455	26.3	0.2440
HP	2/ 89 (2.2)	14/ 84 (16.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	4/ 88 (4.5)	7/ 82 (8.5)	90.9	0/ 12 (0.0)	1/ 34 (2.9)	9.1	1.92 (0.61, 6.04)	0.2641	0.0	0.9169
Other ILD	3/ 43 (7.0)	2/ 38 (5.3)	85.0	0/ 5 (0.0)	0/ 6 (0.0)	15.0	0.79 (0.16, 3.82)	0.7707	0.0	0.8944
Region										
Europe										
Asia	1/ 76 (1.3)	3/ 79 (3.8)	69.6	0/ 27 (0.0)	4/ 54 (7.4)	30.4	4.14 (0.62,27.53)	0.1422	0.0	0.6751
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	10/331 (3.0)	34/332 (10.2)	90.0	0/ 27 (0.0)	4/ 54 (7.4)	10.0	7.22 (3.75, 10.69)	0.0	0.9984
Age									
<65 years	3/121 (2.5)	14/139 (10.1)	90.2	0/ 9 (0.0)	2/ 25 (8.0)	9.8	7.59 (2.21, 12.97)	0.0	0.9965
>=65 years	7/210 (3.3)	20/193 (10.4)	89.7	0/ 18 (0.0)	2/ 29 (6.9)	10.3	6.99 (2.39, 11.58)	0.0	0.9497
Sex									
Male	4/177 (2.3)	19/179 (10.6)	91.6	0/ 11 (0.0)	2/ 26 (7.7)	8.4	8.27 (3.52, 13.02)	0.0	0.8920
Female	6/154 (3.9)	15/153 (9.8)	87.8	0/ 16 (0.0)	2/ 28 (7.1)	12.2	6.02 (0.86, 11.18)	0.0	0.8948
Baseline FVC percent predicted									
<=70%	5/193 (2.6)	19/196 (9.7)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	6.64 (2.15, 11.13)	0.0	0.3382
>70%	5/138 (3.6)	15/136 (11.0)	85.0	0/ 17 (0.0)	4/ 37 (10.8)	15.0	7.86 (2.35, 13.37)	0.0	0.6618
Baseline HRCT pattern									
UIP-like	3/206 (1.5)	20/206 (9.7)	86.8	0/ 23 (0.0)	3/ 45 (6.7)	13.2	8.02 (4.05, 11.99)	0.0	0.7306
Other fibrotic patterns	7/125 (5.6)	14/126 (11.1)	95.2	0/ 4 (0.0)	1/ 9 (11.1)	4.8	5.71 (-0.95, 12.37)	0.0	0.8050
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	2/ 64 (3.1)	86.8	0/ 7 (0.0)	3/ 11 (27.3)	13.2	4.53 (-1.54, 10.60)	55.1	0.1356
Unclassifiable IIP	0/ 50 (0.0)	9/ 64 (14.1)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	13.05 (4.09, 22.01)	0.0	0.6138
HP	2/ 89 (2.2)	14/ 84 (16.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	4/ 88 (4.5)	7/ 82 (8.5)	82.1	0/ 12 (0.0)	1/ 34 (2.9)	17.9	3.78 (-2.63, 10.19)	0.0	0.8595
Other ILD	3/ 43 (7.0)	2/ 38 (5.3)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	-1.48 (-11.31, 8.35)	0.0	0.9134
Region									
Europe									
Asia	1/ 76 (1.3)	3/ 79 (3.8)	67.7	0/ 27 (0.0)	4/ 54 (7.4)	32.3	4.01 (-0.28, 8.31)	0.0	0.3384
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2 p-value
Overall	10/331 (3.0)	34/332 (10.2)	95.7	0/ 27 (0.0)	4/ 54 (7.4)	4.3	3.83 (1.89, 7.77)	0.0 0.6949
Age								
<65 years	3/121 (2.5)	14/139 (10.1)	89.2	0/ 9 (0.0)	2/ 25 (8.0)	10.8	4.37 (1.29,14.73)	0.0 0.9676
>=65 years	7/210 (3.3)	20/193 (10.4)	93.3	0/ 18 (0.0)	2/ 29 (6.9)	6.7	3.43 (1.46, 8.08)	0.0 0.8664
Sex								
Male	4/177 (2.3)	19/179 (10.6)	90.5	0/ 11 (0.0)	2/ 26 (7.7)	9.5	5.04 (1.75,14.55)	0.0 0.9176
Female	6/154 (3.9)	15/153 (9.8)	92.8	0/ 16 (0.0)	2/ 28 (7.1)	7.2	2.81 (1.10, 7.17)	0.0 0.7854
Baseline FVC percent predicted								
<=70%	5/193 (2.6)	19/196 (9.7)	91.0	0/ 10 (0.0)	0/ 17 (0.0)	9.0	3.76 (1.42, 9.95)	0.0 0.5201
>70%	5/138 (3.6)	15/136 (11.0)	92.1	0/ 17 (0.0)	4/ 37 (10.8)	7.9	3.64 (1.34, 9.88)	0.0 0.6643
Baseline HRCT pattern								
UIP-like	3/206 (1.5)	20/206 (9.7)	86.8	0/ 23 (0.0)	3/ 45 (6.7)	13.2	7.10 (2.21,22.75)	0.0 0.9147
Other fibrotic patterns	7/125 (5.6)	14/126 (11.1)	94.6	0/ 4 (0.0)	1/ 9 (11.1)	5.4	2.14 (0.85, 5.36)	0.0 0.9026
Underlying ILD diagnosis								
iNSIP	1/ 61 (1.6)	2/ 64 (3.1)	74.8	0/ 7 (0.0)	3/ 11 (27.3)	25.2	3.46 (0.51,23.40)	0.0 0.5109
Unclassifiable IIP	0/ 50 (0.0)	9/ 64 (14.1)	50.5	0/ 3 (0.0)	0/ 2 (0.0)	49.5	10.49 (1.18,93.69)	18.3 0.2687
HP	2/ 89 (2.2)	14/ 84 (16.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC NC
Autoimmune ILD	4/ 88 (4.5)	7/ 82 (8.5)	90.6	0/ 12 (0.0)	1/ 34 (2.9)	9.4	2.00 (0.60, 6.73)	0.0 0.9240
Other ILD	3/ 43 (7.0)	2/ 38 (5.3)	85.3	0/ 5 (0.0)	0/ 6 (0.0)	14.7	0.78 (0.15, 4.17)	0.0 0.8958
Region								
Europe								
Asia	1/ 76 (1.3)	3/ 79 (3.8)	70.7	0/ 27 (0.0)	4/ 54 (7.4)	29.3	4.31 (0.65,28.72)	0.0 0.6634
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain upper

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo: Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	7/331 (2.1)	33/332 (9.9)	94.0	0/ 27 (0.0)	5/ 54 (9.3)	6.0	4.93 (2.25,10.79)	<.0001	0.0	0.7439
Age										
<65 years	4/121 (3.3)	10/139 (7.2)	91.7	0/ 9 (0.0)	3/ 25 (12.0)	8.3	2.42 (0.81, 7.20)	0.1127	0.0	0.6805
>=65 years	3/210 (1.4)	23/193 (11.9)	85.9	0/ 18 (0.0)	2/ 29 (6.9)	14.1	7.76 (2.55,23.62)	0.0003	0.0	0.7085
Sex										
Male	3/177 (1.7)	13/179 (7.3)	87.8	0/ 11 (0.0)	1/ 26 (3.8)	12.2	4.06 (1.25,13.13)	0.0194	0.0	0.7816
Female	4/154 (2.6)	20/153 (13.1)	89.6	0/ 16 (0.0)	4/ 28 (14.3)	10.4	5.27 (1.93,14.39)	0.0012	0.0	0.8351
Baseline FVC percent predicted										
<=70%	3/193 (1.6)	25/196 (12.8)	86.6	0/ 10 (0.0)	0/ 17 (0.0)	13.4	7.24 (2.39,21.91)	0.0005	0.0	0.3213
>70%	4/138 (2.9)	8/136 (5.9)	90.2	0/ 17 (0.0)	5/ 37 (13.5)	9.8	2.64 (0.87, 8.06)	0.0875	0.0	0.4598
Baseline HRCT pattern										
UIP-like	5/206 (2.4)	18/206 (8.7)	91.8	0/ 23 (0.0)	3/ 45 (6.7)	8.2	3.76 (1.47, 9.62)	0.0057	0.0	0.8160
Other fibrotic patterns	2/125 (1.6)	15/126 (11.9)	82.5	0/ 4 (0.0)	2/ 9 (22.2)	17.5	6.82 (1.79,26.02)	0.0050	0.0	0.7412
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	8/ 64 (12.5)	68.3	0/ 7 (0.0)	1/ 11 (9.1)	31.7	6.04 (1.08,33.90)	0.0409	0.0	0.5988
Unclassifiable IIP	2/ 50 (4.0)	5/ 64 (7.8)	82.4	0/ 3 (0.0)	0/ 2 (0.0)	17.6	1.79 (0.41, 7.69)	0.4368	0.0	0.7450
HP	1/ 89 (1.1)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	2/ 88 (2.3)	10/ 82 (12.2)	83.3	0/ 12 (0.0)	3/ 34 (8.8)	16.7	5.31 (1.31,21.54)	0.0193	0.0	0.9780
Other ILD	1/ 43 (2.3)	3/ 38 (7.9)	65.4	0/ 5 (0.0)	1/ 6 (16.7)	34.6	3.20 (0.52,19.53)	0.2074	0.0	0.9263
Region										
Europe										
Asia	3/ 76 (3.9)	9/ 79 (11.4)	87.3	0/ 27 (0.0)	5/ 54 (9.3)	12.7	3.60 (1.08,11.94)	0.0364	0.0	0.5659
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain upper

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	7/331 (2.1)	33/332 (9.9)	90.0	0/ 27 (0.0)	5/ 54 (9.3)	10.0	7.95 (4.61, 11.28)	0.0	0.8057
Age									
<65 years	4/121 (3.3)	10/139 (7.2)	90.2	0/ 9 (0.0)	3/ 25 (12.0)	9.8	4.62 (-0.48, 9.72)	0.0	0.4098
>=65 years	3/210 (1.4)	23/193 (11.9)	89.7	0/ 18 (0.0)	2/ 29 (6.9)	10.3	10.09 (5.57, 14.60)	0.0	0.5543
Sex									
Male	3/177 (1.7)	13/179 (7.3)	91.6	0/ 11 (0.0)	1/ 26 (3.8)	8.4	5.41 (1.37, 9.45)	0.0	0.7807
Female	4/154 (2.6)	20/153 (13.1)	87.8	0/ 16 (0.0)	4/ 28 (14.3)	12.2	10.86 (5.37, 16.36)	0.0	0.6974
Baseline FVC percent predicted									
<=70%	3/193 (1.6)	25/196 (12.8)	93.5	0/ 10 (0.0)	0/ 17 (0.0)	6.5	10.47 (5.73, 15.22)	55.6	0.1334
>70%	4/138 (2.9)	8/136 (5.9)	85.0	0/ 17 (0.0)	5/ 37 (13.5)	15.0	4.49 (-0.06, 9.04)	51.5	0.1510
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	18/206 (8.7)	86.8	0/ 23 (0.0)	3/ 45 (6.7)	13.2	6.33 (2.33, 10.33)	0.0	0.9744
Other fibrotic patterns	2/125 (1.6)	15/126 (11.9)	95.2	0/ 4 (0.0)	2/ 9 (22.2)	4.8	10.74 (4.72, 16.76)	0.0	0.6217
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	8/ 64 (12.5)	86.8	0/ 7 (0.0)	1/ 11 (9.1)	13.2	10.51 (2.29, 18.72)	0.0	0.8393
Unclassifiable IIP	2/ 50 (4.0)	5/ 64 (7.8)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	3.60 (-4.99, 12.18)	0.0	0.8891
HP	1/ 89 (1.1)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	2/ 88 (2.3)	10/ 82 (12.2)	82.1	0/ 12 (0.0)	3/ 34 (8.8)	17.9	9.66 (2.91, 16.41)	0.0	0.8479
Other ILD	1/ 43 (2.3)	3/ 38 (7.9)	86.2	0/ 5 (0.0)	1/ 6 (16.7)	13.8	6.74 (-3.05, 16.54)	0.0	0.6636
Region									
Europe									
Asia	3/ 76 (3.9)	9/ 79 (11.4)	67.7	0/ 27 (0.0)	5/ 54 (9.3)	32.3	7.96 (1.66, 14.26)	0.0	0.7981
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain upper

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	7/331 (2.1)	33/332 (9.9)	94.1	0/ 27 (0.0)	5/ 54 (9.3)	5.9	5.36 (2.39,12.03)	0.0	0.7433
Age									
<65 years	4/121 (3.3)	10/139 (7.2)	92.2	0/ 9 (0.0)	3/ 25 (12.0)	7.8	2.54 (0.82, 7.85)	0.0	0.6631
>=65 years	3/210 (1.4)	23/193 (11.9)	85.4	0/ 18 (0.0)	2/ 29 (6.9)	14.6	8.64 (2.74,27.26)	0.0	0.6996
Sex									
Male	3/177 (1.7)	13/179 (7.3)	87.7	0/ 11 (0.0)	1/ 26 (3.8)	12.3	4.29 (1.28,14.45)	0.0	0.7809
Female	4/154 (2.6)	20/153 (13.1)	89.9	0/ 16 (0.0)	4/ 28 (14.3)	10.1	5.92 (2.08,16.87)	0.0	0.8250
Baseline FVC percent predicted									
<=70%	3/193 (1.6)	25/196 (12.8)	85.4	0/ 10 (0.0)	0/ 17 (0.0)	14.6	8.05 (2.56,25.35)	2.6	0.3110
>70%	4/138 (2.9)	8/136 (5.9)	91.0	0/ 17 (0.0)	5/ 37 (13.5)	9.0	2.76 (0.89, 8.56)	0.0	0.4376
Baseline HRCT pattern									
UIP-like	5/206 (2.4)	18/206 (8.7)	91.7	0/ 23 (0.0)	3/ 45 (6.7)	8.3	4.02 (1.52,10.63)	0.0	0.8194
Other fibrotic patterns	2/125 (1.6)	15/126 (11.9)	84.9	0/ 4 (0.0)	2/ 9 (22.2)	15.1	7.79 (1.93,31.52)	0.0	0.8047
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	8/ 64 (12.5)	68.5	0/ 7 (0.0)	1/ 11 (9.1)	31.5	6.78 (1.12,41.17)	0.0	0.6109
Unclassifiable IIP	2/ 50 (4.0)	5/ 64 (7.8)	83.4	0/ 3 (0.0)	0/ 2 (0.0)	16.6	1.86 (0.39, 8.80)	0.0	0.7641
HP	1/ 89 (1.1)	7/ 84 (8.3)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	2/ 88 (2.3)	10/ 82 (12.2)	83.1	0/ 12 (0.0)	3/ 34 (8.8)	16.9	5.90 (1.38,25.29)	0.0	0.9726
Other ILD	1/ 43 (2.3)	3/ 38 (7.9)	69.0	0/ 5 (0.0)	1/ 6 (16.7)	31.0	3.52 (0.51,24.22)	0.0	0.9726
Region									
Europe									
Asia	3/ 76 (3.9)	9/ 79 (11.4)	87.2	0/ 27 (0.0)	5/ 54 (9.3)	12.8	3.93 (1.13,13.64)	0.0	0.5693
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo			
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	85/331 (25.7)	240/332 (72.3)	94.1	4/ 27 (14.8)	19/ 54 (35.2)	5.9	2.79 (2.30, 3.38)	<.0001	0.0	0.7374
Age										
<65 years	25/121 (20.7)	99/139 (71.2)	94.8	1/ 9 (11.1)	5/ 25 (20.0)	5.2	3.36 (2.35, 4.81)	<.0001	0.0	0.5325
>=65 years	60/210 (28.6)	141/193 (73.1)	93.9	3/ 18 (16.7)	14/ 29 (48.3)	6.1	2.58 (2.05, 3.23)	<.0001	0.0	0.8278
Sex										
Male	47/177 (26.6)	132/179 (73.7)	99.1	0/ 11 (0.0)	8/ 26 (30.8)	0.9	2.86 (2.20, 3.72)	<.0001	0.0	0.4157
Female	38/154 (24.7)	108/153 (70.6)	88.2	4/ 16 (25.0)	11/ 28 (39.3)	11.8	2.71 (2.05, 3.58)	<.0001	26.1	0.2447
Baseline FVC percent predicted										
<=70%	50/193 (25.9)	140/196 (71.4)	97.6	1/ 10 (10.0)	6/ 17 (35.3)	2.4	2.78 (2.15, 3.58)	<.0001	0.0	0.8073
>70%	35/138 (25.4)	100/136 (73.5)	89.4	3/ 17 (17.6)	13/ 37 (35.1)	10.6	2.80 (2.09, 3.76)	<.0001	0.0	0.5243
Baseline HRCT pattern										
UIP-like	56/206 (27.2)	154/206 (74.8)	93.4	3/ 23 (13.0)	17/ 45 (37.8)	6.6	2.76 (2.18, 3.49)	<.0001	0.0	0.9293
Other fibrotic patterns	29/125 (23.2)	86/126 (68.3)	95.5	1/ 4 (25.0)	2/ 9 (22.2)	4.5	2.85 (2.04, 3.98)	<.0001	18.4	0.2683
Underlying ILD diagnosis										
iNSIP	13/ 61 (21.3)	43/ 64 (67.2)	91.6	1/ 7 (14.3)	7/ 11 (63.6)	8.4	3.26 (1.99, 5.36)	<.0001	0.0	0.7266
Unclassifiable IIP	9/ 50 (18.0)	48/ 64 (75.0)	95.5	0/ 3 (0.0)	1/ 2 (50.0)	4.5	4.14 (2.29, 7.48)	<.0001	0.0	0.8989
HP	27/ 89 (30.3)	66/ 84 (78.6)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	25/ 88 (28.4)	56/ 82 (68.3)	94.2	1/ 12 (8.3)	10/ 34 (29.4)	5.8	2.47 (1.72, 3.55)	<.0001	0.0	0.7040
Other ILD	11/ 43 (25.6)	27/ 38 (71.1)	82.5	2/ 5 (40.0)	1/ 6 (16.7)	17.5	2.37 (1.41, 3.96)	0.0010	66.3	0.0848
Region										
Europe										
Asia	21/ 76 (27.6)	62/ 79 (78.5)	80.1	4/ 27 (14.8)	19/ 54 (35.2)	19.9	2.75 (1.92, 3.94)	<.0001	0.0	0.7375
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	85/331 (25.7)	240/332 (72.3)	90.2	4/ 27 (14.8)	19/ 54 (35.2)	9.8	44.04 (37.70, 50.38)	85.4	0.0090
Age									
<65 years	25/121 (20.7)	99/139 (71.2)	90.7	1/ 9 (11.1)	5/ 25 (20.0)	9.3	46.69 (36.94, 56.45)	88.4	0.0034
>=65 years	60/210 (28.6)	141/193 (73.1)	90.1	3/ 18 (16.7)	14/ 29 (48.3)	9.9	43.21 (34.94, 51.47)	0.0	0.3414
Sex									
Male	47/177 (26.6)	132/179 (73.7)	91.6	0/ 11 (0.0)	8/ 26 (30.8)	8.4	45.68 (37.13, 54.23)	62.2	0.1039
Female	38/154 (24.7)	108/153 (70.6)	88.3	4/ 16 (25.0)	11/ 28 (39.3)	11.7	42.21 (32.86, 51.56)	77.2	0.0362
Baseline FVC percent predicted									
<=70%	50/193 (25.9)	140/196 (71.4)	93.9	1/ 10 (10.0)	6/ 17 (35.3)	6.1	44.29 (35.80, 52.79)	40.2	0.1960
>70%	35/138 (25.4)	100/136 (73.5)	85.5	3/ 17 (17.6)	13/ 37 (35.1)	14.5	43.71 (34.19, 53.23)	81.4	0.0204
Baseline HRCT pattern									
UIP-like	56/206 (27.2)	154/206 (74.8)	87.1	3/ 23 (13.0)	17/ 45 (37.8)	12.9	44.63 (36.81, 52.46)	76.9	0.0373
Other fibrotic patterns	29/125 (23.2)	86/126 (68.3)	95.8	1/ 4 (25.0)	2/ 9 (22.2)	4.2	43.03 (32.29, 53.77)	69.7	0.0691
Underlying ILD diagnosis									
iNSIP	13/ 61 (21.3)	43/ 64 (67.2)	88.0	1/ 7 (14.3)	7/ 11 (63.6)	12.0	46.29 (31.96, 60.63)	0.0	0.8695
Unclassifiable IIP	9/ 50 (18.0)	48/ 64 (75.0)	94.4	0/ 3 (0.0)	1/ 2 (50.0)	5.6	55.80 (41.11, 70.48)	0.0	0.5460
HP	27/ 89 (30.3)	66/ 84 (78.6)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	25/ 88 (28.4)	56/ 82 (68.3)	82.7	1/ 12 (8.3)	10/ 34 (29.4)	17.3	36.63 (24.61, 48.65)	50.7	0.1543
Other ILD	11/ 43 (25.6)	27/ 38 (71.1)	88.1	2/ 5 (40.0)	1/ 6 (16.7)	11.9	37.28 (19.05, 55.50)	82.9	0.0156
Region									
Europe									
Asia	21/ 76 (27.6)	62/ 79 (78.5)	68.3	4/ 27 (14.8)	19/ 54 (35.2)	31.7	41.18 (30.23, 52.12)	85.3	0.0091
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	85/331 (25.7)	240/332 (72.3)	87.2	4/ 27 (14.8)	19/ 54 (35.2)	12.8	6.98 (5.01, 9.74)	48.0	0.1655
Age									
<65 years	25/121 (20.7)	99/139 (71.2)	86.7	1/ 9 (11.1)	5/ 25 (20.0)	13.3	8.51 (4.85,14.93)	39.9	0.1972
>=65 years	60/210 (28.6)	141/193 (73.1)	89.0	3/ 18 (16.7)	14/ 29 (48.3)	11.0	6.55 (4.31, 9.95)	0.0	0.6263
Sex									
Male	47/177 (26.6)	132/179 (73.7)	97.8	0/ 11 (0.0)	8/ 26 (30.8)	2.2	7.99 (5.00,12.77)	0.0	0.6680
Female	38/154 (24.7)	108/153 (70.6)	78.3	4/ 16 (25.0)	11/ 28 (39.3)	21.7	6.16 (3.84, 9.88)	68.9	0.0732
Baseline FVC percent predicted									
<=70%	50/193 (25.9)	140/196 (71.4)	94.6	1/ 10 (10.0)	6/ 17 (35.3)	5.4	7.03 (4.53,10.91)	0.0	0.7524
>70%	35/138 (25.4)	100/136 (73.5)	77.5	3/ 17 (17.6)	13/ 37 (35.1)	22.5	6.91 (4.16,11.47)	56.5	0.1295
Baseline HRCT pattern									
UIP-like	56/206 (27.2)	154/206 (74.8)	85.1	3/ 23 (13.0)	17/ 45 (37.8)	14.9	7.35 (4.83,11.20)	0.0	0.3545
Other fibrotic patterns	29/125 (23.2)	86/126 (68.3)	89.6	1/ 4 (25.0)	2/ 9 (22.2)	10.4	6.46 (3.74,11.19)	54.1	0.1401
Underlying ILD diagnosis									
iNSIP	13/ 61 (21.3)	43/ 64 (67.2)	90.8	1/ 7 (14.3)	7/ 11 (63.6)	9.2	7.83 (3.65,16.81)	0.0	0.8027
Unclassifiable IIP	9/ 50 (18.0)	48/ 64 (75.0)	91.3	0/ 3 (0.0)	1/ 2 (50.0)	8.7	13.00 (5.36,31.56)	0.0	0.6640
HP	27/ 89 (30.3)	66/ 84 (78.6)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	25/ 88 (28.4)	56/ 82 (68.3)	88.0	1/ 12 (8.3)	10/ 34 (29.4)	12.0	5.33 (2.83,10.03)	0.0	0.8841
Other ILD	11/ 43 (25.6)	27/ 38 (71.1)	62.2	2/ 5 (40.0)	1/ 6 (16.7)	37.8	4.55 (1.88,11.02)	77.3	0.0359
Region									
Europe									
Asia	21/ 76 (27.6)	62/ 79 (78.5)	57.1	4/ 27 (14.8)	19/ 54 (35.2)	42.9	6.80 (3.61,12.78)	58.8	0.1193
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo: Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	33/331 (10.0)	100/332 (30.1)	96.1	1/ 27 (3.7)	4/ 54 (7.4)	3.9	2.98 (2.09, 4.26)	<.0001	0.0	0.7098
Age										
<65 years	11/121 (9.1)	42/139 (30.2)	96.8	0/ 9 (0.0)	2/ 25 (8.0)	3.2	3.34 (1.81, 6.15)	0.0001	0.0	0.9556
>=65 years	22/210 (10.5)	58/193 (30.1)	94.5	1/ 18 (5.6)	2/ 29 (6.9)	5.5	2.78 (1.79, 4.32)	<.0001	0.0	0.4886
Sex										
Male	14/177 (7.9)	39/179 (21.8)	97.1	0/ 11 (0.0)	1/ 26 (3.8)	2.9	2.75 (1.56, 4.85)	0.0005	0.0	0.9483
Female	19/154 (12.3)	61/153 (39.9)	93.7	1/ 16 (6.3)	3/ 28 (10.7)	6.3	3.14 (1.99, 4.93)	<.0001	0.0	0.5769
Baseline FVC percent predicted										
<=70%	22/193 (11.4)	61/196 (31.1)	94.6	1/ 10 (10.0)	4/ 17 (23.5)	5.4	2.71 (1.75, 4.19)	<.0001	0.0	0.8893
>70%	11/138 (8.0)	39/136 (28.7)	96.2	0/ 17 (0.0)	0/ 37 (0.0)	3.8	3.50 (1.89, 6.48)	<.0001	0.0	0.5529
Baseline HRCT pattern										
UIP-like	17/206 (8.3)	59/206 (28.6)	97.4	0/ 23 (0.0)	3/ 45 (6.7)	2.6	3.52 (2.14, 5.81)	<.0001	0.0	0.7953
Other fibrotic patterns	16/125 (12.8)	41/126 (32.5)	92.1	1/ 4 (25.0)	1/ 9 (11.1)	7.9	2.38 (1.43, 3.93)	0.0008	43.8	0.1823
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	18/ 64 (28.1)	68.3	0/ 7 (0.0)	1/ 11 (9.1)	31.7	12.55 (2.39,65.88)	0.0028	0.0	0.3493
Unclassifiable IIP	3/ 50 (6.0)	26/ 64 (40.6)	87.5	0/ 3 (0.0)	0/ 2 (0.0)	12.5	6.05 (2.08,17.62)	0.0010	0.0	0.3333
HP	13/ 89 (14.6)	25/ 84 (29.8)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	11/ 88 (12.5)	22/ 82 (26.8)	96.5	0/ 12 (0.0)	2/ 34 (5.9)	3.5	2.20 (1.15, 4.23)	0.0178	0.0	0.7899
Other ILD	5/ 43 (11.6)	9/ 38 (23.7)	74.7	1/ 5 (20.0)	0/ 6 (0.0)	25.3	1.60 (0.65, 3.96)	0.3082	29.6	0.2332
Region										
Europe										
Asia	2/ 76 (2.6)	28/ 79 (35.4)	60.5	1/ 27 (3.7)	4/ 54 (7.4)	39.5	8.93 (2.93,27.20)	0.0001	53.1	0.1440
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo: Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo: Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	33/331 (10.0)	100/332 (30.1)	90.2	1/ 27 (3.7)	4/ 54 (7.4)	9.8	18.54 (13.13, 23.95)	87.1	0.0054
Age									
<65 years	11/121 (9.1)	42/139 (30.2)	90.2	0/ 9 (0.0)	2/ 25 (8.0)	9.8	19.80 (11.37, 28.23)	53.7	0.1419
>=65 years	22/210 (10.5)	58/193 (30.1)	90.1	1/ 18 (5.6)	2/ 29 (6.9)	9.9	17.76 (10.71, 24.82)	80.0	0.0255
Sex									
Male	14/177 (7.9)	39/179 (21.8)	91.6	0/ 11 (0.0)	1/ 26 (3.8)	8.4	13.02 (6.30, 19.74)	46.1	0.1733
Female	19/154 (12.3)	61/153 (39.9)	88.3	1/ 16 (6.3)	3/ 28 (10.7)	11.7	24.83 (16.36, 33.30)	82.4	0.0170
Baseline FVC percent predicted									
<=70%	22/193 (11.4)	61/196 (31.1)	93.9	1/ 10 (10.0)	4/ 17 (23.5)	6.1	19.35 (11.76, 26.93)	0.0	0.6705
>70%	11/138 (8.0)	39/136 (28.7)	85.0	0/ 17 (0.0)	0/ 37 (0.0)	15.0	17.60 (10.00, 25.20)	91.9	0.0005
Baseline HRCT pattern									
UIP-like	17/206 (8.3)	59/206 (28.6)	86.8	0/ 23 (0.0)	3/ 45 (6.7)	13.2	18.55 (12.16, 24.94)	81.8	0.0191
Other fibrotic patterns	16/125 (12.8)	41/126 (32.5)	95.8	1/ 4 (25.0)	1/ 9 (11.1)	4.2	18.32 (8.48, 28.16)	46.5	0.1715
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	18/ 64 (28.1)	86.8	0/ 7 (0.0)	1/ 11 (9.1)	13.2	24.07 (13.61, 34.53)	43.6	0.1830
Unclassifiable IIP	3/ 50 (6.0)	26/ 64 (40.6)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	32.67 (19.39, 45.95)	35.1	0.2144
HP	13/ 89 (14.6)	25/ 84 (29.8)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	11/ 88 (12.5)	22/ 82 (26.8)	82.1	0/ 12 (0.0)	2/ 34 (5.9)	17.9	12.77 (2.84, 22.71)	3.7	0.3081
Other ILD	5/ 43 (11.6)	9/ 38 (23.7)	86.2	1/ 5 (20.0)	0/ 6 (0.0)	13.8	8.06 (-7.24, 23.37)	42.2	0.1885
Region									
Europe									
Asia	2/ 76 (2.6)	28/ 79 (35.4)	68.3	1/ 27 (3.7)	4/ 54 (7.4)	31.7	23.58 (15.34, 31.82)	93.1	0.0001
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	33/331 (10.0)	100/332 (30.1)	94.9	1/ 27 (3.7)	4/ 54 (7.4)	5.1	3.80 (2.49, 5.80)	0.0	0.5905
Age									
<65 years	11/121 (9.1)	42/139 (30.2)	95.9	0/ 9 (0.0)	2/ 25 (8.0)	4.1	4.32 (2.13, 8.77)	0.0	0.9731
>=65 years	22/210 (10.5)	58/193 (30.1)	92.8	1/ 18 (5.6)	2/ 29 (6.9)	7.2	3.50 (2.07, 5.92)	0.0	0.4078
Sex									
Male	14/177 (7.9)	39/179 (21.8)	96.6	0/ 11 (0.0)	1/ 26 (3.8)	3.4	3.22 (1.69, 6.12)	0.0	0.9015
Female	19/154 (12.3)	61/153 (39.9)	90.9	1/ 16 (6.3)	3/ 28 (10.7)	9.1	4.45 (2.53, 7.81)	0.0	0.4363
Baseline FVC percent predicted									
<=70%	22/193 (11.4)	61/196 (31.1)	94.1	1/ 10 (10.0)	4/ 17 (23.5)	5.9	3.47 (2.05, 5.86)	0.0	0.8468
>70%	11/138 (8.0)	39/136 (28.7)	94.8	0/ 17 (0.0)	0/ 37 (0.0)	5.2	4.45 (2.19, 9.05)	0.0	0.4860
Baseline HRCT pattern									
UIP-like	17/206 (8.3)	59/206 (28.6)	96.7	0/ 23 (0.0)	3/ 45 (6.7)	3.3	4.51 (2.54, 8.01)	0.0	0.8777
Other fibrotic patterns	16/125 (12.8)	41/126 (32.5)	89.8	1/ 4 (25.0)	1/ 9 (11.1)	10.2	2.99 (1.60, 5.58)	45.5	0.1754
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	18/ 64 (28.1)	64.1	0/ 7 (0.0)	1/ 11 (9.1)	35.9	16.08 (2.84,91.04)	0.0	0.3238
Unclassifiable IIP	3/ 50 (6.0)	26/ 64 (40.6)	82.9	0/ 3 (0.0)	0/ 2 (0.0)	17.1	9.06 (2.79,29.45)	6.2	0.3020
HP	13/ 89 (14.6)	25/ 84 (29.8)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	11/ 88 (12.5)	22/ 82 (26.8)	95.6	0/ 12 (0.0)	2/ 34 (5.9)	4.4	2.63 (1.20, 5.75)	0.0	0.8402
Other ILD	5/ 43 (11.6)	9/ 38 (23.7)	71.0	1/ 5 (20.0)	0/ 6 (0.0)	29.0	1.75 (0.59, 5.15)	33.9	0.2188
Region									
Europe									
Asia	2/ 76 (2.6)	28/ 79 (35.4)	51.6	1/ 27 (3.7)	4/ 54 (7.4)	48.4	11.49 (3.48,37.96)	63.9	0.0963
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Vomiting

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
Overall	16/331 (4.8)	64/332 (19.3)	92.3	1/ 27 (3.7)	7/ 54 (13.0)	7.7	3.95 (2.37, 6.58)	<.0001	0.0	0.9035
Age										
<65 years	5/121 (4.1)	24/139 (17.3)	93.2	0/ 9 (0.0)	3/ 25 (12.0)	6.8	4.24 (1.71,10.53)	0.0018	0.0	0.9234
>=65 years	11/210 (5.2)	40/193 (20.7)	89.5	1/ 18 (5.6)	4/ 29 (13.8)	10.5	3.80 (2.07, 6.99)	<.0001	0.0	0.6787
Sex										
Male	8/177 (4.5)	20/179 (11.2)	95.1	0/ 11 (0.0)	0/ 26 (0.0)	4.9	2.40 (1.10, 5.22)	0.0273	0.0	0.6804
Female	8/154 (5.2)	44/153 (28.8)	86.2	1/ 16 (6.3)	7/ 28 (25.0)	13.8	5.32 (2.71,10.47)	<.0001	0.0	0.7648
Baseline FVC percent predicted										
<=70%	9/193 (4.7)	43/196 (21.9)	87.8	1/ 10 (10.0)	3/ 17 (17.6)	12.2	4.35 (2.26, 8.34)	<.0001	0.0	0.3895
>70%	7/138 (5.1)	21/136 (15.4)	94.2	0/ 17 (0.0)	4/ 37 (10.8)	5.8	3.27 (1.46, 7.31)	0.0040	0.0	0.6646
Baseline HRCT pattern										
UIP-like	13/206 (6.3)	37/206 (18.0)	96.7	0/ 23 (0.0)	6/ 45 (13.3)	3.3	3.09 (1.70, 5.60)	0.0002	0.0	0.4757
Other fibrotic patterns	3/125 (2.4)	27/126 (21.4)	68.5	1/ 4 (25.0)	1/ 9 (11.1)	31.5	6.26 (2.35,16.64)	0.0002	77.9	0.0336
Underlying ILD diagnosis										
iNSIP	2/ 61 (3.3)	12/ 64 (18.8)	81.2	0/ 7 (0.0)	1/ 11 (9.1)	18.8	5.14 (1.36,19.37)	0.0156	0.0	0.6804
Unclassifiable IIP	0/ 50 (0.0)	12/ 64 (18.8)	50.6	0/ 3 (0.0)	0/ 2 (0.0)	49.4	11.82 (1.38, >99)	0.0242	39.0	0.2006
HP	6/ 89 (6.7)	21/ 84 (25.0)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	6/ 88 (6.8)	15/ 82 (18.3)	93.8	0/ 12 (0.0)	5/ 34 (14.7)	6.2	3.00 (1.24, 7.28)	0.0151	0.0	0.6001
Other ILD	2/ 43 (4.7)	4/ 38 (10.5)	54.2	1/ 5 (20.0)	0/ 6 (0.0)	45.8	1.37 (0.37, 5.07)	0.6377	25.7	0.2459
Region										
Europe										
Asia	1/ 76 (1.3)	12/ 79 (15.2)	43.3	1/ 27 (3.7)	7/ 54 (13.0)	56.7	6.99 (1.74,28.05)	0.0061	0.0	0.4151
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Vomiting

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	16/331 (4.8)	64/332 (19.3)	90.2	1/ 27 (3.7)	7/ 54 (13.0)	9.8	13.94 (9.44, 18.44)	0.0	0.4135
Age									
<65 years	5/121 (4.1)	24/139 (17.3)	90.2	0/ 9 (0.0)	3/ 25 (12.0)	9.8	12.96 (6.24, 19.67)	0.0	0.8475
>=65 years	11/210 (5.2)	40/193 (20.7)	90.1	1/ 18 (5.6)	4/ 29 (13.8)	9.9	14.77 (8.72, 20.81)	0.0	0.4206
Sex									
Male	8/177 (4.5)	20/179 (11.2)	91.6	0/ 11 (0.0)	0/ 26 (0.0)	8.4	6.10 (0.94, 11.25)	12.7	0.2845
Female	8/154 (5.2)	44/153 (28.8)	88.3	1/ 16 (6.3)	7/ 28 (25.0)	11.7	23.00 (15.57, 30.42)	0.0	0.6606
Baseline FVC percent predicted									
<=70%	9/193 (4.7)	43/196 (21.9)	93.9	1/ 10 (10.0)	3/ 17 (17.6)	6.1	16.69 (10.37, 23.01)	0.0	0.4808
>70%	7/138 (5.1)	21/136 (15.4)	85.0	0/ 17 (0.0)	4/ 37 (10.8)	15.0	10.38 (4.08, 16.67)	0.0	0.9937
Baseline HRCT pattern									
UIP-like	13/206 (6.3)	37/206 (18.0)	86.8	0/ 23 (0.0)	6/ 45 (13.3)	13.2	11.82 (6.24, 17.41)	0.0	0.8418
Other fibrotic patterns	3/125 (2.4)	27/126 (21.4)	95.8	1/ 4 (25.0)	1/ 9 (11.1)	4.2	17.64 (10.04, 25.23)	45.2	0.1767
Underlying ILD diagnosis									
iNSIP	2/ 61 (3.3)	12/ 64 (18.8)	86.8	0/ 7 (0.0)	1/ 11 (9.1)	13.2	14.51 (4.80, 24.22)	0.0	0.5907
Unclassifiable IIP	0/ 50 (0.0)	12/ 64 (18.8)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	17.40 (7.59, 27.22)	0.0	0.5023
HP	6/ 89 (6.7)	21/ 84 (25.0)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	6/ 88 (6.8)	15/ 82 (18.3)	82.1	0/ 12 (0.0)	5/ 34 (14.7)	17.9	11.94 (3.42, 20.46)	0.0	0.7696
Other ILD	2/ 43 (4.7)	4/ 38 (10.5)	86.2	1/ 5 (20.0)	0/ 6 (0.0)	13.8	2.73 (-8.69, 14.16)	13.6	0.2821
Region									
Europe									
Asia	1/ 76 (1.3)	12/ 79 (15.2)	68.3	1/ 27 (3.7)	7/ 54 (13.0)	31.7	12.41 (5.67, 19.15)	0.0	0.5227
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Vomiting

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	16/331 (4.8)	64/332 (19.3)	91.8	1/ 27 (3.7)	7/ 54 (13.0)	8.2	4.63 (2.66, 8.06)	0.0	0.8642
Age									
<65 years	5/121 (4.1)	24/139 (17.3)	93.0	0/ 9 (0.0)	3/ 25 (12.0)	7.0	4.91 (1.86,12.93)	0.0	0.9351
>=65 years	11/210 (5.2)	40/193 (20.7)	88.7	1/ 18 (5.6)	4/ 29 (13.8)	11.3	4.50 (2.31, 8.79)	0.0	0.6489
Sex									
Male	8/177 (4.5)	20/179 (11.2)	94.6	0/ 11 (0.0)	0/ 26 (0.0)	5.4	2.57 (1.12, 5.90)	0.0	0.6652
Female	8/154 (5.2)	44/153 (28.8)	85.6	1/ 16 (6.3)	7/ 28 (25.0)	14.4	7.03 (3.33,14.83)	0.0	0.7451
Baseline FVC percent predicted									
<=70%	9/193 (4.7)	43/196 (21.9)	87.2	1/ 10 (10.0)	3/ 17 (17.6)	12.8	5.26 (2.58,10.73)	0.0	0.3971
>70%	7/138 (5.1)	21/136 (15.4)	93.9	0/ 17 (0.0)	4/ 37 (10.8)	6.1	3.67 (1.55, 8.71)	0.0	0.6746
Baseline HRCT pattern									
UIP-like	13/206 (6.3)	37/206 (18.0)	96.5	0/ 23 (0.0)	6/ 45 (13.3)	3.5	3.54 (1.85, 6.78)	0.0	0.4833
Other fibrotic patterns	3/125 (2.4)	27/126 (21.4)	65.8	1/ 4 (25.0)	1/ 9 (11.1)	34.2	7.42 (2.56,21.53)	75.2	0.0447
Underlying ILD diagnosis									
iNSIP	2/ 61 (3.3)	12/ 64 (18.8)	80.1	0/ 7 (0.0)	1/ 11 (9.1)	19.9	6.03 (1.47,24.80)	0.0	0.6693
Unclassifiable IIP	0/ 50 (0.0)	12/ 64 (18.8)	49.1	0/ 3 (0.0)	0/ 2 (0.0)	50.9	14.01 (1.63, >99)	33.9	0.2188
HP	6/ 89 (6.7)	21/ 84 (25.0)	NC	0/ 0 (NC)	1/ 1 (100.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	6/ 88 (6.8)	15/ 82 (18.3)	93.6	0/ 12 (0.0)	5/ 34 (14.7)	6.4	3.44 (1.31, 9.03)	0.0	0.6037
Other ILD	2/ 43 (4.7)	4/ 38 (10.5)	53.4	1/ 5 (20.0)	0/ 6 (0.0)	46.6	1.41 (0.33, 5.96)	26.6	0.2431
Region									
Europe									
Asia	1/ 76 (1.3)	12/ 79 (15.2)	42.7	1/ 27 (3.7)	7/ 54 (13.0)	57.3	7.95 (1.84,34.46)	0.0	0.4136
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders
PT: Hepatic function abnormal

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	3/331 (0.9)	19/332 (5.7)	53.0	2/ 27 (7.4)	12/ 54 (22.2)	47.0	4.76 (1.92,11.81)	0.0008	0.0	0.4347
Age										
<65 years	1/121 (0.8)	8/139 (5.8)	73.3	0/ 9 (0.0)	7/ 25 (28.0)	26.7	7.91 (1.26,49.82)	0.0276	0.0	0.8518
>=65 years	2/210 (1.0)	11/193 (5.7)	43.7	2/ 18 (11.1)	5/ 29 (17.2)	56.3	3.49 (1.25, 9.77)	0.0174	34.6	0.2161
Sex										
Male	2/177 (1.1)	10/179 (5.6)	41.7	2/ 11 (18.2)	5/ 26 (19.2)	58.3	2.68 (0.98, 7.36)	0.0559	51.2	0.1521
Female	1/154 (0.6)	9/153 (5.9)	68.3	0/ 16 (0.0)	7/ 28 (25.0)	31.7	9.99 (1.73,57.73)	0.0101	0.0	0.8866
Baseline FVC percent predicted										
<=70%	1/193 (0.5)	12/196 (6.1)	68.4	0/ 10 (0.0)	6/ 17 (35.3)	31.6	11.41 (2.05,63.64)	0.0055	0.0	0.9527
>70%	2/138 (1.4)	7/136 (5.1)	42.0	2/ 17 (11.8)	6/ 37 (16.2)	58.0	2.29 (0.80, 6.58)	0.1232	0.0	0.3894
Baseline HRCT pattern										
UIP-like	3/206 (1.5)	11/206 (5.3)	53.1	2/ 23 (8.7)	10/ 45 (22.2)	46.9	3.15 (1.22, 8.08)	0.0173	0.0	0.7109
Other fibrotic patterns	0/125 (0.0)	8/126 (6.3)	54.0	0/ 4 (0.0)	2/ 9 (22.2)	46.0	10.93 (1.28,93.74)	0.0291	0.0	0.5273
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	2/ 76 (2.6)	18/ 79 (22.8)	43.3	2/ 27 (7.4)	12/ 54 (22.2)	56.7	5.45 (2.04,14.56)	0.0007	5.9	0.3027
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders
PT: Hepatic function abnormal

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	3/331 (0.9)	19/332 (5.7)	90.2	2/ 27 (7.4)	12/ 54 (22.2)	9.8	5.80 (2.96, 8.63)	40.7	0.1942
Age									
<65 years	1/121 (0.8)	8/139 (5.8)	90.2	0/ 9 (0.0)	7/ 25 (28.0)	9.8	7.03 (2.76, 11.30)	76.0	0.0412
>=65 years	2/210 (1.0)	11/193 (5.7)	90.1	2/ 18 (11.1)	5/ 29 (17.2)	9.9	4.88 (1.14, 8.63)	0.0	0.8938
Sex									
Male	2/177 (1.1)	10/179 (5.6)	92.0	2/ 11 (18.2)	5/ 26 (19.2)	8.0	4.18 (0.13, 8.24)	0.0	0.8089
Female	1/154 (0.6)	9/153 (5.9)	87.8	0/ 16 (0.0)	7/ 28 (25.0)	12.2	7.51 (3.45, 11.56)	76.3	0.0399
Baseline FVC percent predicted									
<=70%	1/193 (0.5)	12/196 (6.1)	93.5	0/ 10 (0.0)	6/ 17 (35.3)	6.5	7.38 (3.73, 11.02)	78.3	0.0316
>70%	2/138 (1.4)	7/136 (5.1)	85.5	2/ 17 (11.8)	6/ 37 (16.2)	14.5	3.81 (-0.77, 8.38)	0.0	0.9406
Baseline HRCT pattern									
UIP-like	3/206 (1.5)	11/206 (5.3)	87.1	2/ 23 (8.7)	10/ 45 (22.2)	12.9	5.13 (1.41, 8.84)	18.2	0.2689
Other fibrotic patterns	0/125 (0.0)	8/126 (6.3)	95.2	0/ 4 (0.0)	2/ 9 (22.2)	4.8	6.92 (2.33, 11.51)	0.0	0.4722
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia	2/ 76 (2.6)	18/ 79 (22.8)	68.3	2/ 27 (7.4)	12/ 54 (22.2)	31.7	18.46 (10.21, 26.71)	0.0	0.5580
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders
PT: Hepatic function abnormal

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)		I^2	p-value
Overall	3/331 (0.9)	19/332 (5.7)	57.7	2/ 27 (7.4)	12/ 54 (22.2)	42.3	5.34 (2.04,14.01)		0.0	0.5433
Age										
<65 years	1/121 (0.8)	8/139 (5.8)	78.5	0/ 9 (0.0)	7/ 25 (28.0)	21.5	8.86 (1.40,56.03)		0.0	0.7661
>=65 years	2/210 (1.0)	11/193 (5.7)	46.9	2/ 18 (11.1)	5/ 29 (17.2)	53.1	3.83 (1.25,11.72)		20.2	0.2628
Sex										
Male	2/177 (1.1)	10/179 (5.6)	45.5	2/ 11 (18.2)	5/ 26 (19.2)	54.5	2.94 (0.95, 9.10)		40.8	0.1939
Female	1/154 (0.6)	9/153 (5.9)	73.3	0/ 16 (0.0)	7/ 28 (25.0)	26.7	11.25 (1.92,65.93)		0.0	0.8025
Baseline FVC percent predicted										
<=70%	1/193 (0.5)	12/196 (6.1)	76.1	0/ 10 (0.0)	6/ 17 (35.3)	23.9	13.34 (2.30,77.38)		0.0	0.9049
>70%	2/138 (1.4)	7/136 (5.1)	45.1	2/ 17 (11.8)	6/ 37 (16.2)	54.9	2.46 (0.78, 7.80)		0.0	0.4343
Baseline HRCT pattern										
UIP-like	3/206 (1.5)	11/206 (5.3)	58.0	2/ 23 (8.7)	10/ 45 (22.2)	42.0	3.47 (1.27, 9.52)		0.0	0.8192
Other fibrotic patterns	0/125 (0.0)	8/126 (6.3)	59.6	0/ 4 (0.0)	2/ 9 (22.2)	40.4	12.76 (1.31, >99)		0.0	0.5978
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia	2/ 76 (2.6)	18/ 79 (22.8)	43.1	2/ 27 (7.4)	12/ 54 (22.2)	56.9	6.74 (2.31,19.68)		1.3	0.3142
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	p-value	Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid					
Overall	23/331 (6.9)	54/332 (16.3)	98.1	0/ 27 (0.0)	5/ 54 (9.3)	1.9	2.46 (1.55, 3.89)	0.0001	0.0	0.4695
Age										
<65 years	2/121 (1.7)	22/139 (15.8)	84.6	0/ 9 (0.0)	2/ 25 (8.0)	15.4	8.67 (2.30,32.75)	0.0014	0.0	0.6569
>=65 years	21/210 (10.0)	32/193 (16.6)	97.7	0/ 18 (0.0)	3/ 29 (10.3)	2.3	1.75 (1.06, 2.92)	0.0300	0.0	0.4560
Sex										
Male	13/177 (7.3)	27/179 (15.1)	96.9	0/ 11 (0.0)	4/ 26 (15.4)	3.1	2.20 (1.18, 4.09)	0.0129	0.0	0.5310
Female	10/154 (6.5)	27/153 (17.6)	95.6	0/ 16 (0.0)	1/ 28 (3.6)	4.4	2.71 (1.38, 5.34)	0.0039	0.0	0.9760
Baseline FVC percent predicted										
<=70%	13/193 (6.7)	31/196 (15.8)	96.6	0/ 10 (0.0)	4/ 17 (23.5)	3.4	2.52 (1.38, 4.62)	0.0028	0.0	0.5002
>70%	10/138 (7.2)	23/136 (16.9)	95.8	0/ 17 (0.0)	1/ 37 (2.7)	4.2	2.34 (1.17, 4.67)	0.0162	0.0	0.9786
Baseline HRCT pattern										
UIP-like	14/206 (6.8)	37/206 (18.0)	96.9	0/ 23 (0.0)	5/ 45 (11.1)	3.1	2.83 (1.59, 5.04)	0.0004	0.0	0.5086
Other fibrotic patterns	9/125 (7.2)	17/126 (13.5)	95.5	0/ 4 (0.0)	0/ 9 (0.0)	4.5	1.83 (0.86, 3.90)	0.1151	0.0	0.7681
Underlying ILD diagnosis										
iNSIP	3/ 61 (4.9)	10/ 64 (15.6)	86.6	0/ 7 (0.0)	2/ 11 (18.2)	13.4	3.32 (1.04,10.62)	0.0426	0.0	0.8673
Unclassifiable IIP	3/ 50 (6.0)	13/ 64 (20.3)	87.5	0/ 3 (0.0)	0/ 2 (0.0)	12.5	3.09 (1.00, 9.56)	0.0506	0.0	0.5393
HP	13/ 89 (14.6)	9/ 84 (10.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	1/ 88 (1.1)	15/ 82 (18.3)	71.4	0/ 12 (0.0)	2/ 34 (5.9)	28.6	12.56 (2.22,70.98)	0.0042	0.0	0.5168
Other ILD	3/ 43 (7.0)	7/ 38 (18.4)	85.0	0/ 5 (0.0)	1/ 6 (16.7)	15.0	2.67 (0.82, 8.73)	0.1044	0.0	0.9673
Region										
Europe										
Asia	8/ 76 (10.5)	20/ 79 (25.3)	94.8	0/ 27 (0.0)	5/ 54 (9.3)	5.2	2.72 (1.29, 5.73)	0.0085	0.0	0.4852
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	Heterogeneity p-value
Overall	23/331 (6.9)	54/332 (16.3)	90.0	0/ 27 (0.0)	5/ 54 (9.3)	10.0	9.29 (4.86, 13.72)	0.0	0.9570
Age									
<65 years	2/121 (1.7)	22/139 (15.8)	90.2	0/ 9 (0.0)	2/ 25 (8.0)	9.8	13.53 (7.49, 19.57)	0.0	0.4425
>=65 years	21/210 (10.0)	32/193 (16.6)	89.7	0/ 18 (0.0)	3/ 29 (10.3)	10.3	6.93 (0.82, 13.03)	0.0	0.6578
Sex									
Male	13/177 (7.3)	27/179 (15.1)	91.6	0/ 11 (0.0)	4/ 26 (15.4)	8.4	8.31 (2.19, 14.43)	0.0	0.4555
Female	10/154 (6.5)	27/153 (17.6)	87.8	0/ 16 (0.0)	1/ 28 (3.6)	12.2	10.21 (3.76, 16.66)	26.2	0.2444
Baseline FVC percent predicted									
<=70%	13/193 (6.7)	31/196 (15.8)	93.5	0/ 10 (0.0)	4/ 17 (23.5)	6.5	9.91 (3.92, 15.91)	12.0	0.2863
>70%	10/138 (7.2)	23/136 (16.9)	85.0	0/ 17 (0.0)	1/ 37 (2.7)	15.0	8.61 (1.97, 15.24)	27.6	0.2400
Baseline HRCT pattern									
UIP-like	14/206 (6.8)	37/206 (18.0)	86.8	0/ 23 (0.0)	5/ 45 (11.1)	13.2	11.12 (5.50, 16.73)	0.0	0.9528
Other fibrotic patterns	9/125 (7.2)	17/126 (13.5)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	5.99 (-1.26, 13.24)	0.0	0.6637
Underlying ILD diagnosis									
iNSIP	3/ 61 (4.9)	10/ 64 (15.6)	86.8	0/ 7 (0.0)	2/ 11 (18.2)	13.2	11.45 (1.70, 21.21)	0.0	0.7072
Unclassifiable IIP	3/ 50 (6.0)	13/ 64 (20.3)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	13.50 (1.93, 25.08)	0.0	0.6049
HP	13/ 89 (14.6)	9/ 84 (10.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	1/ 88 (1.1)	15/ 82 (18.3)	82.1	0/ 12 (0.0)	2/ 34 (5.9)	17.9	15.09 (7.68, 22.51)	57.9	0.1233
Other ILD	3/ 43 (7.0)	7/ 38 (18.4)	86.2	0/ 5 (0.0)	1/ 6 (16.7)	13.8	11.81 (-1.69, 25.31)	0.0	0.8962
Region									
Europe									
Asia	8/ 76 (10.5)	20/ 79 (25.3)	67.7	0/ 27 (0.0)	5/ 54 (9.3)	32.3	12.93 (4.43, 21.44)	0.0	0.4469
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	23/331 (6.9)	54/332 (16.3)	98.0	0/ 27 (0.0)	5/ 54 (9.3)	2.0	2.74 (1.65, 4.54)	0.0	0.4812
Age									
<65 years	2/121 (1.7)	22/139 (15.8)	83.8	0/ 9 (0.0)	2/ 25 (8.0)	16.2	10.03 (2.52,39.88)	0.0	0.6434
>=65 years	21/210 (10.0)	32/193 (16.6)	97.6	0/ 18 (0.0)	3/ 29 (10.3)	2.4	1.90 (1.07, 3.39)	0.0	0.4603
Sex									
Male	13/177 (7.3)	27/179 (15.1)	97.0	0/ 11 (0.0)	4/ 26 (15.4)	3.0	2.41 (1.22, 4.76)	0.0	0.5212
Female	10/154 (6.5)	27/153 (17.6)	94.9	0/ 16 (0.0)	1/ 28 (3.6)	5.1	3.06 (1.45, 6.48)	0.0	0.9384
Baseline FVC percent predicted									
<=70%	13/193 (6.7)	31/196 (15.8)	96.9	0/ 10 (0.0)	4/ 17 (23.5)	3.1	2.81 (1.45, 5.46)	0.0	0.4691
>70%	10/138 (7.2)	23/136 (16.9)	95.2	0/ 17 (0.0)	1/ 37 (2.7)	4.8	2.60 (1.21, 5.61)	0.0	0.9878
Baseline HRCT pattern									
UIP-like	14/206 (6.8)	37/206 (18.0)	96.7	0/ 23 (0.0)	5/ 45 (11.1)	3.3	3.22 (1.71, 6.08)	0.0	0.5226
Other fibrotic patterns	9/125 (7.2)	17/126 (13.5)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	1.96 (0.85, 4.52)	0.0	0.7598
Underlying ILD diagnosis									
iNSIP	3/ 61 (4.9)	10/ 64 (15.6)	87.4	0/ 7 (0.0)	2/ 11 (18.2)	12.6	3.78 (1.08,13.21)	0.0	0.8484
Unclassifiable IIP	3/ 50 (6.0)	13/ 64 (20.3)	86.7	0/ 3 (0.0)	0/ 2 (0.0)	13.3	3.60 (1.04,12.40)	0.0	0.5480
HP	13/ 89 (14.6)	9/ 84 (10.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	1/ 88 (1.1)	15/ 82 (18.3)	68.9	0/ 12 (0.0)	2/ 34 (5.9)	31.1	14.64 (2.37,90.46)	0.0	0.4913
Other ILD	3/ 43 (7.0)	7/ 38 (18.4)	85.6	0/ 5 (0.0)	1/ 6 (16.7)	14.4	3.06 (0.81,11.51)	0.0	0.9567
Region									
Europe									
Asia	8/ 76 (10.5)	20/ 79 (25.3)	93.9	0/ 27 (0.0)	5/ 54 (9.3)	6.1	3.28 (1.39, 7.72)	0.0	0.5254
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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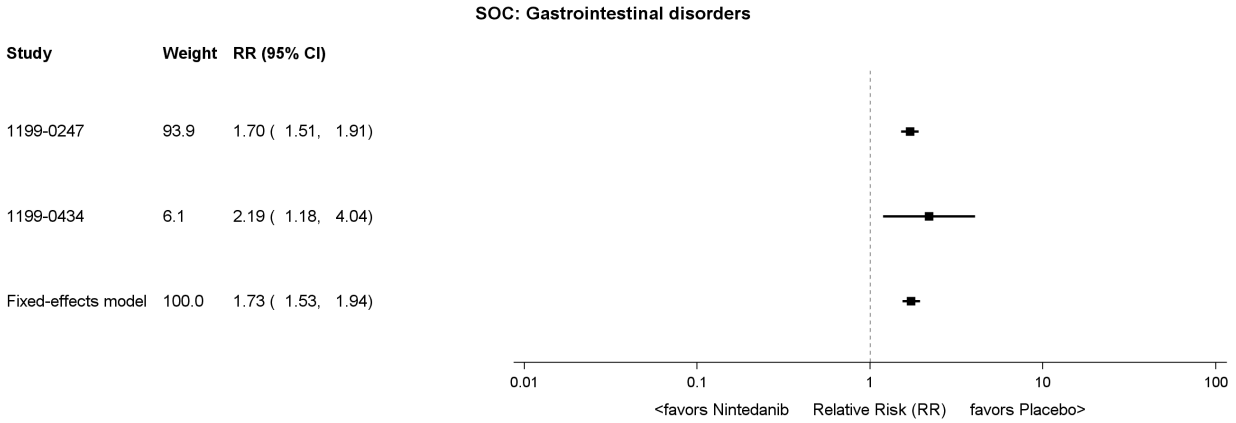

Figure M.2.2.1.5: 1 Forest Plot comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

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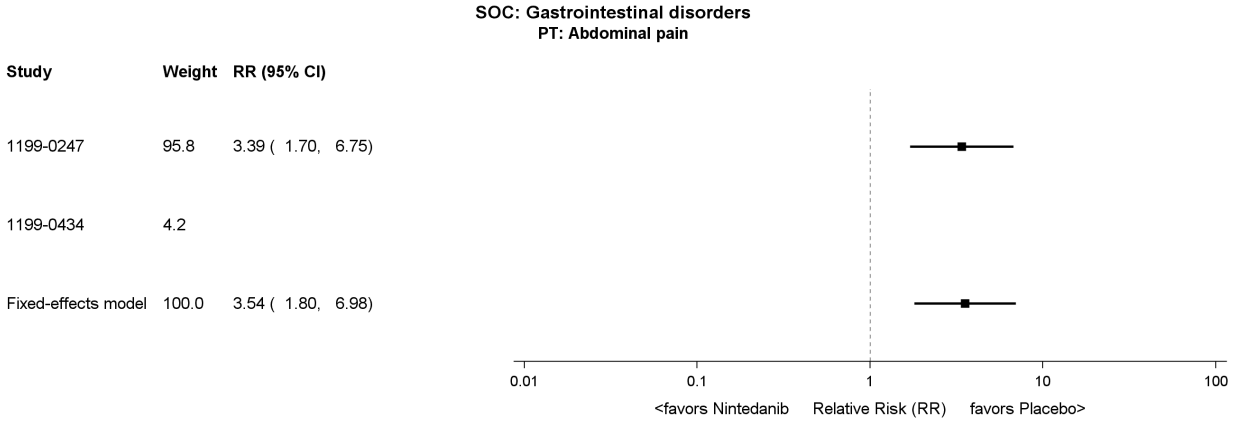

Figure M.2.2.1.5: 1 Forest Plot comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

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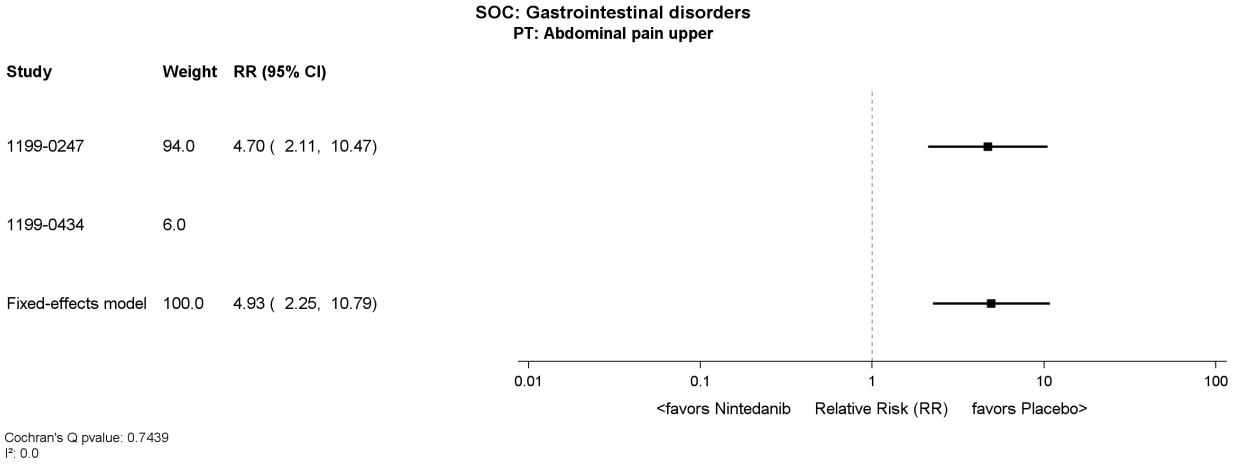

Figure M.2.2.1.5: 1 Forest Plot comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

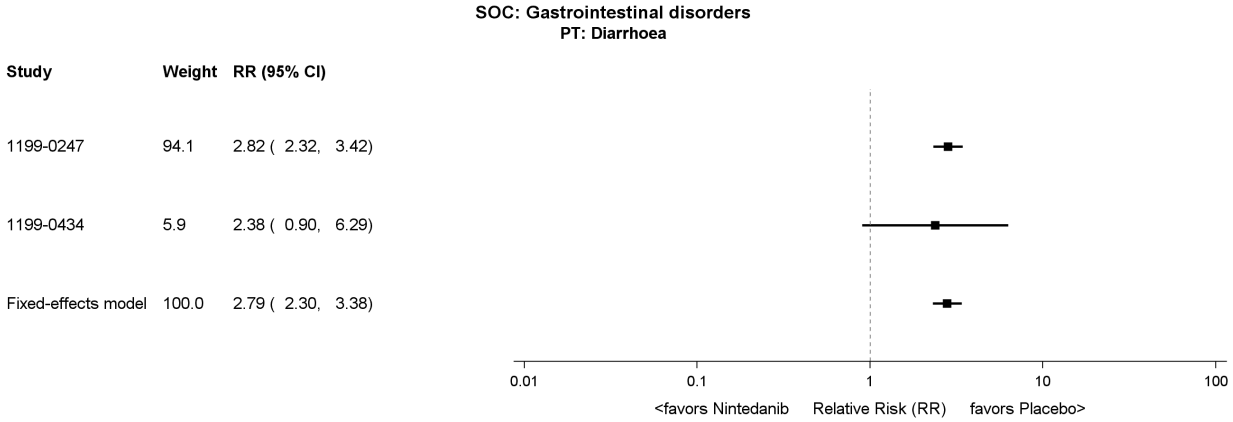

Figure M.2.2.1.5: 1 Forest Plot comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

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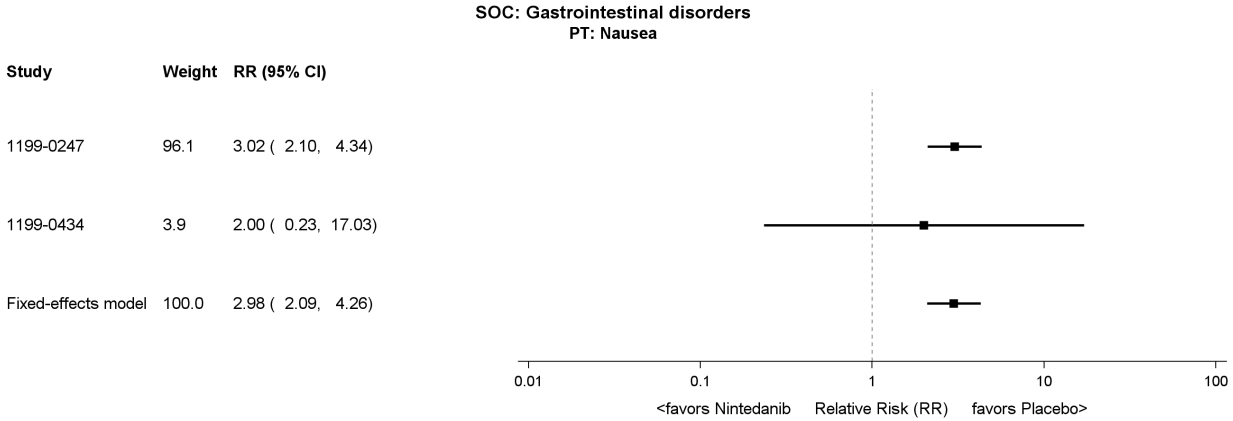

Figure M.2.2.1.5: 1 Forest Plot comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

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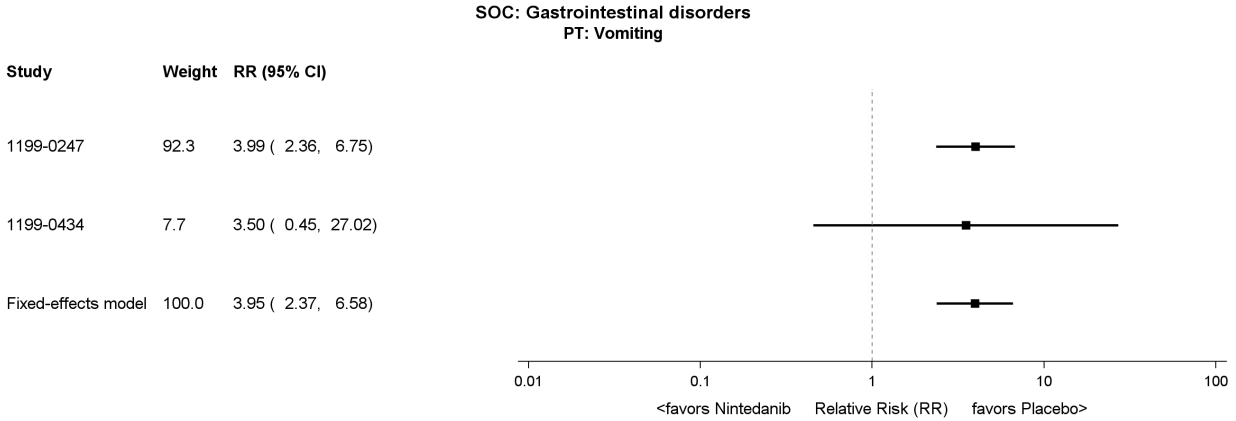

Figure M.2.2.1.5: 1 Forest Plot comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

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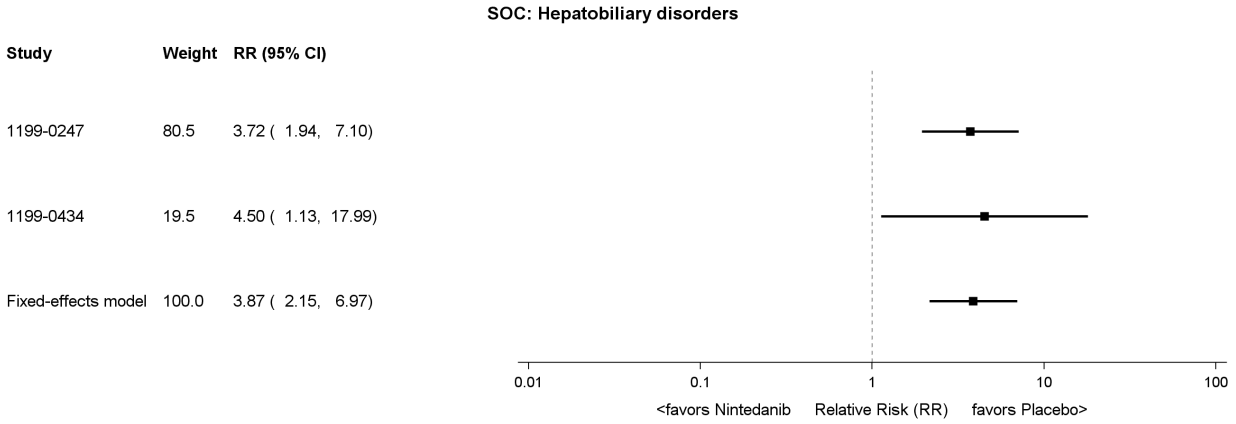

Figure M.2.2.1.5: 1 Forest Plot comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

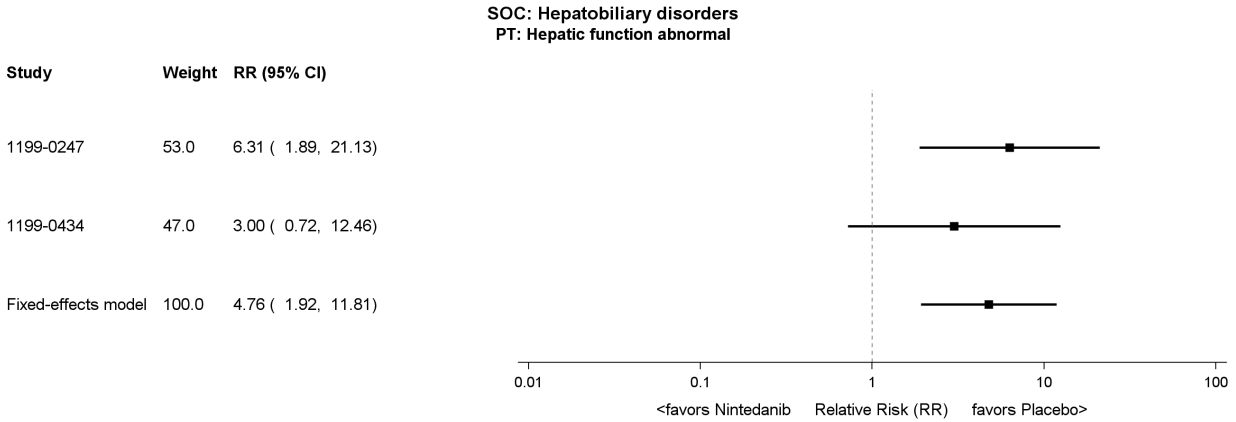

Figure M.2.2.1.5: 1 Forest Plot comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

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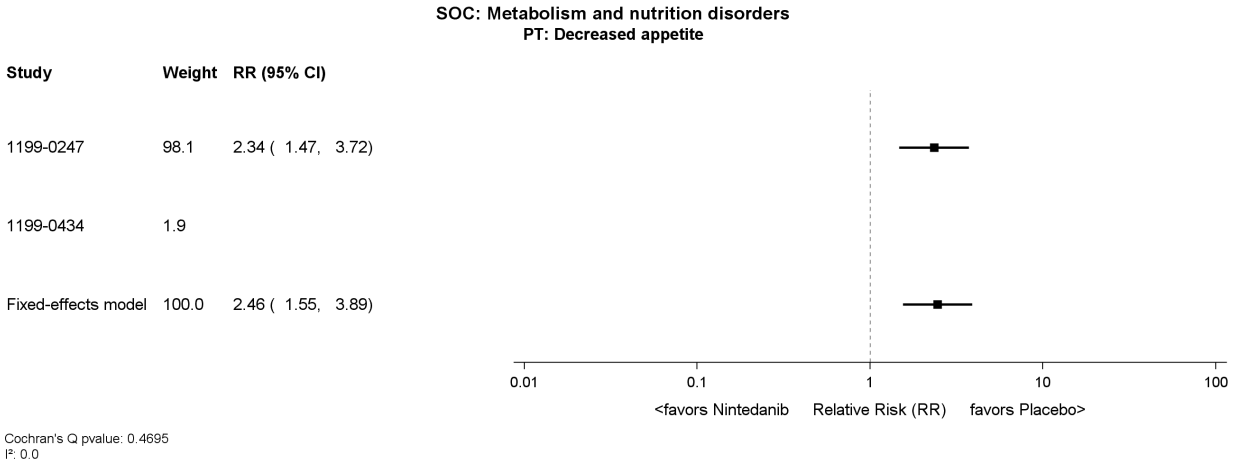

Figure M.2.2.1.5: 1 Forest Plot comparing Nintedanib versus Placebo for patients with specific AEs over the whole trial

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Table M.2.2.1.5: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with specific serious AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	6/331 (1.8)	15/332 (4.5)	93.1	0/ 27 (0.0)	1/ 54 (1.9)	6.9	2.49 (1.01, 6.17)	0.0483	0.0	0.9988
Age										
<65 years										
>=65 years										
Sex										
Male										
Female										
Baseline FVC percent predicted										
<=70%										
>70%										
Baseline HRCT pattern										
UIP-like										
Other fibrotic patterns										
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with specific serious AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)	Heterogeneity I^2	p-value
Overall	6/331 (1.8)	15/332 (4.5)	90.0	0/ 27 (0.0)	1/ 54 (1.9)	10.0	2.62 (0.15, 5.08)	0.0	0.7904
Age									
<65 years									
>=65 years									
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with specific serious AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	6/331 (1.8)	15/332 (4.5)	93.0	0/ 27 (0.0)	1/ 54 (1.9)	7.0	2.56 (1.01, 6.49)	0.0	0.9974
Age									
<65 years									
>=65 years									
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with specific serious AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	4/331 (1.2)	12/332 (3.6)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	2.79 (0.95, 8.17)	0.0608	0.0	0.6160
Age										
<65 years										
>=65 years										
Sex										
Male										
Female										
Baseline FVC percent predicted										
<=70%										
>70%										
Baseline HRCT pattern										
UIP-like										
Other fibrotic patterns										
Underlying ILD diagnosis										
iNSIP										
Unclassifiable IIP										
HP										
Autoimmune ILD										
Other ILD										
Region										
Europe										
Asia										
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with specific serious AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup / Category	Trial 1199_0247: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0247: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0247: Wt	Trial 1199_0434: Nin 150bid vs Placebo: Placebo n / N (%)	Trial 1199_0434: Nin 150bid vs Placebo: Nin 150bid n / N (%)	Trial 1199_0434: Wt	Fixed effects: Nin 150bid vs Placebo: Risk difference (95% CI)	Heterogeneity: I^2	Heterogeneity: p-value
Overall	4/331 (1.2)	12/332 (3.6)	90.0	0/ 27 (0.0)	0/ 54 (0.0)	10.0	2.17 (0.01, 4.32)	0.0	0.3909
Age									
<65 years									
>=65 years									
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with specific serious AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	4/331 (1.2)	12/332 (3.6)	89.8	0/ 27 (0.0)	0/ 54 (0.0)	10.2	2.85 (0.95, 8.56)	0.0	0.6126
Age									
<65 years									
>=65 years									
Sex									
Male									
Female									
Baseline FVC percent predicted									
<=70%									
>70%									
Baseline HRCT pattern									
UIP-like									
Other fibrotic patterns									
Underlying ILD diagnosis									
iNSIP									
Unclassifiable IIP									
HP									
Autoimmune ILD									
Other ILD									
Region									
Europe									
Asia									
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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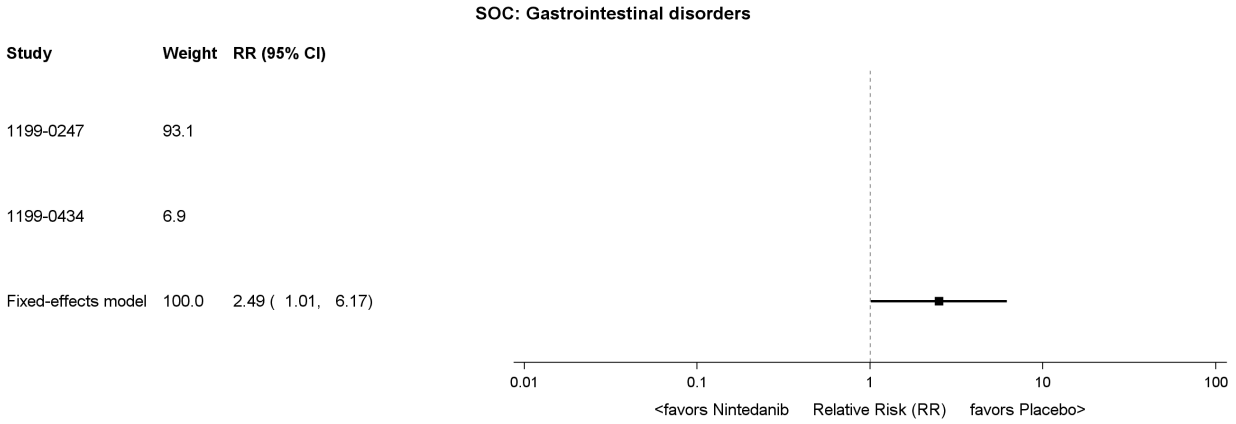

Figure M.2.2.1.5: 2 Forest Plot comparing Nintedanib versus Placebo for patients with specific serious AEs over the whole trial

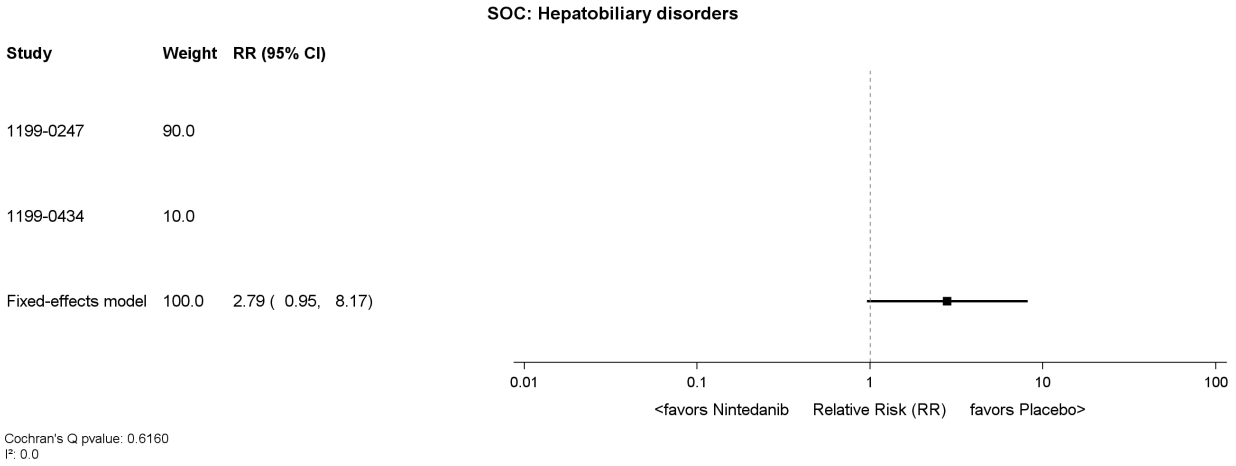

Figure M.2.2.1.5: 2 Forest Plot comparing Nintedanib versus Placebo for patients with specific serious AEs over the whole trial

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Table M.2.2.1.5: 3 Meta-analysis comparing Nintedanib versus Placebo for patients with Diarrhoea with CTCAE grade >=3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0247 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0247 Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Trial 1199_0434 Nin 150bid vs Placebo Nin 150bid n / N (%)	Trial 1199_0434 Wt	Fixed effects Nin 150bid vs Placebo Risk ratio (95% CI)	Fixed effects Nin 150bid vs Placebo p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	6/331 (1.8)	33/332 (9.9)	93.1	0/ 27 (0.0)	1/ 54 (1.9)	6.9	5.28 (2.30,12.12)	<.0001	0.0	0.6845
Age										
<65 years	3/121 (2.5)	10/139 (7.2)	89.2	0/ 9 (0.0)	0/ 25 (0.0)	10.8	2.70 (0.81, 9.02)	0.1074	0.0	0.6470
>=65 years	3/210 (1.4)	23/193 (11.9)	85.9	0/ 18 (0.0)	1/ 29 (3.4)	14.1	7.53 (2.48,22.89)	0.0004	0.0	0.5366
Sex										
Male	3/177 (1.7)	15/179 (8.4)	87.8	0/ 11 (0.0)	1/ 26 (3.8)	12.2	4.64 (1.46,14.77)	0.0094	0.0	0.7284
Female	3/154 (1.9)	18/153 (11.8)	86.6	0/ 16 (0.0)	0/ 28 (0.0)	13.4	5.36 (1.74,16.58)	0.0035	0.0	0.4019
Baseline FVC percent predicted										
<=70%	6/193 (3.1)	17/196 (8.7)	92.8	0/ 10 (0.0)	1/ 17 (5.9)	7.2	2.78 (1.15, 6.69)	0.0230	0.0	0.9674
>70%	0/138 (0.0)	16/136 (11.8)	53.7	0/ 17 (0.0)	0/ 37 (0.0)	46.3	18.30 (2.31, >99)	0.0059	46.4	0.1721
Baseline HRCT pattern										
UIP-like	3/206 (1.5)	25/206 (12.1)	87.0	0/ 23 (0.0)	1/ 45 (2.2)	13.0	7.58 (2.49,23.06)	0.0004	0.0	0.5414
Other fibrotic patterns	3/125 (2.4)	8/126 (6.3)	87.6	0/ 4 (0.0)	0/ 9 (0.0)	12.4	2.44 (0.71, 8.37)	0.1558	0.0	0.6578
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	5/ 64 (7.8)	68.3	0/ 7 (0.0)	0/ 11 (0.0)	31.7	3.57 (0.59,21.52)	0.1647	0.0	0.4921
Unclassifiable IIP	0/ 50 (0.0)	7/ 64 (10.9)	50.6	0/ 3 (0.0)	0/ 2 (0.0)	49.4	7.31 (0.82,64.96)	0.0741	12.0	0.2863
HP	1/ 89 (1.1)	14/ 84 (16.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	3/ 88 (3.4)	5/ 82 (6.1)	88.2	0/ 12 (0.0)	1/ 34 (2.9)	11.8	1.85 (0.49, 6.99)	0.3613	0.0	0.9005
Other ILD	1/ 43 (2.3)	2/ 38 (5.3)	65.4	0/ 5 (0.0)	0/ 6 (0.0)	34.6	1.83 (0.25,13.13)	0.5495	0.0	0.7195
Region										
Europe										
Asia	0/ 76 (0.0)	4/ 79 (5.1)	52.9	0/ 27 (0.0)	1/ 54 (1.9)	47.1	5.86 (0.64,53.86)	0.1182	0.0	0.5991
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 3 Meta-analysis comparing Nintedanib versus Placebo for patients with Diarrhoea with CTCAE grade >=3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo		Heterogeneity	
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk difference (95% CI)		I^2	p-value
Overall	6/331 (1.8)	33/332 (9.9)	90.0	0/ 27 (0.0)	1/ 54 (1.9)	10.0	7.49 (4.26, 10.72)		67.9	0.0775
Age										
<65 years	3/121 (2.5)	10/139 (7.2)	90.2	0/ 9 (0.0)	0/ 25 (0.0)	9.8	4.25 (-0.51, 9.02)		0.0	0.4838
>=65 years	3/210 (1.4)	23/193 (11.9)	89.7	0/ 18 (0.0)	1/ 29 (3.4)	10.3	9.75 (5.28, 14.22)		35.0	0.2148
Sex										
Male	3/177 (1.7)	15/179 (8.4)	91.6	0/ 11 (0.0)	1/ 26 (3.8)	8.4	6.43 (2.19, 10.68)		0.0	0.6614
Female	3/154 (1.9)	18/153 (11.8)	87.8	0/ 16 (0.0)	0/ 28 (0.0)	12.2	8.62 (3.63, 13.61)		70.9	0.0636
Baseline FVC percent predicted										
<=70%	6/193 (3.1)	17/196 (8.7)	93.5	0/ 10 (0.0)	1/ 17 (5.9)	6.5	5.56 (1.08, 10.04)		0.0	0.9922
>70%	0/138 (0.0)	16/136 (11.8)	85.1	0/ 17 (0.0)	0/ 37 (0.0)	14.9	9.94 (5.09, 14.78)		83.5	0.0138
Baseline HRCT pattern										
UIP-like	3/206 (1.5)	25/206 (12.1)	86.8	0/ 23 (0.0)	1/ 45 (2.2)	13.2	9.55 (5.32, 13.78)		73.4	0.0524
Other fibrotic patterns	3/125 (2.4)	8/126 (6.3)	95.2	0/ 4 (0.0)	0/ 9 (0.0)	4.8	3.76 (-1.21, 8.73)		0.0	0.7808
Underlying ILD diagnosis										
iNSIP	1/ 61 (1.6)	5/ 64 (7.8)	86.8	0/ 7 (0.0)	0/ 11 (0.0)	13.2	5.36 (-1.49, 12.21)		0.0	0.5629
Unclassifiable IIP	0/ 50 (0.0)	7/ 64 (10.9)	94.4	0/ 3 (0.0)	0/ 2 (0.0)	5.6	10.15 (1.88, 18.42)		0.0	0.6940
HP	1/ 89 (1.1)	14/ 84 (16.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)		NC	NC
Autoimmune ILD	3/ 88 (3.4)	5/ 82 (6.1)	82.1	0/ 12 (0.0)	1/ 34 (2.9)	17.9	2.71 (-2.89, 8.31)		0.0	0.9836
Other ILD	1/ 43 (2.3)	2/ 38 (5.3)	86.2	0/ 5 (0.0)	0/ 6 (0.0)	13.8	2.53 (-5.75, 10.82)		0.0	0.8492
Region										
Europe										
Asia	0/ 76 (0.0)	4/ 79 (5.1)	68.0	0/ 27 (0.0)	1/ 54 (1.9)	32.0	3.98 (-0.15, 8.11)		0.0	0.4396
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 3 Meta-analysis comparing Nintedanib versus Placebo for patients with Diarrhoea with CTCAE grade >=3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Trial 1199_0434 Nin 150bid vs Placebo Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Fixed effects Nin 150bid vs Placebo Odds ratio (95% CI)	Heterogeneity I^2	p-value
Overall	6/331 (1.8)	33/332 (9.9)	92.6	0/ 27 (0.0)	1/ 54 (1.9)	7.4	5.73 (2.42,13.53)	0.0	0.6640
Age									
<65 years	3/121 (2.5)	10/139 (7.2)	88.7	0/ 9 (0.0)	0/ 25 (0.0)	11.3	2.82 (0.80, 9.93)	0.0	0.6415
>=65 years	3/210 (1.4)	23/193 (11.9)	85.0	0/ 18 (0.0)	1/ 29 (3.4)	15.0	8.34 (2.64,26.32)	0.0	0.5209
Sex									
Male	3/177 (1.7)	15/179 (8.4)	87.6	0/ 11 (0.0)	1/ 26 (3.8)	12.4	4.96 (1.49,16.45)	0.0	0.7250
Female	3/154 (1.9)	18/153 (11.8)	85.4	0/ 16 (0.0)	0/ 28 (0.0)	14.6	5.87 (1.81,19.03)	0.0	0.3859
Baseline FVC percent predicted									
<=70%	6/193 (3.1)	17/196 (8.7)	92.9	0/ 10 (0.0)	1/ 17 (5.9)	7.1	2.94 (1.17, 7.41)	0.0	0.9686
>70%	0/138 (0.0)	16/136 (11.8)	50.9	0/ 17 (0.0)	0/ 37 (0.0)	49.1	19.66 (2.26, >99)	48.5	0.1635
Baseline HRCT pattern									
UIP-like	3/206 (1.5)	25/206 (12.1)	85.9	0/ 23 (0.0)	1/ 45 (2.2)	14.1	8.39 (2.66,26.52)	0.0	0.5186
Other fibrotic patterns	3/125 (2.4)	8/126 (6.3)	87.6	0/ 4 (0.0)	0/ 9 (0.0)	12.4	2.54 (0.70, 9.21)	0.0	0.6656
Underlying ILD diagnosis									
iNSIP	1/ 61 (1.6)	5/ 64 (7.8)	67.6	0/ 7 (0.0)	0/ 11 (0.0)	32.4	3.76 (0.58,24.45)	0.0	0.4944
Unclassifiable IIP	0/ 50 (0.0)	7/ 64 (10.9)	51.4	0/ 3 (0.0)	0/ 2 (0.0)	48.6	8.25 (0.90,76.03)	0.8	0.3153
HP	1/ 89 (1.1)	14/ 84 (16.7)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC
Autoimmune ILD	3/ 88 (3.4)	5/ 82 (6.1)	88.1	0/ 12 (0.0)	1/ 34 (2.9)	11.9	1.91 (0.48, 7.58)	0.0	0.9028
Other ILD	1/ 43 (2.3)	2/ 38 (5.3)	66.0	0/ 5 (0.0)	0/ 6 (0.0)	34.0	1.88 (0.24,14.99)	0.0	0.7277
Region									
Europe									
Asia	0/ 76 (0.0)	4/ 79 (5.1)	52.2	0/ 27 (0.0)	1/ 54 (1.9)	47.8	6.08 (0.62,60.06)	0.0	0.5947
Canada and USA									
Rest of the World									

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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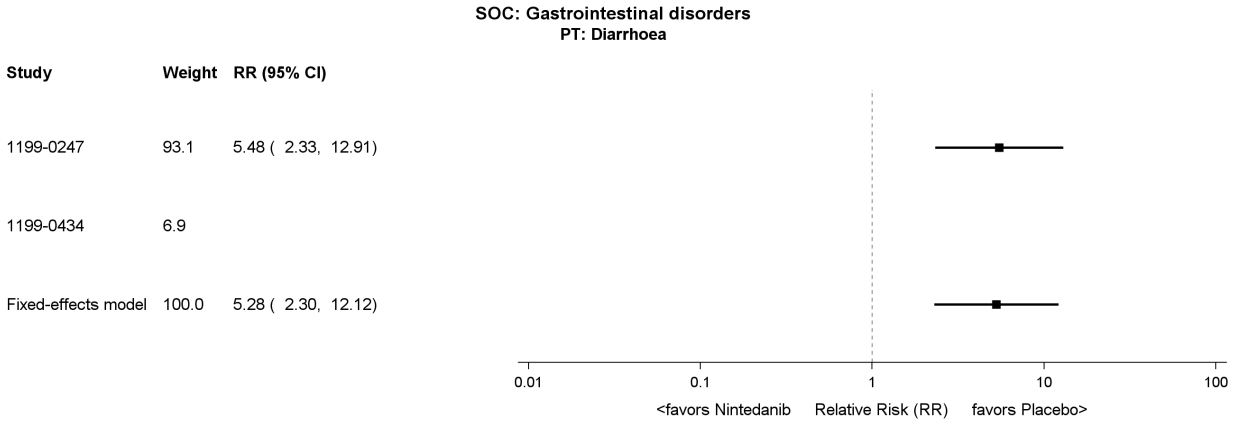

Figure M.2.2.1.5: 3 Forest Plot comparing Nintedanib versus Placebo for patients with Diarrhoea with CTCAE grade >=3 over the whole trial

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Table M.2.2.1.5: 4 Meta-analysis comparing Nintedanib versus Placebo for patients with Diarrhoea with CTCAE grade <3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo			
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Risk ratio (95% CI)	p-value	Heterogeneity I^2	Heterogeneity p-value
Overall	79/331 (23.9)	207/332 (62.3)	93.7	4/ 27 (14.8)	18/ 54 (33.3)	6.3	2.59 (2.11, 3.18)	<.0001	0.0	0.7703
Age										
<65 years	22/121 (18.2)	89/139 (64.0)	94.1	1/ 9 (11.1)	5/ 25 (20.0)	5.9	3.42 (2.32, 5.05)	<.0001	0.0	0.5204
>=65 years	57/210 (27.1)	118/193 (61.1)	93.6	3/ 18 (16.7)	13/ 29 (44.8)	6.4	2.28 (1.79, 2.91)	<.0001	0.0	0.7597
Sex										
Male	44/177 (24.9)	117/179 (65.4)	99.1	0/ 11 (0.0)	7/ 26 (26.9)	0.9	2.71 (2.05, 3.58)	<.0001	0.0	0.4382
Female	35/154 (22.7)	90/153 (58.8)	87.3	4/ 16 (25.0)	11/ 28 (39.3)	12.7	2.46 (1.82, 3.33)	<.0001	0.0	0.3363
Baseline FVC percent predicted										
<=70%	44/193 (22.8)	123/196 (62.8)	97.2	1/ 10 (10.0)	5/ 17 (29.4)	2.8	2.76 (2.09, 3.65)	<.0001	0.0	0.9487
>70%	35/138 (25.4)	84/136 (61.8)	89.4	3/ 17 (17.6)	13/ 37 (35.1)	10.6	2.39 (1.76, 3.24)	<.0001	0.0	0.7336
Baseline HRCT pattern										
UIP-like	53/206 (25.7)	129/206 (62.6)	93.0	3/ 23 (13.0)	16/ 45 (35.6)	7.0	2.45 (1.91, 3.15)	<.0001	0.0	0.8475
Other fibrotic patterns	26/125 (20.8)	78/126 (61.9)	95.0	1/ 4 (25.0)	2/ 9 (22.2)	5.0	2.87 (2.00, 4.12)	<.0001	19.6	0.2648
Underlying ILD diagnosis										
iNSIP	12/ 61 (19.7)	38/ 64 (59.4)	91.0	1/ 7 (14.3)	7/ 11 (63.6)	9.0	3.15 (1.86, 5.33)	<.0001	0.0	0.6952
Unclassifiable IIP	9/ 50 (18.0)	41/ 64 (64.1)	95.5	0/ 3 (0.0)	1/ 2 (50.0)	4.5	3.56 (1.95, 6.50)	<.0001	0.0	0.9903
HP	26/ 89 (29.2)	52/ 84 (61.9)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC	NC	NC
Autoimmune ILD	22/ 88 (25.0)	51/ 82 (62.2)	93.5	1/ 12 (8.3)	9/ 34 (26.5)	6.5	2.53 (1.70, 3.77)	<.0001	0.0	0.8106
Other ILD	10/ 43 (23.3)	25/ 38 (65.8)	81.1	2/ 5 (40.0)	1/ 6 (16.7)	18.9	2.37 (1.37, 4.10)	0.0020	66.6	0.0834
Region										
Europe										
Asia	21/ 76 (27.6)	58/ 79 (73.4)	80.1	4/ 27 (14.8)	18/ 54 (33.3)	19.9	2.58 (1.79, 3.71)	<.0001	0.0	0.7571
Canada and USA										
Rest of the World										

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 4 Meta-analysis comparing Nintedanib versus Placebo for patients with Diarrhoea with CTCAE grade <3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo n / N (%)		Wt	Trial 1199_0434 Nin 150bid vs Placebo n / N (%)		Wt	Fixed effects Nin 150bid vs Placebo Risk difference (95% CI)			Heterogeneity I^2	p-value
	Placebo	Nin 150bid		Placebo	Nin 150bid						
Overall	79/331 (23.9)	207/332 (62.3)	90.2	4/ 27 (14.8)	18/ 54 (33.3)	9.8	36.53 (30.01,	43.05)		74.8	0.0464
Age											
<65 years	22/121 (18.2)	89/139 (64.0)	90.7	1/ 9 (11.1)	5/ 25 (20.0)	9.3	42.42 (32.57,	52.27)		85.2	0.0094
>=65 years	57/210 (27.1)	118/193 (61.1)	90.1	3/ 18 (16.7)	13/ 29 (44.8)	9.9	33.42 (24.82,	42.01)		0.0	0.6672
Sex											
Male	44/177 (24.9)	117/179 (65.4)	91.6	0/ 11 (0.0)	7/ 26 (26.9)	8.4	39.25 (30.45,	48.05)		47.1	0.1693
Female	35/154 (22.7)	90/153 (58.8)	88.3	4/ 16 (25.0)	11/ 28 (39.3)	11.7	33.54 (23.94,	43.14)		51.7	0.1500
Baseline FVC percent predicted											
<=70%	44/193 (22.8)	123/196 (62.8)	93.9	1/ 10 (10.0)	5/ 17 (29.4)	6.1	38.71 (30.09,	47.33)		44.8	0.1785
>70%	35/138 (25.4)	84/136 (61.8)	85.5	3/ 17 (17.6)	13/ 37 (35.1)	14.5	33.65 (23.70,	43.61)		50.2	0.1565
Baseline HRCT pattern											
UIP-like	53/206 (25.7)	129/206 (62.6)	87.1	3/ 23 (13.0)	16/ 45 (35.6)	12.9	35.04 (26.88,	43.20)		41.6	0.1908
Other fibrotic patterns	26/125 (20.8)	78/126 (61.9)	95.8	1/ 4 (25.0)	2/ 9 (22.2)	4.2	39.25 (28.44,	50.06)		64.0	0.0954
Underlying ILD diagnosis											
iNSIP	12/ 61 (19.7)	38/ 64 (59.4)	88.0	1/ 7 (14.3)	7/ 11 (63.6)	12.0	40.87 (26.36,	55.37)		0.0	0.6488
Unclassifiable IIP	9/ 50 (18.0)	41/ 64 (64.1)	94.4	0/ 3 (0.0)	1/ 2 (50.0)	5.6	45.48 (30.04,	60.92)		0.0	0.7697
HP	26/ 89 (29.2)	52/ 84 (61.9)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC,	NC)		NC	NC
Autoimmune ILD	22/ 88 (25.0)	51/ 82 (62.2)	82.7	1/ 12 (8.3)	9/ 34 (26.5)	17.3	33.90 (21.85,	45.95)		53.0	0.1449
Other ILD	10/ 43 (23.3)	25/ 38 (65.8)	88.1	2/ 5 (40.0)	1/ 6 (16.7)	11.9	34.69 (16.28,	53.10)		81.3	0.0208
Region											
Europe											
Asia	21/ 76 (27.6)	58/ 79 (73.4)	68.3	4/ 27 (14.8)	18/ 54 (33.3)	31.7	37.14 (25.94,	48.33)		81.3	0.0207
Canada and USA											
Rest of the World											

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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Table M.2.2.1.5: 4 Meta-analysis comparing Nintedanib versus Placebo for patients with Diarrhoea with CTCAE grade <3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Trial 1199_0247 Nin 150bid vs Placebo			Trial 1199_0434 Nin 150bid vs Placebo			Fixed effects Nin 150bid vs Placebo	Heterogeneity
	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Placebo n / N (%)	Nin 150bid n / N (%)	Wt	Odds ratio (95% CI)	I^2 p-value
Overall	79/331 (23.9)	207/332 (62.4)	89.3	4/ 27 (14.8)	18/ 54 (33.3)	10.7	5.03 (3.63, 6.95)	0.0 0.3399
Age								
<65 years	22/121 (18.2)	89/139 (64.0)	87.8	1/ 9 (11.1)	5/ 25 (20.0)	12.2	7.28 (4.14,12.79)	24.1 0.2511
>=65 years	57/210 (27.1)	118/193 (61.1)	91.2	3/ 18 (16.7)	13/ 29 (44.8)	8.8	4.21 (2.81, 6.30)	0.0 0.9596
Sex								
Male	44/177 (24.9)	117/179 (65.4)	98.1	0/ 11 (0.0)	7/ 26 (26.9)	1.9	5.88 (3.73, 9.28)	0.0 0.6182
Female	35/154 (22.7)	90/153 (58.8)	82.3	4/ 16 (25.0)	11/ 28 (39.3)	17.7	4.34 (2.73, 6.91)	35.0 0.2150
Baseline FVC percent predicted								
<=70%	44/193 (22.8)	123/196 (62.8)	94.9	1/ 10 (10.0)	5/ 17 (29.4)	5.1	5.61 (3.62, 8.67)	0.0 0.7270
>70%	35/138 (25.4)	84/136 (61.8)	83.3	3/ 17 (17.6)	13/ 37 (35.1)	16.7	4.38 (2.69, 7.13)	0.0 0.4120
Baseline HRCT pattern								
UIP-like	53/206 (25.7)	129/206 (62.6)	88.6	3/ 23 (13.0)	16/ 45 (35.6)	11.4	4.70 (3.14, 7.04)	0.0 0.7060
Other fibrotic patterns	26/125 (20.8)	78/126 (61.9)	90.2	1/ 4 (25.0)	2/ 9 (22.2)	9.8	5.67 (3.27, 9.82)	47.3 0.1683
Underlying ILD diagnosis								
iNSIP	12/ 61 (19.7)	38/ 64 (59.4)	91.8	1/ 7 (14.3)	7/ 11 (63.6)	8.2	6.34 (2.96,13.59)	0.0 0.6674
Unclassifiable IIP	9/ 50 (18.0)	41/ 64 (64.1)	93.8	0/ 3 (0.0)	1/ 2 (50.0)	6.2	7.99 (3.39,18.84)	0.0 0.8728
HP	26/ 89 (29.2)	52/ 84 (61.9)	NC	0/ 0 (NC)	0/ 1 (0.0)	NC	NC (NC, NC)	NC NC
Autoimmune ILD	22/ 88 (25.0)	51/ 82 (62.2)	88.1	1/ 12 (8.3)	9/ 34 (26.5)	11.9	4.82 (2.56, 9.08)	0.0 0.8499
Other ILD	10/ 43 (23.3)	25/ 38 (65.8)	63.8	2/ 5 (40.0)	1/ 6 (16.7)	36.2	4.16 (1.72,10.04)	75.5 0.0433
Region								
Europe								
Asia	21/ 76 (27.6)	58/ 79 (73.4)	61.5	4/ 27 (14.8)	18/ 54 (33.3)	38.5	5.56 (3.00,10.28)	40.4 0.1952
Canada and USA								
Rest of the World								

The fixed-effect model was calculated using the Mantel-Haenszel method. A treatment-arm continuity correction was applied in trials with zero events.
N = number of patients, n = number of patients with at least one event, NC = not calculable, Wt = study weight in the meta-analysis.
Heterogeneity p-value was based on Cochran's Q test. The omission of an estimate indicates that no data is available
for the corresponding treatment comparison and that a Meta-analysis could not be calculated. Only treatment-emergent adverse events
with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0434) are displayed.

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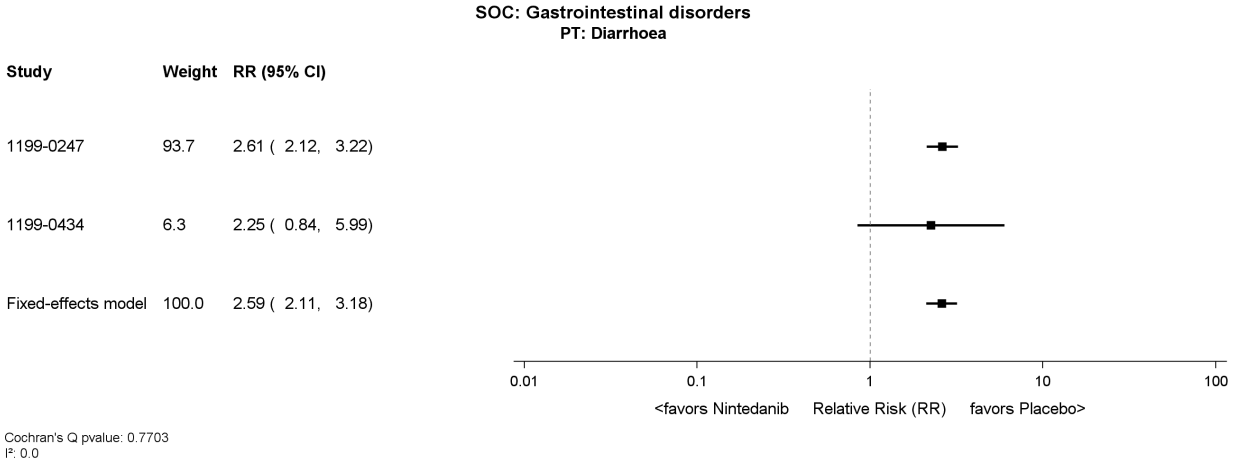

Figure M.2.2.1.5: 4 Forest Plot comparing Nintedanib versus Placebo for patients with Diarrhoea with CTCAE grade <3 over the whole trial

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3 Auswertungen zum indirekten Vergleich

3.1 Indirekter Vergleich von FIBRONEER®-ILD und Metaanalyse der Nintedanib-Studien

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M.3 Nerandomilast 18mg versus Nintedanib (1199.247+1199.434)

M.3.1 Efficacy Analysis

M.3.1.1 Time to event analyses

M.3.1.1.1 Analyses of composite endpoints

M.3.1.1.1.1 Time to first confirmed acute ILD exacerbation or death

Table M.3.1.1.1.1: 1 Indirect treatment comparison for the time to first confirmed acute ILD exacerbation or death over the whole trial

Subgroup Category	Nera 18mg vs Placebo Hazard ratio (95% CI)	Nin 150bid vs Placebo Hazard ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Hazard ratio (95% CI)	p-value	Interaction p-value
Overall	0.57 (0.35, 0.92)	0.68 (0.48, 0.96)	0.84 (0.46, 1.52)	0.5616	
Age					0.2003
<65 years	0.82 (0.34, 1.94)	0.55 (0.28, 1.08)	1.48 (0.49, 4.42)	0.4878	
>=65 years	0.48 (0.27, 0.85)	0.76 (0.50, 1.15)	0.63 (0.31, 1.28)	0.1991	
Sex					0.1105
Male	0.48 (0.25, 0.94)	0.84 (0.54, 1.32)	0.57 (0.26, 1.28)	0.1732	
Female	0.68 (0.34, 1.38)	0.44 (0.24, 0.81)	1.56 (0.62, 3.93)	0.3504	
Baseline FVC percent predicted					0.1671
<=70%	0.45 (0.25, 0.82)	0.68 (0.44, 1.05)	0.66 (0.32, 1.39)	0.2765	
>70%	0.93 (0.40, 2.20)	0.56 (0.30, 1.06)	1.65 (0.57, 4.80)	0.3541	
Baseline HRCT pattern					
UIP-like	0.53 (0.30, 0.94)	0.59 (0.39, 0.90)	0.90 (0.44, 1.82)	0.7646	
Other fibrotic patterns	0.66 (0.27, 1.61)				
Underlying ILD diagnosis					0.6804
iNSIP	0.84 (0.32, 2.26)	0.68 (0.28, 1.68)	1.23 (0.33, 4.68)	0.7578	
Unclassifiable IIP	0.92 (0.28, 3.02)				
HP	0.32 (0.09, 1.15)				
Autoimmune ILD	0.34 (0.12, 0.94)	0.60 (0.30, 1.18)	0.56 (0.16, 1.94)	0.3646	
Other ILD	0.90 (0.31, 2.64)	0.89 (0.32, 2.47)	1.01 (0.23, 4.46)	0.9912	
Region					
Europe	1.20 (0.45, 3.16)				
Asia	0.70 (0.35, 1.42)	0.40 (0.19, 0.82)	1.76 (0.64, 4.81)	0.2717	
Canada and USA	0.00 (NC, NC)				
Rest of the World	0.22 (0.06, 0.79)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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M.3.1.1.2 Analyses of single endpoints

M.3.1.1.2.1 Time to death

Table M.3.1.1.2.1: 1 Indirect treatment comparison for the time to death over the whole trial

Subgroup Category	Nera 18mg vs Placebo Hazard ratio (95% CI)	Nin 150bid vs Placebo Hazard ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Hazard ratio (95% CI)	p-value	Interaction p-value
Overall	0.45 (0.24, 0.82)	0.80 (0.53, 1.21)	0.56 (0.27, 1.17)	0.1212	
Age					
<65 years	0.77 (0.24, 2.45)				
>=65 years	0.36 (0.18, 0.75)	0.82 (0.52, 1.32)	0.44 (0.19, 1.04)	0.0628	
Sex					0.4251
Male	0.45 (0.20, 0.98)	0.96 (0.58, 1.59)	0.46 (0.18, 1.18)	0.1059	
Female	0.45 (0.17, 1.17)	0.52 (0.23, 1.14)	0.87 (0.25, 3.01)	0.8259	
Baseline FVC percent predicted					0.1136
<=70%	0.32 (0.15, 0.71)	0.87 (0.52, 1.44)	0.37 (0.15, 0.95)	0.0395	
>70%	0.84 (0.29, 2.41)	0.62 (0.29, 1.32)	1.36 (0.37, 4.97)	0.6417	
Baseline HRCT pattern					
UIP-like	0.45 (0.22, 0.91)	0.70 (0.43, 1.13)	0.64 (0.27, 1.52)	0.3147	
Other fibrotic patterns	0.44 (0.14, 1.40)				
Underlying ILD diagnosis					
iNSIP	1.15 (0.31, 4.33)	0.71 (0.26, 1.96)	1.63 (0.31, 8.60)	0.5671	
Unclassifiable IIP	0.61 (0.15, 2.59)				
HP	0.31 (0.07, 1.45)				
Autoimmune ILD	0.35 (0.11, 1.12)				
Other ILD	0.20 (0.03, 1.64)				
Region					
Europe	0.84 (0.27, 2.60)				
Asia	0.78 (0.31, 1.95)	0.47 (0.19, 1.21)	1.64 (0.44, 6.09)	0.4571	
Canada and USA	0.00 (NC, NC)				
Rest of the World	0.10 (0.01, 0.75)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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M.3.1.1.2.2 Time to first confirmed acute ILD exacerbation

Table M.3.1.1.2.2: 1 Indirect treatment comparison for the time to first confirmed acute ILD exacerbation over the whole trial

Subgroup Category	Nera 18mg vs Placebo Hazard ratio (95% CI)	Nin 150bid vs Placebo Hazard ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Hazard ratio (95% CI)	p-value	Interaction p-value
Overall	0.69 (0.34, 1.38)	0.59 (0.37, 0.94)	1.17 (0.51, 2.73)	0.7084	
Age					
<65 years	0.98 (0.29, 3.25)				
>=65 years	0.57 (0.24, 1.35)				
Sex					
Male	0.45 (0.16, 1.27)				
Female	1.05 (0.40, 2.81)				
Baseline FVC percent predicted					
<=70%	0.65 (0.29, 1.46)				
>70%	0.84 (0.21, 3.38)				
Baseline HRCT pattern					
UIP-like	0.48 (0.20, 1.17)				
Other fibrotic patterns	1.47 (0.41, 5.25)				
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	2.10 (0.41, 10.90)				
Asia	0.59 (0.22, 1.58)				
Canada and USA	0.00 (NC, NC)				
Rest of the World	0.49 (0.09, 2.68)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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M.3.2 Safety analysis

M.3.2.1 Safety analysis over the whole trial

M.3.2.1.1 Adverse events overall over the whole trial

Table M.3.2.1.1: 1 Indirect treatment comparison for the proportion of patients with any adverse events over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.98 (0.94, 1.02)	1.06 (1.02, 1.09)	0.93 (0.88, 0.98)	0.0055	
Age					0.1605
<65 years	0.94 (0.87, 1.03)	1.07 (1.01, 1.14)	0.88 (0.79, 0.98)	0.0166	
>=65 years	1.01 (0.96, 1.05)	1.05 (1.01, 1.09)	0.96 (0.90, 1.01)	0.1333	
Sex					0.9413
Male	0.99 (0.94, 1.04)	1.06 (1.02, 1.11)	0.93 (0.87, 1.00)	0.0402	
Female	0.97 (0.91, 1.04)	1.05 (1.00, 1.10)	0.93 (0.85, 1.00)	0.0638	
Baseline FVC percent predicted					0.6842
<=70%	0.94 (0.88, 1.01)	1.03 (1.00, 1.07)	0.91 (0.84, 0.98)	0.0164	
>70%	1.02 (0.96, 1.08)	1.09 (1.03, 1.16)	0.93 (0.86, 1.01)	0.1017	
Baseline HRCT pattern					0.6038
UIP-like	0.98 (0.92, 1.04)	1.07 (1.02, 1.11)	0.92 (0.86, 0.98)	0.0157	
Other fibrotic patterns	0.99 (0.93, 1.04)	1.04 (0.99, 1.10)	0.94 (0.87, 1.02)	0.1325	
Underlying ILD diagnosis					0.4949
iNSIP	0.93 (0.85, 1.03)	1.11 (0.99, 1.24)	0.84 (0.72, 0.98)	0.0259	
Unclassifiable IIP	1.01 (0.90, 1.12)	1.04 (0.97, 1.11)	0.97 (0.85, 1.10)	0.6152	
HP	0.96 (0.86, 1.07)				
Autoimmune ILD	1.01 (0.93, 1.11)	1.05 (0.99, 1.12)	0.96 (0.86, 1.07)	0.4804	
Other ILD	0.99 (0.93, 1.06)	1.06 (0.97, 1.17)	0.93 (0.83, 1.05)	0.2374	
Region					
Europe	0.96 (0.91, 1.01)				
Asia	0.98 (0.93, 1.03)	1.04 (0.99, 1.09)	0.94 (0.88, 1.01)	0.0929	
Canada and USA	0.97 (0.85, 1.12)				
Rest of the World	0.99 (0.85, 1.15)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.1.1: 1 Indirect treatment comparison for the proportion of patients with any adverse events over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-1.86 (-6.23, 2.38)	5.35 (2.37, 8.33)	-7.21 (-12.44, -1.97)
Age			
<65 years	-5.41 (-14.00, 2.99)	6.63 (0.93, 12.33)	-12.04 (-22.27, -1.81)
>=65 years	0.57 (-4.38, 5.47)	4.75 (1.38, 8.11)	-4.18 (-10.15, 1.79)
Sex			
Male	-1.06 (-7.05, 4.64)	5.92 (1.68, 10.15)	-6.97 (-14.19, 0.24)
Female	-2.62 (-9.64, 4.24)	4.71 (0.42, 8.99)	-7.33 (-15.48, 0.82)
Baseline FVC percent predicted			
<=70%	-5.79 (-13.24, 0.39)	3.05 (-0.34, 6.44)	-8.84 (-16.45, -1.23)
>70%	1.74 (-4.20, 8.40)	8.22 (2.96, 13.48)	-6.48 (-14.68, 1.73)
Baseline HRCT pattern			
UIP-like	-2.08 (-7.83, 3.48)	6.04 (2.32, 9.75)	-8.11 (-14.88, -1.35)
Other fibrotic patterns	-1.47 (-8.94, 5.65)	4.11 (-0.95, 9.18)	-5.58 (-14.46, 3.30)
Underlying ILD diagnosis			
iNSIP	-6.59 (-17.28, 5.00)	9.08 (-0.99, 19.15)	-15.67 (-30.68, -0.66)
Unclassifiable IIP	0.56 (-11.63, 13.65)	3.71 (-2.91, 10.34)	-3.16 (-17.43, 11.12)
HP	-4.10 (-18.91, 7.56)		
Autoimmune ILD	1.33 (-7.68, 10.42)	5.02 (-0.96, 11.01)	-3.70 (-14.55, 7.16)
Other ILD	0.00 (NC, NC)	5.89 (-2.61, 14.39)	
Region			
Europe	-3.77 (-12.75, 5.40)		
Asia	-1.84 (-7.94, 3.96)	4.08 (-0.44, 8.60)	-5.92 (-13.40, 1.55)
Canada and USA	-2.55 (-23.83, 11.64)		
Rest of the World	-0.76 (-15.00, 13.06)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.1.1: 1 Indirect treatment comparison for the proportion of patients with any adverse events over the whole trial

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.67 (0.28, 1.61)	4.30 (1.81, 10.22)	0.16 (0.05, 0.54)
Age			
<65 years	0.44 (0.13, 1.50)	3.55 (1.19, 10.63)	0.13 (0.02, 0.64)
>=65 years	1.19 (0.31, 4.55)	5.43 (1.40, 21.01)	0.22 (0.03, 1.47)
Sex			
Male	0.76 (0.20, 2.90)	4.67 (1.44, 15.14)	0.16 (0.03, 0.97)
Female	0.63 (0.20, 1.98)	3.54 (1.06, 11.82)	0.18 (0.03, 0.93)
Baseline FVC percent predicted			
<=70%	0.29 (0.07, 1.11)	2.95 (0.86, 10.11)	0.10 (0.02, 0.61)
>70%	1.46 (0.43, 4.92)	5.28 (1.65, 16.94)	0.28 (0.05, 1.49)
Baseline HRCT pattern			
UIP-like	0.69 (0.27, 1.77)	5.49 (1.73, 17.40)	0.13 (0.03, 0.56)
Other fibrotic patterns	0.51 (0.04, 5.74)	2.74 (0.77, 9.69)	0.19 (0.01, 2.86)
Underlying ILD diagnosis			
iNSIP	0.26 (0.03, 2.29)	2.76 (0.87, 8.71)	0.09 (0.01, 1.10)
Unclassifiable IIP	1.12 (0.15, 8.37)	3.55 (0.35, 36.16)	0.31 (0.01, 6.80)
HP	0.37 (0.03, 4.27)		
Autoimmune ILD	1.25 (0.32, 4.86)	3.28 (0.78, 13.86)	0.38 (0.05, 2.76)
Other ILD	NC (NC, NC)	4.07 (0.42, 39.16)	
Region			
Europe	0.00 (NC, NC)		
Asia	0.59 (0.14, 2.55)	6.28 (0.80, 49.23)	0.09 (0.01, 1.18)
Canada and USA	0.55 (0.03, 9.43)		
Rest of the World	0.93 (0.25, 3.46)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.1.1: 2 Indirect treatment comparison for the proportion of patients with any adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.99 (0.95, 1.04)	1.06 (1.02, 1.09)	0.94 (0.89, 0.99)	0.0182	
Age					
<65 years	0.97 (0.88, 1.06)				
>=65 years	1.01 (0.96, 1.05)				
Sex					
Male	0.99 (0.94, 1.04)				
Female	0.99 (0.92, 1.07)				
Baseline FVC percent predicted					
<=70%	0.95 (0.89, 1.02)				
>70%	1.03 (0.97, 1.10)				
Baseline HRCT pattern					
UIP-like	0.98 (0.92, 1.04)				
Other fibrotic patterns	1.02 (0.95, 1.09)				
Underlying ILD diagnosis					
iNSIP	0.93 (0.85, 1.03)				
Unclassifiable IIP	1.01 (0.90, 1.12)				
HP	0.96 (0.86, 1.07)				
Autoimmune ILD	1.05 (0.95, 1.15)				
Other ILD	0.99 (0.93, 1.06)				
Region					
Europe	0.96 (0.91, 1.01)				
Asia	0.99 (0.94, 1.05)				
Canada and USA	0.97 (0.85, 1.12)				
Rest of the World	1.02 (0.87, 1.19)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.1.1: 2 Indirect treatment comparison for the proportion of patients with any adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.95 (-5.45, 3.47)	5.35 (2.37, 8.33)	-6.30 (-11.67, -0.94)
Age			
<65 years	-3.00 (-11.96, 6.01)		
>=65 years	0.57 (-4.38, 5.47)		
Sex			
Male	-1.06 (-7.05, 4.64)		
Female	-0.74 (-8.04, 6.60)		
Baseline FVC percent predicted			
<=70%	-4.94 (-12.49, 1.49)		
>70%	2.70 (-3.42, 9.61)		
Baseline HRCT pattern			
UIP-like	-2.08 (-7.83, 3.48)		
Other fibrotic patterns	1.66 (-6.32, 10.16)		
Underlying ILD diagnosis			
iNSIP	-6.59 (-17.28, 5.00)		
Unclassifiable IIP	0.56 (-11.63, 13.65)		
HP	-4.10 (-18.91, 7.56)		
Autoimmune ILD	4.14 (-5.36, 13.90)		
Other ILD	0.00 (NC, NC)		
Region			
Europe	-3.77 (-12.75, 5.40)		
Asia	-0.90 (-7.14, 5.24)		
Canada and USA	-2.55 (-23.83, 11.64)		
Rest of the World	1.42 (-13.18, 15.64)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.1.1: 2 Indirect treatment comparison for the proportion of patients with any adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.83 (0.36, 1.90)	4.30 (1.81, 10.22)	0.19 (0.06, 0.64)
Age			
<65 years	0.68 (0.23, 2.01)		
>=65 years	1.19 (0.31, 4.55)		
Sex			
Male	0.76 (0.20, 2.90)		
Female	0.89 (0.31, 2.55)		
Baseline FVC percent predicted			
<=70%	0.39 (0.11, 1.32)		
>70%	1.72 (0.53, 5.58)		
Baseline HRCT pattern			
UIP-like	0.69 (0.27, 1.77)		
Other fibrotic patterns	1.57 (0.25, 9.74)		
Underlying ILD diagnosis			
iNSIP	0.26 (0.03, 2.29)		
Unclassifiable IIP	1.12 (0.15, 8.37)		
HP	0.37 (0.03, 4.27)		
Autoimmune ILD	1.80 (0.50, 6.46)		
Other ILD	NC (NC, NC)		
Region			
Europe	0.00 (NC, NC)		
Asia	0.80 (0.21, 3.06)		
Canada and USA	0.55 (0.03, 9.43)		
Rest of the World	1.14 (0.32, 4.05)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.1.1: 3 Indirect treatment comparison for the proportion of patients with serious adverse events over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.84 (0.69, 1.03)	0.89 (0.76, 1.04)	0.94 (0.73, 1.22)	0.6620	
Age					0.6674
<65 years	0.73 (0.50, 1.05)	0.84 (0.63, 1.13)	0.86 (0.54, 1.38)	0.5323	
>=65 years	0.91 (0.72, 1.15)	0.94 (0.78, 1.12)	0.97 (0.72, 1.31)	0.8507	
Sex					0.5571
Male	0.82 (0.63, 1.06)	0.92 (0.76, 1.11)	0.89 (0.64, 1.23)	0.4878	
Female	0.87 (0.64, 1.19)	0.84 (0.65, 1.09)	1.04 (0.70, 1.55)	0.8478	
Baseline FVC percent predicted					0.5767
<=70%	0.78 (0.60, 1.01)	0.86 (0.72, 1.03)	0.90 (0.66, 1.24)	0.5343	
>70%	0.98 (0.71, 1.35)	0.93 (0.71, 1.23)	1.05 (0.69, 1.60)	0.8169	
Baseline HRCT pattern					0.0339
UIP-like	0.97 (0.77, 1.23)	0.86 (0.71, 1.04)	1.13 (0.84, 1.53)	0.4217	
Other fibrotic patterns	0.59 (0.40, 0.86)	0.96 (0.72, 1.26)	0.61 (0.38, 0.99)	0.0453	
Underlying ILD diagnosis					0.8801
iNSIP	0.76 (0.49, 1.18)	0.83 (0.53, 1.31)	0.92 (0.49, 1.73)	0.7901	
Unclassifiable IIP	0.99 (0.65, 1.52)	0.79 (0.56, 1.11)	1.26 (0.73, 2.17)	0.4114	
HP	0.68 (0.38, 1.25)				
Autoimmune ILD	1.01 (0.68, 1.51)	1.00 (0.75, 1.33)	1.02 (0.62, 1.66)	0.9443	
Other ILD	0.69 (0.44, 1.10)	0.72 (0.45, 1.13)	0.97 (0.51, 1.85)	0.9160	
Region					
Europe	1.02 (0.68, 1.53)				
Asia	0.87 (0.67, 1.13)	0.86 (0.66, 1.12)	1.01 (0.70, 1.46)	0.9459	
Canada and USA	0.50 (0.20, 1.29)				
Rest of the World	0.59 (0.32, 1.08)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.1.1: 3 Indirect treatment comparison for the proportion of patients with serious adverse events over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-8.17 (-17.27, 1.12)	-5.48 (-12.68, 1.72)	-2.69 (-14.37, 8.98)
Age			
<65 years	-12.90 (-26.86, 1.77)	-6.47 (-17.73, 4.78)	-6.43 (-24.64, 11.78)
>=65 years	-4.75 (-16.39, 7.07)	-3.37 (-12.63, 5.89)	-1.38 (-16.33, 13.56)
Sex			
Male	-10.13 (-22.63, 2.84)	-4.52 (-14.46, 5.42)	-5.61 (-21.76, 10.54)
Female	-5.86 (-18.73, 7.28)	-6.98 (-17.25, 3.29)	1.12 (-15.45, 17.69)
Baseline FVC percent predicted			
<=70%	-13.29 (-26.09, 0.10)	-7.82 (-17.38, 1.74)	-5.47 (-21.69, 10.74)
>70%	-0.87 (-13.48, 11.66)	-2.74 (-13.38, 7.89)	1.87 (-14.59, 18.34)
Baseline HRCT pattern			
UIP-like	-1.36 (-12.28, 9.60)	-7.35 (-16.33, 1.63)	5.99 (-8.17, 20.14)
Other fibrotic patterns	-24.53 (-39.77, -7.37)	-1.98 (-13.93, 9.97)	-22.55 (-42.68, -2.42)
Underlying ILD diagnosis			
iNSIP	-12.50 (-31.30, 7.47)	-6.46 (-22.02, 9.10)	-6.04 (-30.90, 18.81)
Unclassifiable IIP	-0.28 (-21.66, 21.19)	-12.25 (-29.86, 5.35)	11.98 (-15.75, 39.71)
HP	-15.38 (-36.03, 7.86)		
Autoimmune ILD	0.58 (-15.28, 16.42)	-0.15 (-13.80, 13.49)	0.74 (-20.17, 21.65)
Other ILD	-21.44 (-43.36, 3.21)	-15.52 (-35.38, 4.34)	-5.92 (-36.53, 24.68)
Region			
Europe	0.94 (-18.80, 20.60)		
Asia	-7.06 (-20.04, 6.26)	-7.27 (-20.18, 5.63)	0.21 (-18.21, 18.64)
Canada and USA	-23.14 (-45.29, 5.73)		
Rest of the World	-17.90 (-35.71, 1.87)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.1.1: 3 Indirect treatment comparison for the proportion of patients with serious adverse events over the whole trial

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.72 (0.49, 1.05)	0.80 (0.60, 1.07)	0.90 (0.56, 1.44)
Age			
<65 years	0.58 (0.32, 1.08)	0.76 (0.47, 1.23)	0.77 (0.35, 1.68)
>=65 years	0.83 (0.51, 1.33)	0.87 (0.60, 1.27)	0.95 (0.52, 1.73)
Sex			
Male	0.67 (0.39, 1.12)	0.83 (0.56, 1.24)	0.80 (0.41, 1.54)
Female	0.79 (0.46, 1.35)	0.75 (0.49, 1.15)	1.05 (0.53, 2.10)
Baseline FVC percent predicted			
<=70%	0.58 (0.34, 1.01)	0.73 (0.49, 1.07)	0.80 (0.41, 1.56)
>70%	0.96 (0.57, 1.64)	0.89 (0.57, 1.40)	1.08 (0.54, 2.18)
Baseline HRCT pattern			
UIP-like	0.95 (0.61, 1.48)	0.74 (0.52, 1.07)	1.27 (0.72, 2.26)
Other fibrotic patterns	0.37 (0.18, 0.74)	0.92 (0.56, 1.51)	0.40 (0.17, 0.94)
Underlying ILD diagnosis			
iNSIP	0.60 (0.27, 1.37)	0.75 (0.38, 1.50)	0.80 (0.27, 2.34)
Unclassifiable IIP	0.99 (0.40, 2.44)	0.61 (0.29, 1.26)	1.63 (0.51, 5.22)
HP	0.53 (0.20, 1.41)		
Autoimmune ILD	1.02 (0.52, 2.00)	0.99 (0.57, 1.72)	1.03 (0.43, 2.45)
Other ILD	0.41 (0.14, 1.17)	0.54 (0.24, 1.23)	0.75 (0.20, 2.84)
Region			
Europe	1.04 (0.46, 2.36)		
Asia	0.75 (0.44, 1.29)	0.74 (0.44, 1.26)	1.01 (0.48, 2.15)
Canada and USA	0.35 (0.09, 1.33)		
Rest of the World	0.45 (0.18, 1.10)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.1.1: 4 Indirect treatment comparison for the proportion of patients with serious adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.85 (0.69, 1.05)	0.92 (0.78, 1.08)	0.93 (0.71, 1.21)	0.5831	
Age					
<65 years	0.74 (0.50, 1.08)				
>=65 years	0.92 (0.72, 1.17)				
Sex					
Male	0.84 (0.64, 1.10)				
Female	0.87 (0.63, 1.20)				
Baseline FVC percent predicted					
<=70%	0.77 (0.58, 1.02)				
>70%	1.00 (0.73, 1.38)				
Baseline HRCT pattern					
UIP-like	0.98 (0.77, 1.26)				
Other fibrotic patterns	0.59 (0.40, 0.89)				
Underlying ILD diagnosis					
iNSIP	0.80 (0.50, 1.28)				
Unclassifiable IIP	1.00 (0.64, 1.57)				
HP	0.62 (0.33, 1.16)				
Autoimmune ILD	1.05 (0.70, 1.57)				
Other ILD	0.72 (0.45, 1.15)				
Region					
Europe	0.99 (0.64, 1.53)				
Asia	0.90 (0.69, 1.18)				
Canada and USA	0.50 (0.20, 1.29)				
Rest of the World	0.62 (0.33, 1.15)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.1.1: 4 Indirect treatment comparison for the proportion of patients with serious adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-7.29 (-16.37, 1.98)	-3.84 (-11.00, 3.33)	-3.45 (-15.09, 8.19)
Age			
<65 years	-11.62 (-25.56, 2.92)		
>=65 years	-4.11 (-15.76, 7.70)		
Sex			
Male	-8.44 (-20.99, 4.50)		
Female	-5.81 (-18.61, 7.26)		
Baseline FVC percent predicted			
<=70%	-13.03 (-25.83, 0.41)		
>70%	0.09 (-12.52, 12.57)		
Baseline HRCT pattern			
UIP-like	-0.76 (-11.66, 10.17)		
Other fibrotic patterns	-22.92 (-38.24, -5.82)		
Underlying ILD diagnosis			
iNSIP	-9.32 (-28.32, 10.34)		
Unclassifiable IIP	0.00 (-21.45, 21.45)		
HP	-18.72 (-38.85, 4.52)		
Autoimmune ILD	1.99 (-13.88, 17.73)		
Other ILD	-18.67 (-40.91, 6.01)		
Region			
Europe	-0.33 (-20.04, 19.31)		
Asia	-5.17 (-18.22, 8.14)		
Canada and USA	-23.14 (-45.29, 5.73)		
Rest of the World	-15.72 (-33.60, 3.88)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.1.1: 4 Indirect treatment comparison for the proportion of patients with serious adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.74 (0.51, 1.08)	0.86 (0.64, 1.15)	0.87 (0.54, 1.40)
Age			
<65 years	0.61 (0.33, 1.14)		
>=65 years	0.85 (0.53, 1.37)		
Sex			
Male	0.71 (0.42, 1.20)		
Female	0.79 (0.46, 1.36)		
Baseline FVC percent predicted			
<=70%	0.59 (0.34, 1.02)		
>70%	1.00 (0.59, 1.71)		
Baseline HRCT pattern			
UIP-like	0.97 (0.62, 1.51)		
Other fibrotic patterns	0.39 (0.19, 0.79)		
Underlying ILD diagnosis			
iNSIP	0.68 (0.30, 1.56)		
Unclassifiable IIP	1.00 (0.41, 2.46)		
HP	0.45 (0.17, 1.23)		
Autoimmune ILD	1.09 (0.55, 2.13)		
Other ILD	0.46 (0.16, 1.31)		
Region			
Europe	0.99 (0.43, 2.25)		
Asia	0.81 (0.47, 1.39)		
Canada and USA	0.35 (0.09, 1.33)		
Rest of the World	0.49 (0.20, 1.20)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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M.3.2.2 Adverse events leading to treatment discontinuation over the whole trial

Table M.3.2.2: 1 Indirect treatment comparison for the proportion of patients with any adverse events leading to treatment discontinuation over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.79 (0.47, 1.34)	1.61 (1.16, 2.23)	0.49 (0.27, 0.91)	0.0250	
Age					0.7651
<65 years	0.57 (0.22, 1.49)	1.34 (0.70, 2.57)	0.42 (0.13, 1.36)	0.1478	
>=65 years	0.94 (0.50, 1.76)	1.80 (1.24, 2.60)	0.52 (0.25, 1.08)	0.0808	
Sex					0.6600
Male	0.65 (0.31, 1.38)	1.52 (0.98, 2.36)	0.43 (0.18, 1.02)	0.0549	
Female	0.97 (0.46, 2.07)	1.71 (1.05, 2.79)	0.57 (0.23, 1.39)	0.2156	
Baseline FVC percent predicted					0.3446
<=70%	0.48 (0.21, 1.10)	1.41 (0.94, 2.12)	0.34 (0.13, 0.86)	0.0220	
>70%	1.26 (0.59, 2.68)	1.97 (1.15, 3.38)	0.64 (0.25, 1.62)	0.3442	
Baseline HRCT pattern					0.8445
UIP-like	0.83 (0.46, 1.51)	1.79 (1.20, 2.68)	0.46 (0.23, 0.95)	0.0370	
Other fibrotic patterns	0.69 (0.23, 2.07)	1.29 (0.74, 2.26)	0.53 (0.16, 1.83)	0.3185	
Underlying ILD diagnosis					0.8088
iNSIP	1.70 (0.47, 6.16)	2.05 (0.91, 4.62)	0.83 (0.18, 3.79)	0.8062	
Unclassifiable IIP	0.90 (0.13, 6.06)	1.06 (0.54, 2.08)	0.85 (0.11, 6.40)	0.8719	
HP	0.43 (0.09, 2.00)				
Autoimmune ILD	0.61 (0.23, 1.58)	1.67 (0.88, 3.17)	0.36 (0.12, 1.15)	0.0862	
Other ILD	1.03 (0.37, 2.88)	1.64 (0.66, 4.07)	0.63 (0.16, 2.47)	0.5043	
Region					
Europe	1.06 (0.36, 3.09)				
Asia	0.87 (0.33, 2.31)	1.62 (0.90, 2.92)	0.53 (0.17, 1.67)	0.2820	
Canada and USA	0.59 (0.13, 2.60)				
Rest of the World	0.71 (0.28, 1.84)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.2: 1 Indirect treatment comparison for the proportion of patients with any adverse events leading to treatment discontinuation over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-2.61 (-8.62, 3.38)	8.20 (2.78, 13.62)	-10.82 (-18.90, -2.73)
Age			
<65 years	-5.23 (-14.69, 3.81)	3.38 (-3.95, 10.70)	-8.61 (-20.41, 3.19)
>=65 years	-0.83 (-8.82, 7.27)	12.38 (4.84, 19.92)	-13.21 (-24.23, -2.18)
Sex			
Male	-4.78 (-13.25, 3.72)	7.45 (-0.14, 15.04)	-12.23 (-23.62, -0.85)
Female	-0.31 (-9.05, 8.34)	9.15 (1.38, 16.92)	-9.46 (-21.12, 2.20)
Baseline FVC percent predicted			
<=70%	-7.96 (-16.40, 0.87)	6.43 (-1.02, 13.89)	-14.40 (-25.80, -2.99)
>70%	2.48 (-6.07, 10.62)	10.45 (2.58, 18.32)	-7.96 (-19.43, 3.50)
Baseline HRCT pattern			
UIP-like	-2.25 (-9.63, 5.15)	10.47 (3.61, 17.33)	-12.73 (-22.81, -2.65)
Other fibrotic patterns	-3.36 (-14.21, 7.17)	4.13 (-4.69, 12.96)	-7.50 (-21.36, 6.37)
Underlying ILD diagnosis			
iNSIP	5.23 (-8.71, 17.54)	11.19 (-0.59, 22.97)	-5.96 (-23.59, 11.67)
Unclassifiable IIP	-0.56 (-13.65, 11.63)	1.36 (-13.55, 16.26)	-1.91 (-21.46, 17.63)
HP	-8.72 (-23.85, 8.05)		
Autoimmune ILD	-5.51 (-16.46, 5.36)	8.50 (-1.57, 18.56)	-14.01 (-28.85, 0.83)
Other ILD	0.56 (-18.60, 22.00)	8.39 (-6.83, 23.61)	-7.83 (-33.21, 17.54)
Region			
Europe	0.71 (-14.45, 14.30)		
Asia	-1.01 (-8.44, 6.33)	8.54 (-1.09, 18.17)	-9.55 (-21.68, 2.59)
Canada and USA	-8.24 (-27.51, 16.66)		
Rest of the World	-5.61 (-21.10, 10.41)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.2: 1 Indirect treatment comparison for the proportion of patients with any adverse events leading to treatment discontinuation over the whole trial

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.77 (0.43, 1.39)	1.78 (1.21, 2.63)	0.43 (0.21, 0.88)
Age			
<65 years	0.53 (0.19, 1.54)	1.39 (0.67, 2.90)	0.38 (0.11, 1.39)
>=65 years	0.93 (0.45, 1.90)	2.10 (1.32, 3.35)	0.44 (0.19, 1.04)
Sex			
Male	0.62 (0.27, 1.43)	1.67 (0.98, 2.84)	0.37 (0.14, 1.00)
Female	0.97 (0.41, 2.26)	1.91 (1.08, 3.37)	0.51 (0.18, 1.41)
Baseline FVC percent predicted			
<=70%	0.44 (0.17, 1.09)	1.52 (0.93, 2.51)	0.29 (0.10, 0.81)
>70%	1.29 (0.55, 3.02)	2.24 (1.19, 4.21)	0.58 (0.20, 1.66)
Baseline HRCT pattern			
UIP-like	0.81 (0.41, 1.60)	2.04 (1.26, 3.31)	0.40 (0.17, 0.91)
Other fibrotic patterns	0.67 (0.20, 2.22)	1.36 (0.70, 2.64)	0.49 (0.12, 1.94)
Underlying ILD diagnosis			
iNSIP	1.80 (0.44, 7.43)	2.35 (0.92, 6.02)	0.77 (0.14, 4.21)
Unclassifiable IIP	0.89 (0.12, 6.70)	1.08 (0.45, 2.57)	0.83 (0.09, 7.41)
HP	0.39 (0.07, 2.10)		
Autoimmune ILD	0.57 (0.20, 1.67)	1.85 (0.87, 3.92)	0.31 (0.08, 1.15)
Other ILD	1.04 (0.29, 3.73)	1.83 (0.61, 5.48)	0.57 (0.10, 3.07)
Region			
Europe	1.07 (0.31, 3.64)		
Asia	0.86 (0.30, 2.46)	1.81 (0.90, 3.67)	0.47 (0.13, 1.68)
Canada and USA	0.53 (0.09, 2.99)		
Rest of the World	0.67 (0.22, 2.06)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.2: 2 Indirect treatment comparison for the proportion of patients with any adverse events leading to treatment discontinuation (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.93 (0.53, 1.60)	1.83 (1.29, 2.59)	0.51 (0.26, 0.97)	0.0394	
Age					0.8364
<65 years	0.71 (0.26, 1.95)	1.57 (0.79, 3.14)	0.45 (0.13, 1.53)	0.2016	
>=65 years	1.05 (0.55, 2.02)	2.01 (1.35, 2.99)	0.52 (0.24, 1.12)	0.0958	
Sex					0.9025
Male	0.80 (0.37, 1.76)	1.67 (1.06, 2.64)	0.48 (0.19, 1.19)	0.1141	
Female	1.06 (0.49, 2.30)	2.03 (1.20, 3.44)	0.52 (0.20, 1.33)	0.1738	
Baseline FVC percent predicted					0.4691
<=70%	0.57 (0.24, 1.35)	1.57 (1.02, 2.42)	0.36 (0.14, 0.95)	0.0390	
>70%	1.40 (0.64, 3.06)	2.31 (1.29, 4.15)	0.60 (0.23, 1.61)	0.3142	
Baseline HRCT pattern					0.9091
UIP-like	1.03 (0.54, 1.94)	2.02 (1.32, 3.09)	0.51 (0.24, 1.09)	0.0832	
Other fibrotic patterns	0.69 (0.23, 2.07)	1.48 (0.81, 2.70)	0.47 (0.13, 1.63)	0.2323	
Underlying ILD diagnosis					0.6055
iNSIP	5.09 (0.65, 39.76)	2.81 (1.12, 7.05)	1.81 (0.19, 17.26)	0.6040	
Unclassifiable IIP	0.90 (0.13, 6.06)	1.16 (0.58, 2.34)	0.77 (0.10, 5.89)	0.8034	
HP	0.43 (0.09, 2.00)				
Autoimmune ILD	0.68 (0.25, 1.80)	1.96 (0.99, 3.87)	0.35 (0.10, 1.14)	0.0806	
Other ILD	1.20 (0.41, 3.50)	1.73 (0.64, 4.66)	0.69 (0.16, 2.98)	0.6214	
Region					
Europe	1.32 (0.41, 4.20)				
Asia	0.87 (0.33, 2.31)	1.86 (1.00, 3.47)	0.46 (0.15, 1.48)	0.1949	
Canada and USA	0.88 (0.18, 4.33)				
Rest of the World	0.80 (0.30, 2.12)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.2: 2 Indirect treatment comparison for the proportion of patients with any adverse events leading to treatment discontinuation (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.81 (-6.61, 4.99)	9.57 (4.32, 14.82)	-10.38 (-18.21, -2.55)
Age			
<65 years	-2.82 (-11.84, 5.82)	4.87 (-2.22, 11.96)	-7.69 (-19.01, 3.63)
>=65 years	0.61 (-7.20, 8.54)	13.59 (6.26, 20.92)	-12.98 (-23.73, -2.23)
Sex			
Male	-2.20 (-10.30, 5.96)	8.49 (1.09, 15.90)	-10.69 (-21.69, 0.31)
Female	0.63 (-7.96, 9.16)	10.86 (3.38, 18.34)	-10.23 (-21.59, 1.14)
Baseline FVC percent predicted			
<=70%	-5.42 (-13.53, 3.10)	7.90 (0.64, 15.15)	-13.32 (-24.35, -2.28)
>70%	3.44 (-4.93, 11.44)	11.68 (4.09, 19.26)	-8.23 (-19.39, 2.93)
Baseline HRCT pattern			
UIP-like	0.28 (-6.78, 7.39)	11.74 (5.06, 18.43)	-11.46 (-21.21, -1.72)
Other fibrotic patterns	-3.36 (-14.21, 7.17)	5.66 (-2.80, 14.12)	-9.02 (-22.66, 4.61)
Underlying ILD diagnosis			
iNSIP	10.23 (-1.98, 21.70)	14.03 (2.80, 25.27)	-3.81 (-20.13, 12.52)
Unclassifiable IIP	-0.56 (-13.65, 11.63)	3.24 (-11.39, 17.88)	-3.80 (-23.14, 15.54)
HP	-8.72 (-23.85, 8.05)		
Autoimmune ILD	-4.10 (-14.83, 6.55)	10.38 (0.57, 20.18)	-14.48 (-28.98, 0.02)
Other ILD	3.33 (-15.53, 24.39)	8.13 (-6.34, 22.59)	-4.79 (-29.44, 19.86)
Region			
Europe	3.21 (-11.45, 16.32)		
Asia	-1.01 (-8.44, 6.33)	10.34 (0.93, 19.76)	-11.35 (-23.31, 0.62)
Canada and USA	-1.57 (-19.98, 22.39)		
Rest of the World	-3.44 (-18.68, 12.25)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.3.2.2: 2 Indirect treatment comparison for the proportion of patients with any adverse events leading to treatment discontinuation (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.92 (0.50, 1.69)	2.05 (1.37, 3.09)	0.45 (0.21, 0.93)
Age			
<65 years	0.69 (0.23, 2.07)	1.66 (0.77, 3.59)	0.41 (0.11, 1.58)
>=65 years	1.06 (0.51, 2.22)	2.39 (1.47, 3.87)	0.44 (0.18, 1.07)
Sex			
Male	0.78 (0.33, 1.87)	1.85 (1.07, 3.21)	0.42 (0.15, 1.18)
Female	1.07 (0.45, 2.54)	2.30 (1.26, 4.20)	0.47 (0.16, 1.34)
Baseline FVC percent predicted			
<=70%	0.54 (0.21, 1.38)	1.73 (1.03, 2.89)	0.31 (0.11, 0.91)
>70%	1.45 (0.61, 3.47)	2.66 (1.36, 5.19)	0.55 (0.18, 1.64)
Baseline HRCT pattern			
UIP-like	1.03 (0.50, 2.10)	2.33 (1.41, 3.85)	0.44 (0.18, 1.06)
Other fibrotic patterns	0.67 (0.20, 2.22)	1.58 (0.79, 3.18)	0.42 (0.10, 1.69)
Underlying ILD diagnosis			
iNSIP	5.69 (0.67, 48.22)	3.31 (1.17, 9.35)	1.72 (0.16, 18.50)
Unclassifiable IIP	0.89 (0.12, 6.70)	1.21 (0.50, 2.94)	0.74 (0.08, 6.64)
HP	0.39 (0.07, 2.10)		
Autoimmune ILD	0.65 (0.22, 1.92)	2.21 (1.01, 4.86)	0.29 (0.08, 1.12)
Other ILD	1.25 (0.34, 4.65)	1.91 (0.60, 6.13)	0.65 (0.11, 3.78)
Region			
Europe	1.37 (0.37, 5.04)		
Asia	0.86 (0.30, 2.46)	2.13 (1.02, 4.43)	0.40 (0.11, 1.45)
Canada and USA	0.87 (0.14, 5.31)		
Rest of the World	0.77 (0.24, 2.44)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434. An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable. Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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M.3.2.3 Adverse events on SOC level over the whole trial

Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Cardiac disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.77 (1.05, 2.96)	1.04 (0.72, 1.49)	1.70 (0.91, 3.20)	0.0980	
Age					
<65 years	1.26 (0.46, 3.47)	1.31 (0.64, 2.70)			
>=65 years	2.03 (1.11, 3.70)	0.99 (0.65, 1.50)			
Sex					
Male	2.09 (1.06, 4.11)	0.98 (0.64, 1.48)			
Female	1.40 (0.63, 3.15)	1.16 (0.59, 2.29)			
Baseline FVC percent predicted					
<=70%	2.46 (1.16, 5.22)	1.03 (0.64, 1.64)			
>70%	1.30 (0.64, 2.64)	1.05 (0.60, 1.83)			
Baseline HRCT pattern					
UIP-like	2.13 (1.14, 3.97)	0.92 (0.59, 1.43)			
Other fibrotic patterns	1.11 (0.43, 2.88)	1.34 (0.71, 2.53)			
Underlying ILD diagnosis					
iNSIP	1.21 (0.31, 4.78)	0.93 (0.35, 2.46)			
Unclassifiable IIP	1.26 (0.44, 3.62)	1.21 (0.52, 2.84)			
HP	1.63 (0.48, 5.54)				
Autoimmune ILD	2.37 (0.96, 5.81)	1.82 (0.82, 4.01)			
Other ILD	2.88 (0.57, 14.54)	0.68 (0.28, 1.66)			
Region					
Europe	1.04 (0.46, 2.34)				
Asia	2.23 (1.01, 4.90)	2.02 (0.90, 4.52)			
Canada and USA	1.76 (0.40, 7.80)				
Rest of the World	3.21 (0.35, 29.69)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Cardiac disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	6.90 (0.72, 13.14)	0.50 (-4.47, 5.47)	6.40 (-1.56, 14.35)
Age			
<65 years	1.86 (-6.98, 10.60)	2.64 (-4.12, 9.40)	
>=65 years	10.38 (1.81, 19.02)	-0.20 (-7.08, 6.67)	
Sex			
Male	10.34 (1.10, 19.66)	-0.42 (-8.15, 7.31)	
Female	3.44 (-4.95, 11.84)	1.30 (-4.60, 7.20)	
Baseline FVC percent predicted			
<=70%	11.12 (2.08, 20.76)	0.38 (-6.34, 7.09)	
>70%	3.13 (-5.76, 11.62)	0.66 (-6.77, 8.09)	
Baseline HRCT pattern			
UIP-like	9.30 (1.86, 16.87)	-1.23 (-7.54, 5.08)	
Other fibrotic patterns	1.18 (-10.37, 12.63)	3.69 (-4.36, 11.74)	
Underlying ILD diagnosis			
iNSIP	1.59 (-11.80, 13.17)	-0.74 (-10.59, 9.11)	
Unclassifiable IIP	3.61 (-13.56, 20.04)	3.01 (-9.93, 15.94)	
HP	6.41 (-9.85, 24.41)		
Autoimmune ILD	11.55 (-0.13, 23.27)	7.15 (-1.47, 15.77)	
Other ILD	10.44 (-5.39, 29.53)	-6.76 (-22.26, 8.73)	
Region			
Europe	0.75 (-16.40, 16.62)		
Asia	9.28 (0.39, 18.27)	7.61 (-0.33, 15.55)	
Canada and USA	7.65 (-11.72, 31.93)		
Rest of the World	4.80 (-5.44, 16.57)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Cardiac disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.91 (1.07, 3.43)	1.04 (0.69, 1.58)	1.83 (0.89, 3.76)
Age			
<65 years	1.28 (0.43, 3.87)	1.35 (0.61, 2.97)	
>=65 years	2.30 (1.15, 4.60)	0.99 (0.60, 1.62)	
Sex			
Male	2.36 (1.08, 5.13)	0.97 (0.58, 1.62)	
Female	1.46 (0.60, 3.57)	1.17 (0.56, 2.45)	
Baseline FVC percent predicted			
<=70%	2.79 (1.19, 6.55)	1.03 (0.60, 1.78)	
>70%	1.34 (0.60, 3.01)	1.06 (0.56, 2.01)	
Baseline HRCT pattern			
UIP-like	2.37 (1.17, 4.79)	0.91 (0.55, 1.51)	
Other fibrotic patterns	1.12 (0.38, 3.30)	1.39 (0.67, 2.89)	
Underlying ILD diagnosis			
iNSIP	1.23 (0.28, 5.49)	0.92 (0.31, 2.70)	
Unclassifiable IIP	1.32 (0.38, 4.58)	1.26 (0.46, 3.42)	
HP	1.75 (0.43, 7.18)		
Autoimmune ILD	2.71 (0.98, 7.52)	1.96 (0.83, 4.64)	
Other ILD	3.24 (0.54, 19.25)	0.63 (0.22, 1.84)	
Region			
Europe	1.05 (0.38, 2.91)		
Asia	2.48 (1.03, 5.98)	2.20 (0.91, 5.32)	
Canada and USA	1.93 (0.34, 10.83)		
Rest of the World	3.38 (0.34, 33.76)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Ear and labyrinth disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	5.05 (1.12, 22.76)	0.86 (0.38, 1.94)	5.84 (1.06, 32.33)	0.0432	
Age					
<65 years					
>=65 years					
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like					
Other fibrotic patterns					
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Ear and labyrinth disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	3.64 (0.54, 7.32)	-0.46 (-2.96, 2.04)	4.11 (-0.11, 8.32)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Ear and labyrinth disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	5.24 (1.13, 24.19)	0.86 (0.38, 1.97)	6.09 (1.07, 34.68)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Eye disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.09 (0.51, 2.34)	0.82 (0.49, 1.39)	1.33 (0.53, 3.36)	0.5458	
Age					
<65 years	1.18 (0.33, 4.24)	1.66 (0.45, 6.09)			
>=65 years	1.05 (0.41, 2.72)	0.74 (0.42, 1.33)			
Sex					
Male	0.75 (0.24, 2.28)	0.65 (0.34, 1.26)			
Female	1.56 (0.53, 4.60)	1.24 (0.52, 3.00)			
Baseline FVC percent predicted					
<=70%	1.23 (0.37, 4.12)	1.06 (0.50, 2.24)			
>70%	0.96 (0.36, 2.55)	0.64 (0.31, 1.35)			
Baseline HRCT pattern					
UIP-like	0.82 (0.33, 2.02)	0.90 (0.49, 1.64)			
Other fibrotic patterns	2.42 (0.49, 12.05)	0.64 (0.22, 1.83)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	0.94 (0.27, 3.29)				
Asia	0.99 (0.33, 2.97)	0.63 (0.26, 1.50)			
Canada and USA	1.76 (0.12, 26.45)				
Rest of the World	1.07 (0.07, 16.57)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Eye disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.50 (-4.01, 5.06)	-1.38 (-5.06, 2.31)	1.88 (-3.96, 7.72)
Age			
<65 years	0.86 (-6.78, 8.39)	1.66 (-2.46, 5.78)	
>=65 years	0.31 (-5.67, 6.43)	-2.78 (-8.16, 2.61)	
Sex			
Male	-1.53 (-7.96, 4.87)	-3.70 (-9.29, 1.89)	
Female	2.62 (-4.24, 9.64)	1.18 (-3.56, 5.92)	
Baseline FVC percent predicted			
<=70%	0.97 (-5.10, 7.82)	0.39 (-4.25, 5.03)	
>70%	-0.28 (-7.51, 6.43)	-3.61 (-9.59, 2.38)	
Baseline HRCT pattern			
UIP-like	-1.13 (-6.68, 4.38)	-0.84 (-5.75, 4.07)	
Other fibrotic patterns	4.45 (-4.26, 13.70)	-2.31 (-7.69, 3.07)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	-0.57 (-14.67, 11.83)		
Asia	-0.05 (-6.89, 6.75)	-3.80 (-10.82, 3.22)	
Canada and USA	2.55 (-11.64, 23.83)		
Rest of the World	0.15 (-9.21, 10.05)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Eye disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.10 (0.49, 2.46)	0.81 (0.46, 1.43)	1.36 (0.51, 3.65)
Age			
<65 years	1.19 (0.31, 4.59)	1.69 (0.44, 6.49)	
>=65 years	1.06 (0.38, 2.90)	0.72 (0.38, 1.37)	
Sex			
Male	0.73 (0.23, 2.39)	0.62 (0.30, 1.28)	
Female	1.60 (0.51, 5.06)	1.26 (0.50, 3.21)	
Baseline FVC percent predicted			
<=70%	1.24 (0.35, 4.42)	1.07 (0.48, 2.37)	
>70%	0.96 (0.33, 2.73)	0.62 (0.27, 1.39)	
Baseline HRCT pattern			
UIP-like	0.81 (0.31, 2.11)	0.89 (0.46, 1.73)	
Other fibrotic patterns	2.54 (0.47, 13.60)	0.62 (0.21, 1.88)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	0.94 (0.23, 3.74)		
Asia	0.99 (0.31, 3.17)	0.59 (0.22, 1.57)	
Canada and USA	1.81 (0.11, 30.97)		
Rest of the World	1.07 (0.06, 17.68)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.18 (0.95, 1.46)	1.73 (1.53, 1.94)	0.68 (0.54, 0.87)	0.0024	
Age					0.0198
<65 years	0.86 (0.59, 1.25)	1.89 (1.53, 2.35)	0.46 (0.30, 0.70)	0.0004	
>=65 years	1.41 (1.08, 1.84)	1.66 (1.44, 1.91)	0.85 (0.63, 1.15)	0.2904	
Sex					0.7831
Male	1.19 (0.87, 1.62)	1.68 (1.44, 1.98)	0.70 (0.50, 1.00)	0.0496	
Female	1.17 (0.87, 1.58)	1.78 (1.50, 2.12)	0.66 (0.47, 0.93)	0.0173	
Baseline FVC percent predicted					0.5458
<=70%	1.13 (0.83, 1.53)	1.56 (1.35, 1.80)	0.72 (0.51, 1.02)	0.0612	
>70%	1.24 (0.91, 1.68)	2.00 (1.63, 2.44)	0.62 (0.43, 0.89)	0.0104	
Baseline HRCT pattern					0.2310
UIP-like	1.28 (0.99, 1.65)	1.69 (1.47, 1.96)	0.75 (0.56, 1.01)	0.0589	
Other fibrotic patterns	0.97 (0.64, 1.46)	1.79 (1.46, 2.19)	0.54 (0.34, 0.86)	0.0085	
Underlying ILD diagnosis					0.1942
iNSIP	1.12 (0.63, 1.97)	2.54 (1.72, 3.76)	0.44 (0.22, 0.88)	0.0196	
Unclassifiable IIP	1.18 (0.74, 1.89)	2.27 (1.63, 3.16)	0.52 (0.29, 0.92)	0.0256	
HP	0.99 (0.58, 1.71)				
Autoimmune ILD	1.23 (0.85, 1.79)	1.66 (1.33, 2.08)	0.74 (0.48, 1.15)	0.1792	
Other ILD	1.54 (0.92, 2.59)	1.45 (1.09, 1.93)	1.06 (0.59, 1.92)	0.8368	
Region					
Europe	1.39 (0.82, 2.38)				
Asia	1.10 (0.82, 1.47)	1.75 (1.42, 2.14)	0.63 (0.44, 0.90)	0.0113	
Canada and USA	0.99 (0.57, 1.74)				
Rest of the World	1.56 (0.88, 2.76)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	7.18 (-2.04, 16.23)	34.56 (28.18, 40.93)	-27.38 (-38.52, -16.24)
Age			
<65 years	-5.81 (-20.00, 8.67)	37.52 (27.08, 47.96)	-43.32 (-61.06, -25.59)
>=65 years	15.66 (3.79, 26.93)	33.40 (25.41, 41.39)	-17.74 (-31.80, -3.68)
Sex			
Male	7.11 (-5.63, 19.56)	33.17 (24.41, 41.93)	-26.05 (-41.39, -10.72)
Female	7.11 (-6.10, 19.98)	36.41 (27.16, 45.66)	-29.29 (-45.28, -13.30)
Baseline FVC percent predicted			
<=70%	5.16 (-8.03, 18.19)	29.37 (20.87, 37.87)	-24.22 (-39.84, -8.59)
>70%	9.12 (-3.76, 21.50)	41.05 (31.51, 50.59)	-31.93 (-47.76, -16.10)
Baseline HRCT pattern			
UIP-like	10.74 (-0.26, 21.39)	33.70 (25.82, 41.57)	-22.96 (-36.34, -9.57)
Other fibrotic patterns	-1.28 (-17.73, 15.25)	36.08 (25.30, 46.86)	-37.36 (-57.06, -17.66)
Underlying ILD diagnosis			
iNSIP	3.86 (-15.38, 21.99)	45.33 (30.68, 59.98)	-41.47 (-65.22, -17.72)
Unclassifiable IIP	8.06 (-13.86, 28.89)	51.39 (36.76, 66.02)	-43.33 (-69.23, -17.43)
HP	-0.26 (-22.46, 22.31)		
Autoimmune ILD	9.13 (-7.10, 24.72)	31.77 (20.01, 43.53)	-22.64 (-42.42, -2.85)
Other ILD	21.11 (-4.09, 42.89)	25.48 (7.74, 43.21)	-4.36 (-33.79, 25.07)
Region			
Europe	12.78 (-7.19, 30.95)		
Asia	4.27 (-8.97, 17.29)	36.45 (25.75, 47.15)	-32.19 (-49.13, -15.24)
Canada and USA	-0.39 (-27.84, 26.66)		
Rest of the World	15.93 (-3.91, 34.25)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.34 (0.92, 1.96)	5.24 (3.72, 7.37)	0.26 (0.15, 0.43)
Age			
<65 years	0.78 (0.42, 1.45)	5.48 (3.23, 9.31)	0.14 (0.06, 0.32)
>=65 years	1.89 (1.16, 3.06)	5.32 (3.38, 8.38)	0.35 (0.18, 0.69)
Sex			
Male	1.34 (0.79, 2.28)	4.98 (3.10, 8.01)	0.27 (0.13, 0.55)
Female	1.33 (0.78, 2.29)	5.66 (3.44, 9.31)	0.24 (0.11, 0.49)
Baseline FVC percent predicted			
<=70%	1.23 (0.72, 2.13)	4.19 (2.66, 6.59)	0.29 (0.15, 0.60)
>70%	1.45 (0.86, 2.47)	6.83 (4.06, 11.51)	0.21 (0.10, 0.45)
Baseline HRCT pattern			
UIP-like	1.55 (0.99, 2.43)	5.21 (3.38, 8.03)	0.30 (0.16, 0.56)
Other fibrotic patterns	0.95 (0.47, 1.91)	5.33 (3.04, 9.34)	0.18 (0.07, 0.44)
Underlying ILD diagnosis			
iNSIP	1.19 (0.50, 2.80)	7.10 (3.39, 14.88)	0.17 (0.05, 0.52)
Unclassifiable IIP	1.38 (0.56, 3.41)	17.00 (6.01, 48.10)	0.08 (0.02, 0.32)
HP	0.99 (0.38, 2.59)		
Autoimmune ILD	1.45 (0.74, 2.83)	4.81 (2.48, 9.34)	0.30 (0.12, 0.77)
Other ILD	2.36 (0.83, 6.69)	3.40 (1.32, 8.78)	0.69 (0.17, 2.84)
Region			
Europe	1.72 (0.73, 4.04)		
Asia	1.19 (0.69, 2.04)	7.87 (3.83, 16.17)	0.15 (0.06, 0.37)
Canada and USA	0.98 (0.30, 3.24)		
Rest of the World	2.01 (0.83, 4.84)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: General disorders and administration site conditions

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.72 (0.56, 0.93)	0.87 (0.70, 1.09)	0.83 (0.59, 1.16)	0.2733	
Age					
<65 years	0.70 (0.47, 1.06)	1.07 (0.73, 1.56)			
>=65 years	0.74 (0.53, 1.02)	0.79 (0.60, 1.04)			
Sex					
Male	0.67 (0.47, 0.96)	0.86 (0.64, 1.14)			
Female	0.79 (0.55, 1.13)	0.89 (0.63, 1.25)			
Baseline FVC percent predicted					
<=70%	0.87 (0.63, 1.21)	0.80 (0.61, 1.05)			
>70%	0.61 (0.41, 0.91)	1.01 (0.70, 1.46)			
Baseline HRCT pattern					
UIP-like	0.68 (0.49, 0.94)	0.92 (0.70, 1.21)			
Other fibrotic patterns	0.81 (0.54, 1.21)	0.79 (0.54, 1.16)			
Underlying ILD diagnosis					
iNSIP	1.03 (0.56, 1.91)	1.10 (0.58, 2.08)			
Unclassifiable IIP	0.58 (0.32, 1.07)	1.13 (0.73, 1.74)			
HP	0.47 (0.25, 0.91)				
Autoimmune ILD	0.72 (0.45, 1.16)	0.57 (0.34, 0.97)			
Other ILD	1.11 (0.58, 2.12)	0.88 (0.53, 1.48)			
Region					
Europe	0.91 (0.52, 1.57)				
Asia	0.65 (0.45, 0.94)	1.06 (0.66, 1.72)			
Canada and USA	0.76 (0.36, 1.60)				
Rest of the World	0.74 (0.39, 1.40)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: General disorders and administration site conditions

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-11.44 (-20.12, -2.51)	-4.08 (-10.69, 2.54)	-7.37 (-18.38, 3.65)
Age			
<65 years	-12.62 (-26.33, 1.71)	1.81 (-8.46, 12.08)	
>=65 years	-10.70 (-21.69, 0.71)	-7.47 (-16.06, 1.11)	
Sex			
Male	-14.27 (-26.13, -1.78)	-5.03 (-14.32, 4.26)	
Female	-8.43 (-20.82, 4.30)	-3.23 (-12.59, 6.12)	
Baseline FVC percent predicted			
<=70%	-5.53 (-18.34, 7.68)	-7.53 (-16.55, 1.48)	
>70%	-15.07 (-26.72, -3.07)	0.29 (-9.31, 9.88)	
Baseline HRCT pattern			
UIP-like	-12.62 (-22.66, -2.18)	-2.49 (-10.77, 5.80)	
Other fibrotic patterns	-9.00 (-25.13, 7.81)	-6.99 (-17.82, 3.84)	
Underlying ILD diagnosis			
iNSIP	0.91 (-17.83, 18.64)	2.03 (-11.16, 15.23)	
Unclassifiable IIP	-19.72 (-39.18, 1.89)	5.01 (-12.47, 22.49)	
HP	-29.74 (-48.71, -6.20)		
Autoimmune ILD	-10.87 (-25.72, 4.72)	-12.16 (-23.48, -0.84)	
Other ILD	3.89 (-19.38, 27.49)	-4.88 (-24.66, 14.90)	
Region			
Europe	-3.54 (-22.68, 15.36)		
Asia	-15.37 (-27.62, -2.43)	1.43 (-9.44, 12.29)	
Canada and USA	-11.37 (-36.25, 17.23)		
Rest of the World	-9.20 (-27.15, 9.81)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: General disorders and administration site conditions

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.61 (0.41, 0.90)	0.82 (0.60, 1.13)	0.74 (0.44, 1.22)
Age			
<65 years	0.58 (0.31, 1.08)	1.10 (0.65, 1.85)	
>=65 years	0.63 (0.38, 1.03)	0.71 (0.47, 1.06)	
Sex			
Male	0.53 (0.31, 0.93)	0.80 (0.52, 1.22)	
Female	0.69 (0.39, 1.21)	0.85 (0.53, 1.36)	
Baseline FVC percent predicted			
<=70%	0.80 (0.46, 1.38)	0.71 (0.47, 1.07)	
>70%	0.49 (0.28, 0.87)	1.02 (0.62, 1.67)	
Baseline HRCT pattern			
UIP-like	0.56 (0.35, 0.91)	0.89 (0.60, 1.32)	
Other fibrotic patterns	0.69 (0.34, 1.39)	0.72 (0.42, 1.22)	
Underlying ILD diagnosis			
iNSIP	1.04 (0.43, 2.53)	1.12 (0.51, 2.47)	
Unclassifiable IIP	0.42 (0.16, 1.10)	1.23 (0.59, 2.58)	
HP	0.28 (0.10, 0.78)		
Autoimmune ILD	0.61 (0.30, 1.24)	0.49 (0.25, 0.96)	
Other ILD	1.18 (0.41, 3.37)	0.81 (0.35, 1.89)	
Region			
Europe	0.86 (0.36, 2.02)		
Asia	0.51 (0.29, 0.90)	1.08 (0.58, 2.02)	
Canada and USA	0.62 (0.18, 2.12)		
Rest of the World	0.64 (0.26, 1.61)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Infections and infestations

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.91 (0.81, 1.03)	0.93 (0.84, 1.04)	0.98 (0.83, 1.15)	0.7637	
Age					
<65 years	0.85 (0.70, 1.04)	1.03 (0.86, 1.23)			
>=65 years	0.95 (0.82, 1.10)	0.87 (0.76, 1.01)			
Sex					
Male	0.86 (0.72, 1.01)	0.94 (0.81, 1.10)			
Female	0.97 (0.82, 1.16)	0.93 (0.79, 1.08)			
Baseline FVC percent predicted					
<=70%	0.81 (0.67, 0.97)	0.91 (0.80, 1.04)			
>70%	1.01 (0.86, 1.19)	0.97 (0.80, 1.17)			
Baseline HRCT pattern					
UIP-like	0.91 (0.79, 1.05)	0.94 (0.82, 1.08)			
Other fibrotic patterns	0.91 (0.74, 1.12)	0.92 (0.76, 1.11)			
Underlying ILD diagnosis					
iNSIP	0.83 (0.62, 1.10)	0.86 (0.64, 1.15)			
Unclassifiable IIP	0.87 (0.63, 1.18)	0.93 (0.70, 1.23)			
HP	0.93 (0.67, 1.28)				
Autoimmune ILD	1.08 (0.86, 1.35)	1.03 (0.84, 1.27)			
Other ILD	0.85 (0.69, 1.05)	0.95 (0.68, 1.32)			
Region					
Europe	0.96 (0.75, 1.22)				
Asia	0.87 (0.74, 1.03)	0.88 (0.71, 1.08)			
Canada and USA	0.92 (0.67, 1.25)				
Rest of the World	0.99 (0.70, 1.41)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Infections and infestations

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-6.60 (-14.97, 1.89)	-4.35 (-11.30, 2.60)	-2.25 (-13.18, 8.67)
Age			
<65 years	-11.06 (-24.27, 2.81)	1.79 (-9.37, 12.95)	
>=65 years	-3.68 (-14.32, 7.00)	-8.51 (-17.42, 0.40)	
Sex			
Male	-11.00 (-22.52, 0.87)	-3.92 (-13.54, 5.70)	
Female	-1.97 (-13.95, 10.12)	-4.96 (-15.00, 5.09)	
Baseline FVC percent predicted			
<=70%	-14.81 (-26.89, -2.40)	-6.39 (-15.28, 2.51)	
>70%	0.62 (-10.92, 12.40)	-1.86 (-12.71, 8.99)	
Baseline HRCT pattern			
UIP-like	-6.55 (-16.59, 3.64)	-3.93 (-12.55, 4.69)	
Other fibrotic patterns	-6.87 (-21.61, 8.36)	-5.11 (-16.82, 6.59)	
Underlying ILD diagnosis			
iNSIP	-12.50 (-29.93, 6.90)	-8.31 (-24.57, 7.95)	
Unclassifiable IIP	-9.72 (-29.26, 11.23)	-4.49 (-21.82, 12.83)	
HP	-5.13 (-26.48, 15.88)		
Autoimmune ILD	5.23 (-9.94, 20.05)	1.84 (-11.25, 14.93)	
Other ILD	-14.44 (-33.99, 2.37)	-3.19 (-23.14, 16.77)	
Region			
Europe	-3.30 (-20.42, 15.07)		
Asia	-10.07 (-21.71, 1.96)	-8.10 (-20.72, 4.52)	
Canada and USA	-6.86 (-32.36, 15.06)		
Rest of the World	-0.56 (-20.27, 19.13)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Infections and infestations

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.73 (0.48, 1.10)	0.83 (0.61, 1.12)	0.88 (0.53, 1.46)
Age			
<65 years	0.59 (0.31, 1.15)	1.08 (0.67, 1.75)	
>=65 years	0.83 (0.49, 1.42)	0.69 (0.47, 1.02)	
Sex			
Male	0.59 (0.33, 1.05)	0.85 (0.56, 1.28)	
Female	0.91 (0.51, 1.64)	0.81 (0.52, 1.25)	
Baseline FVC percent predicted			
<=70%	0.50 (0.27, 0.90)	0.74 (0.49, 1.13)	
>70%	1.03 (0.58, 1.84)	0.93 (0.60, 1.44)	
Baseline HRCT pattern			
UIP-like	0.73 (0.45, 1.19)	0.84 (0.58, 1.23)	
Other fibrotic patterns	0.70 (0.32, 1.54)	0.80 (0.49, 1.33)	
Underlying ILD diagnosis			
iNSIP	0.57 (0.24, 1.37)	0.71 (0.37, 1.39)	
Unclassifiable IIP	0.64 (0.24, 1.69)	0.83 (0.39, 1.73)	
HP	0.79 (0.28, 2.20)		
Autoimmune ILD	1.28 (0.62, 2.61)	1.08 (0.61, 1.91)	
Other ILD	0.24 (0.04, 1.33)	0.87 (0.38, 2.03)	
Region			
Europe	0.84 (0.33, 2.15)		
Asia	0.60 (0.33, 1.11)	0.71 (0.42, 1.22)	
Canada and USA	0.65 (0.15, 2.84)		
Rest of the World	0.98 (0.42, 2.27)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Injury, poisoning and procedural complications

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.91 (0.56, 1.48)	0.91 (0.65, 1.27)	1.00 (0.55, 1.81)	0.9950	
Age					
<65 years	1.21 (0.47, 3.11)	1.30 (0.68, 2.50)			
>=65 years	0.82 (0.47, 1.46)	0.81 (0.54, 1.20)			
Sex					
Male	0.60 (0.26, 1.37)	0.65 (0.40, 1.06)			
Female	1.15 (0.63, 2.12)	1.26 (0.78, 2.03)			
Baseline FVC percent predicted					
<=70%	1.84 (0.79, 4.33)	0.72 (0.46, 1.13)			
>70%	0.57 (0.31, 1.04)	1.25 (0.74, 2.10)			
Baseline HRCT pattern					
UIP-like	0.77 (0.44, 1.36)	0.86 (0.56, 1.34)			
Other fibrotic patterns	1.45 (0.55, 3.85)	0.98 (0.58, 1.65)			
Underlying ILD diagnosis					
iNSIP	1.45 (0.28, 7.56)	1.39 (0.43, 4.42)			
Unclassifiable IIP	0.60 (0.24, 1.52)	0.79 (0.36, 1.72)			
HP	0.43 (0.09, 2.00)				
Autoimmune ILD	1.39 (0.60, 3.26)	1.37 (0.73, 2.58)			
Other ILD	1.15 (0.34, 3.87)	0.74 (0.30, 1.83)			
Region					
Europe	0.75 (0.31, 1.84)				
Asia	1.24 (0.61, 2.52)	1.01 (0.51, 2.01)			
Canada and USA	0.11 (0.01, 1.89)				
Rest of the World	1.43 (0.34, 6.01)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Injury, poisoning and procedural complications

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-1.24 (-7.56, 5.08)	-1.50 (-6.68, 3.69)	0.25 (-7.92, 8.43)
Age			
<65 years	1.79 (-7.48, 10.94)	3.01 (-4.29, 10.30)	
>=65 years	-2.91 (-11.47, 5.76)	-3.80 (-10.84, 3.24)	
Sex			
Male	-4.86 (-12.85, 3.08)	-6.23 (-13.28, 0.82)	
Female	2.34 (-7.67, 12.25)	3.80 (-3.89, 11.48)	
Baseline FVC percent predicted			
<=70%	5.72 (-2.24, 14.46)	-5.17 (-12.15, 1.82)	
>70%	-9.06 (-19.00, 0.60)	3.25 (-4.49, 11.00)	
Baseline HRCT pattern			
UIP-like	-3.50 (-11.15, 4.18)	-2.10 (-8.37, 4.17)	
Other fibrotic patterns	4.26 (-7.22, 15.71)	-0.42 (-9.54, 8.70)	
Underlying ILD diagnosis			
iNSIP	2.27 (-10.05, 12.90)	2.45 (-6.17, 11.06)	
Unclassifiable IIP	-10.00 (-27.92, 8.02)	-4.13 (-17.87, 9.61)	
HP	-8.72 (-23.85, 8.05)		
Autoimmune ILD	4.45 (-7.12, 16.07)	4.97 (-4.82, 14.75)	
Other ILD	2.11 (-15.50, 22.33)	-5.08 (-20.18, 10.01)	
Region			
Europe	-4.91 (-21.34, 10.37)		
Asia	2.70 (-6.45, 11.84)	0.18 (-8.35, 8.70)	
Canada and USA	-23.33 (-40.93, -1.59)		
Rest of the World	2.78 (-9.56, 15.80)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Injury, poisoning and procedural complications

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.90 (0.51, 1.56)	0.89 (0.59, 1.33)	1.01 (0.51, 2.00)
Age			
<65 years	1.24 (0.44, 3.49)	1.35 (0.65, 2.82)	
>=65 years	0.80 (0.41, 1.55)	0.77 (0.47, 1.25)	
Sex			
Male	0.57 (0.23, 1.41)	0.60 (0.34, 1.07)	
Female	1.19 (0.57, 2.46)	1.32 (0.75, 2.35)	
Baseline FVC percent predicted			
<=70%	1.96 (0.77, 5.02)	0.67 (0.39, 1.15)	
>70%	0.51 (0.25, 1.05)	1.30 (0.70, 2.42)	
Baseline HRCT pattern			
UIP-like	0.74 (0.38, 1.42)	0.84 (0.50, 1.41)	
Other fibrotic patterns	1.53 (0.51, 4.57)	0.97 (0.51, 1.84)	
Underlying ILD diagnosis			
iNSIP	1.49 (0.26, 8.56)	1.42 (0.41, 4.99)	
Unclassifiable IIP	0.53 (0.17, 1.67)	0.75 (0.29, 1.93)	
HP	0.39 (0.07, 2.10)		
Autoimmune ILD	1.47 (0.55, 3.90)	1.46 (0.68, 3.14)	
Other ILD	1.18 (0.28, 4.92)	0.70 (0.24, 2.06)	
Region			
Europe	0.71 (0.24, 2.09)		
Asia	1.28 (0.57, 2.88)	1.02 (0.46, 2.26)	
Canada and USA	0.00 (NC, NC)		
Rest of the World	1.47 (0.31, 6.98)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Investigations

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.18 (0.86, 1.61)	1.85 (1.47, 2.32)	0.64 (0.43, 0.94)	0.0230	
Age					0.0892
<65 years	0.89 (0.50, 1.58)	2.29 (1.51, 3.47)	0.39 (0.19, 0.79)	0.0091	
>=65 years	1.35 (0.93, 1.96)	1.66 (1.26, 2.20)	0.81 (0.51, 1.30)	0.3850	
Sex					0.6803
Male	1.31 (0.86, 1.99)	1.91 (1.34, 2.71)	0.68 (0.40, 1.19)	0.1769	
Female	1.05 (0.66, 1.66)	1.80 (1.33, 2.45)	0.58 (0.33, 1.01)	0.0550	
Baseline FVC percent predicted					0.8388
<=70%	0.97 (0.63, 1.50)	1.61 (1.20, 2.16)	0.60 (0.36, 1.02)	0.0586	
>70%	1.48 (0.93, 2.36)	2.26 (1.55, 3.29)	0.65 (0.36, 1.19)	0.1644	
Baseline HRCT pattern					0.7504
UIP-like	1.39 (0.96, 1.99)	2.49 (1.82, 3.40)	0.56 (0.35, 0.90)	0.0169	
Other fibrotic patterns	0.74 (0.39, 1.40)	1.15 (0.81, 1.64)	0.64 (0.31, 1.33)	0.2328	
Underlying ILD diagnosis					0.0465
iNSIP	1.45 (0.69, 3.06)	2.74 (1.41, 5.33)	0.53 (0.20, 1.44)	0.2142	
Unclassifiable IIP	2.06 (0.96, 4.42)	1.26 (0.75, 2.12)	1.63 (0.65, 4.12)	0.3009	
HP	0.54 (0.21, 1.37)				
Autoimmune ILD	0.91 (0.53, 1.57)	2.72 (1.69, 4.37)	0.34 (0.16, 0.69)	0.0031	
Other ILD	1.65 (0.68, 3.95)	1.53 (0.82, 2.88)	1.07 (0.36, 3.16)	0.8981	
Region					
Europe	0.97 (0.40, 2.38)				
Asia	1.28 (0.87, 1.88)	2.37 (1.61, 3.49)	0.54 (0.31, 0.93)	0.0269	
Canada and USA	1.24 (0.58, 2.64)				
Rest of the World	1.25 (0.46, 3.42)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Investigations

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	4.31 (-3.91, 12.47)	18.60 (12.07, 25.14)	-14.29 (-24.77, -3.81)
Age			
<65 years	-2.44 (-14.80, 9.86)	22.92 (12.84, 32.99)	-25.35 (-41.28, -9.43)
>=65 years	8.91 (-1.95, 19.55)	16.15 (7.62, 24.69)	-7.24 (-20.97, 6.48)
Sex			
Male	7.39 (-4.24, 18.83)	17.35 (8.68, 26.03)	-9.96 (-24.39, 4.47)
Female	1.16 (-10.40, 12.63)	20.06 (10.29, 29.84)	-18.90 (-34.01, -3.80)
Baseline FVC percent predicted			
<=70%	-0.88 (-12.62, 11.21)	15.06 (6.24, 23.87)	-15.94 (-30.76, -1.12)
>70%	9.65 (-1.75, 20.45)	23.35 (13.68, 33.02)	-13.70 (-28.43, 1.02)
Baseline HRCT pattern			
UIP-like	9.05 (-0.91, 18.80)	26.35 (18.41, 34.28)	-17.30 (-29.95, -4.64)
Other fibrotic patterns	-6.87 (-21.12, 7.63)	4.58 (-6.65, 15.81)	-11.44 (-29.68, 6.80)
Underlying ILD diagnosis			
iNSIP	9.09 (-8.92, 25.23)	23.55 (9.94, 37.16)	-14.46 (-36.29, 7.38)
Unclassifiable IIP	20.56 (-0.16, 38.75)	7.62 (-9.15, 24.39)	12.94 (-12.75, 38.62)
HP	-14.10 (-32.32, 6.74)		
Autoimmune ILD	-2.45 (-16.83, 12.08)	30.01 (17.95, 42.07)	-32.46 (-51.29, -13.64)
Other ILD	12.56 (-8.93, 34.41)	12.56 (-5.62, 30.73)	-0.00 (-28.29, 28.28)
Region			
Europe	-0.52 (-16.93, 14.53)		
Asia	8.14 (-4.49, 20.40)	31.32 (19.44, 43.21)	-23.19 (-40.39, -5.98)
Canada and USA	7.84 (-18.67, 34.67)		
Rest of the World	3.24 (-11.80, 18.58)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Investigations

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.25 (0.82, 1.91)	2.44 (1.76, 3.37)	0.51 (0.30, 0.87)
Age			
<65 years	0.87 (0.42, 1.79)	3.18 (1.83, 5.52)	0.27 (0.11, 0.68)
>=65 years	1.54 (0.91, 2.60)	2.13 (1.42, 3.19)	0.72 (0.37, 1.40)
Sex			
Male	1.45 (0.81, 2.60)	2.43 (1.53, 3.86)	0.60 (0.28, 1.26)
Female	1.06 (0.57, 1.97)	2.47 (1.56, 3.90)	0.43 (0.20, 0.93)
Baseline FVC percent predicted			
<=70%	0.96 (0.52, 1.75)	2.02 (1.32, 3.08)	0.47 (0.23, 0.99)
>70%	1.68 (0.91, 3.11)	3.18 (1.91, 5.31)	0.53 (0.24, 1.17)
Baseline HRCT pattern			
UIP-like	1.57 (0.95, 2.59)	3.69 (2.41, 5.64)	0.43 (0.22, 0.82)
Other fibrotic patterns	0.68 (0.30, 1.54)	1.24 (0.73, 2.09)	0.55 (0.21, 1.45)
Underlying ILD diagnosis			
iNSIP	1.64 (0.62, 4.32)	3.82 (1.64, 8.91)	0.43 (0.12, 1.55)
Unclassifiable IIP	2.76 (0.98, 7.81)	1.41 (0.65, 3.04)	1.96 (0.54, 7.13)
HP	0.45 (0.14, 1.46)		
Autoimmune ILD	0.88 (0.42, 1.86)	4.33 (2.27, 8.27)	0.20 (0.08, 0.55)
Other ILD	1.95 (0.60, 6.33)	1.87 (0.74, 4.73)	1.04 (0.23, 4.65)
Region			
Europe	0.96 (0.33, 2.86)		
Asia	1.44 (0.81, 2.56)	3.99 (2.24, 7.10)	0.36 (0.16, 0.82)
Canada and USA	1.40 (0.41, 4.78)		
Rest of the World	1.30 (0.40, 4.22)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Metabolism and nutrition disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.77 (0.52, 1.14)	1.39 (1.05, 1.85)	0.55 (0.34, 0.90)	0.0172	
Age					0.4271
<65 years	0.61 (0.28, 1.33)	1.54 (0.89, 2.67)	0.39 (0.15, 1.02)	0.0553	
>=65 years	0.86 (0.54, 1.35)	1.39 (1.00, 1.94)	0.62 (0.35, 1.09)	0.0943	
Sex					0.7358
Male	0.86 (0.50, 1.49)	1.44 (0.97, 2.13)	0.60 (0.31, 1.18)	0.1389	
Female	0.68 (0.38, 1.21)	1.33 (0.87, 2.04)	0.51 (0.25, 1.04)	0.0635	
Baseline FVC percent predicted					0.9302
<=70%	0.61 (0.34, 1.10)	1.19 (0.83, 1.70)	0.52 (0.26, 1.02)	0.0583	
>70%	0.98 (0.55, 1.74)	1.81 (1.12, 2.92)	0.54 (0.26, 1.14)	0.1070	
Baseline HRCT pattern					0.6823
UIP-like	0.85 (0.55, 1.32)	1.50 (1.06, 2.11)	0.57 (0.32, 0.99)	0.0470	
Other fibrotic patterns	0.53 (0.21, 1.35)	1.20 (0.72, 1.98)	0.44 (0.15, 1.28)	0.1319	
Underlying ILD diagnosis					0.1803
iNSIP	0.40 (0.15, 1.11)	2.63 (1.04, 6.67)	0.15 (0.04, 0.61)	0.0076	
Unclassifiable IIP	0.77 (0.29, 2.08)	1.35 (0.75, 2.46)	0.57 (0.18, 1.81)	0.3410	
HP	0.65 (0.18, 2.39)				
Autoimmune ILD	0.79 (0.43, 1.46)	2.06 (1.13, 3.74)	0.38 (0.16, 0.91)	0.0288	
Other ILD	1.68 (0.64, 4.40)	1.50 (0.75, 3.01)	1.12 (0.34, 3.67)	0.8540	
Region					
Europe	0.57 (0.21, 1.50)				
Asia	0.72 (0.44, 1.17)	1.35 (0.89, 2.04)	0.53 (0.28, 1.02)	0.0560	
Canada and USA	0.71 (0.15, 3.25)				
Rest of the World	1.60 (0.49, 5.30)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Metabolism and nutrition disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-4.81 (-12.00, 2.43)	6.93 (1.06, 12.79)	-11.74 (-21.04, -2.44)
Age			
<65 years	-6.64 (-17.24, 3.76)	6.83 (-1.60, 15.26)	-13.47 (-26.94, -0.00)
>=65 years	-3.32 (-12.99, 6.49)	7.98 (0.06, 15.90)	-11.30 (-23.86, 1.25)
Sex			
Male	-2.71 (-12.77, 7.49)	7.81 (-0.29, 15.91)	-10.52 (-23.49, 2.45)
Female	-7.02 (-17.33, 3.35)	5.76 (-2.65, 14.18)	-12.78 (-26.11, 0.55)
Baseline FVC percent predicted			
<=70%	-9.15 (-19.32, 1.66)	3.98 (-4.07, 12.02)	-13.12 (-26.34, 0.09)
>70%	-0.37 (-10.46, 9.33)	10.79 (2.33, 19.24)	-11.16 (-24.17, 1.86)
Baseline HRCT pattern			
UIP-like	-3.32 (-12.23, 5.68)	8.96 (1.49, 16.42)	-12.28 (-23.93, -0.62)
Other fibrotic patterns	-8.10 (-20.14, 3.78)	3.35 (-6.02, 12.73)	-11.45 (-26.65, 3.75)
Underlying ILD diagnosis			
iNSIP	-13.41 (-29.27, 1.21)	12.68 (1.62, 23.73)	-26.09 (-44.91, -7.26)
Unclassifiable IIP	-4.44 (-21.93, 12.64)	8.31 (-7.54, 24.17)	-12.76 (-36.22, 10.70)
HP	-5.38 (-21.15, 12.23)		
Autoimmune ILD	-5.35 (-18.94, 8.51)	13.49 (2.84, 24.14)	-18.84 (-36.21, -1.46)
Other ILD	11.33 (-9.16, 32.80)	10.64 (-7.28, 28.55)	0.70 (-26.89, 28.28)
Region			
Europe	-8.68 (-24.62, 6.05)		
Asia	-7.73 (-18.92, 3.67)	8.55 (-3.08, 20.17)	-16.28 (-32.49, -0.07)
Canada and USA	-4.90 (-23.81, 19.52)		
Rest of the World	5.26 (-8.52, 19.57)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Metabolism and nutrition disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.72 (0.45, 1.18)	1.52 (1.06, 2.18)	0.48 (0.26, 0.87)
Age			
<65 years	0.56 (0.23, 1.38)	1.67 (0.87, 3.20)	0.34 (0.11, 1.02)
>=65 years	0.82 (0.46, 1.47)	1.54 (1.00, 2.38)	0.53 (0.26, 1.10)
Sex			
Male	0.84 (0.43, 1.64)	1.58 (0.97, 2.58)	0.53 (0.23, 1.21)
Female	0.62 (0.31, 1.25)	1.43 (0.84, 2.43)	0.43 (0.18, 1.05)
Baseline FVC percent predicted			
<=70%	0.55 (0.27, 1.11)	1.25 (0.79, 1.98)	0.44 (0.19, 1.02)
>70%	0.97 (0.49, 1.95)	2.06 (1.15, 3.69)	0.47 (0.19, 1.17)
Baseline HRCT pattern			
UIP-like	0.82 (0.47, 1.42)	1.68 (1.08, 2.61)	0.49 (0.24, 0.98)
Other fibrotic patterns	0.48 (0.17, 1.39)	1.25 (0.67, 2.32)	0.39 (0.11, 1.32)
Underlying ILD diagnosis			
iNSIP	0.34 (0.11, 1.12)	3.05 (1.07, 8.67)	0.11 (0.02, 0.55)
Unclassifiable IIP	0.73 (0.22, 2.42)	1.52 (0.67, 3.45)	0.48 (0.11, 2.05)
HP	0.61 (0.14, 2.67)		
Autoimmune ILD	0.74 (0.33, 1.63)	2.44 (1.17, 5.11)	0.30 (0.10, 0.89)
Other ILD	1.94 (0.56, 6.70)	1.74 (0.68, 4.46)	1.12 (0.24, 5.30)
Region			
Europe	0.51 (0.16, 1.61)		
Asia	0.65 (0.34, 1.23)	1.52 (0.85, 2.74)	0.43 (0.18, 1.01)
Canada and USA	0.67 (0.11, 3.88)		
Rest of the World	1.70 (0.45, 6.50)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Musculoskeletal and connective tissue disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.75, 1.36)	0.91 (0.73, 1.14)	1.11 (0.76, 1.62)	0.5824	
Age					
<65 years	0.98 (0.60, 1.60)	0.81 (0.57, 1.13)			
>=65 years	1.03 (0.70, 1.51)	0.97 (0.72, 1.31)			
Sex					
Male	0.90 (0.56, 1.44)	0.89 (0.66, 1.21)			
Female	1.09 (0.74, 1.62)	0.93 (0.67, 1.29)			
Baseline FVC percent predicted					
<=70%	1.40 (0.92, 2.13)	0.86 (0.65, 1.15)			
>70%	0.73 (0.47, 1.13)	0.98 (0.68, 1.40)			
Baseline HRCT pattern					
UIP-like	0.92 (0.64, 1.30)	1.09 (0.81, 1.46)			
Other fibrotic patterns	1.32 (0.72, 2.39)	0.70 (0.49, 0.99)			
Underlying ILD diagnosis					
iNSIP	0.65 (0.29, 1.46)	1.00 (0.49, 2.04)			
Unclassifiable IIP	0.99 (0.48, 2.05)	1.14 (0.63, 2.06)			
HP	1.04 (0.47, 2.31)				
Autoimmune ILD	1.17 (0.71, 1.92)	0.76 (0.51, 1.14)			
Other ILD	1.31 (0.66, 2.60)	0.90 (0.48, 1.67)			
Region					
Europe	1.38 (0.78, 2.45)				
Asia	0.74 (0.48, 1.13)	0.93 (0.59, 1.46)			
Canada and USA	1.76 (0.67, 4.62)				
Rest of the World	0.94 (0.37, 2.36)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Musculoskeletal and connective tissue disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.25 (-8.05, 8.55)	-2.81 (-9.31, 3.70)	3.06 (-7.49, 13.60)
Age			
<65 years	-0.44 (-13.73, 12.76)	-6.81 (-17.57, 3.96)	
>=65 years	0.69 (-9.87, 11.30)	-0.72 (-8.90, 7.47)	
Sex			
Male	-2.48 (-13.42, 8.62)	-3.31 (-12.20, 5.58)	
Female	2.84 (-9.51, 15.04)	-2.07 (-11.59, 7.45)	
Baseline FVC percent predicted			
<=70%	9.80 (-2.38, 21.89)	-4.56 (-13.42, 4.29)	
>70%	-8.19 (-19.62, 3.25)	-0.63 (-10.13, 8.87)	
Baseline HRCT pattern			
UIP-like	-2.47 (-12.37, 7.52)	2.29 (-5.64, 10.22)	
Other fibrotic patterns	6.91 (-8.06, 21.42)	-11.92 (-23.10, -0.74)	
Underlying ILD diagnosis			
iNSIP	-8.64 (-25.58, 7.44)	0.00 (-12.35, 12.36)	
Unclassifiable IIP	-0.28 (-20.09, 19.15)	3.48 (-12.40, 19.36)	
HP	1.03 (-18.83, 21.97)		
Autoimmune ILD	4.69 (-10.36, 19.48)	-8.53 (-21.03, 3.97)	
Other ILD	9.44 (-13.82, 32.43)	-3.18 (-21.57, 15.22)	
Region			
Europe	11.51 (-8.19, 29.44)		
Asia	-8.72 (-20.53, 3.41)	-1.68 (-12.59, 9.22)	
Canada and USA	15.29 (-9.66, 40.94)		
Rest of the World	-1.11 (-16.74, 14.90)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Musculoskeletal and connective tissue disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.67, 1.54)	0.87 (0.63, 1.20)	1.16 (0.69, 1.97)
Age			
<65 years	0.98 (0.50, 1.91)	0.73 (0.44, 1.20)	
>=65 years	1.04 (0.61, 1.76)	0.96 (0.63, 1.47)	
Sex			
Male	0.87 (0.47, 1.61)	0.85 (0.54, 1.32)	
Female	1.14 (0.64, 2.03)	0.90 (0.57, 1.44)	
Baseline FVC percent predicted			
<=70%	1.61 (0.89, 2.91)	0.81 (0.53, 1.22)	
>70%	0.66 (0.36, 1.19)	0.97 (0.59, 1.60)	
Baseline HRCT pattern			
UIP-like	0.89 (0.54, 1.45)	1.13 (0.75, 1.70)	
Other fibrotic patterns	1.44 (0.65, 3.20)	0.58 (0.34, 0.97)	
Underlying ILD diagnosis			
iNSIP	0.59 (0.21, 1.61)	1.00 (0.43, 2.35)	
Unclassifiable IIP	0.99 (0.36, 2.70)	1.19 (0.53, 2.69)	
HP	1.05 (0.36, 3.11)		
Autoimmune ILD	1.25 (0.61, 2.56)	0.66 (0.36, 1.21)	
Other ILD	1.52 (0.52, 4.41)	0.86 (0.35, 2.09)	
Region			
Europe	1.66 (0.69, 3.95)		
Asia	0.65 (0.36, 1.19)	0.91 (0.49, 1.69)	
Canada and USA	2.18 (0.57, 8.31)		
Rest of the World	0.92 (0.30, 2.81)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.21 (0.53, 2.74)	0.93 (0.49, 1.74)	1.31 (0.47, 3.67)	0.6115	
Age					
<65 years	0.94 (0.24, 3.65)	1.28 (0.39, 4.22)			
>=65 years	1.40 (0.50, 3.94)	0.84 (0.40, 1.77)			
Sex					
Male	0.65 (0.22, 1.94)	1.07 (0.51, 2.25)			
Female	3.40 (0.72, 16.01)	0.67 (0.21, 2.12)			
Baseline FVC percent predicted					
<=70%	1.64 (0.38, 7.15)	0.88 (0.36, 2.18)			
>70%	0.96 (0.36, 2.55)	0.97 (0.41, 2.29)			
Baseline HRCT pattern					
UIP-like	1.71 (0.64, 4.59)	1.05 (0.50, 2.20)			
Other fibrotic patterns	0.48 (0.09, 2.56)	0.68 (0.21, 2.24)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.95 (-3.32, 5.29)	-0.38 (-3.51, 2.76)	1.33 (-4.00, 6.65)
Age			
<65 years	-0.27 (-7.73, 6.92)	0.91 (-3.44, 5.27)	
>=65 years	1.74 (-3.88, 7.66)	-0.99 (-5.34, 3.36)	
Sex			
Male	-2.39 (-9.03, 4.15)	0.44 (-4.50, 5.39)	
Female	4.54 (-1.22, 10.93)	-1.28 (-5.02, 2.45)	
Baseline FVC percent predicted			
<=70%	1.62 (-3.69, 7.91)	-0.54 (-4.45, 3.36)	
>70%	-0.28 (-7.51, 6.43)	-0.15 (-5.38, 5.08)	
Baseline HRCT pattern			
UIP-like	2.70 (-2.46, 8.14)	0.29 (-3.85, 4.42)	
Other fibrotic patterns	-3.22 (-12.24, 5.06)	-1.55 (-6.34, 3.24)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.22 (0.52, 2.89)	0.92 (0.47, 1.80)	1.33 (0.45, 3.94)
Age			
<65 years	0.94 (0.23, 3.89)	1.29 (0.37, 4.47)	
>=65 years	1.43 (0.48, 4.24)	0.83 (0.38, 1.85)	
Sex			
Male	0.64 (0.20, 2.01)	1.07 (0.48, 2.39)	
Female	3.57 (0.72, 17.59)	0.66 (0.20, 2.20)	
Baseline FVC percent predicted			
<=70%	1.67 (0.36, 7.63)	0.88 (0.34, 2.26)	
>70%	0.96 (0.33, 2.73)	0.97 (0.39, 2.44)	
Baseline HRCT pattern			
UIP-like	1.76 (0.62, 4.96)	1.06 (0.48, 2.32)	
Other fibrotic patterns	0.47 (0.08, 2.65)	0.67 (0.20, 2.31)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Nervous system disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.22 (0.85, 1.75)	1.15 (0.87, 1.52)	1.06 (0.67, 1.67)	0.7990	
Age					
<65 years	0.82 (0.41, 1.61)	1.09 (0.66, 1.78)			
>=65 years	1.47 (0.96, 2.24)	1.21 (0.87, 1.69)			
Sex					
Male	1.23 (0.75, 2.01)	1.01 (0.67, 1.53)			
Female	1.22 (0.72, 2.05)	1.30 (0.89, 1.88)			
Baseline FVC percent predicted					
<=70%	1.29 (0.76, 2.20)	1.10 (0.77, 1.58)			
>70%	1.14 (0.70, 1.86)	1.21 (0.79, 1.86)			
Baseline HRCT pattern					
UIP-like	1.38 (0.90, 2.11)	1.03 (0.72, 1.47)			
Other fibrotic patterns	0.90 (0.46, 1.76)	1.37 (0.88, 2.12)			
Underlying ILD diagnosis					
iNSIP	1.94 (0.55, 6.86)	1.22 (0.55, 2.69)			
Unclassifiable IIP	0.68 (0.26, 1.76)	1.20 (0.67, 2.15)			
HP	1.11 (0.61, 2.04)				
Autoimmune ILD	1.66 (0.85, 3.26)	1.43 (0.80, 2.56)			
Other ILD	1.65 (0.68, 3.95)	1.11 (0.52, 2.34)			
Region					
Europe	1.23 (0.66, 2.31)				
Asia	1.24 (0.68, 2.26)	0.99 (0.51, 1.92)			
Canada and USA	1.47 (0.53, 4.11)				
Rest of the World	0.96 (0.43, 2.14)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Nervous system disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	4.27 (-3.40, 11.89)	3.02 (-2.88, 8.93)	1.24 (-8.42, 10.91)
Age			
<65 years	-3.30 (-14.61, 7.89)	1.48 (-7.33, 10.30)	
>=65 years	9.40 (-0.89, 19.52)	4.63 (-3.25, 12.52)	
Sex			
Male	4.50 (-6.29, 15.24)	0.20 (-7.52, 7.92)	
Female	4.07 (-6.86, 14.84)	6.37 (-2.63, 15.37)	
Baseline FVC percent predicted			
<=70%	5.12 (-5.60, 16.15)	2.18 (-5.75, 10.11)	
>70%	3.04 (-8.02, 13.69)	4.04 (-4.83, 12.92)	
Baseline HRCT pattern			
UIP-like	6.97 (-2.21, 16.06)	0.61 (-6.60, 7.82)	
Other fibrotic patterns	-2.18 (-16.13, 11.76)	7.39 (-2.80, 17.59)	
Underlying ILD diagnosis			
iNSIP	7.05 (-7.16, 19.66)	2.92 (-8.60, 14.43)	
Unclassifiable IIP	-7.22 (-24.96, 10.34)	4.95 (-11.03, 20.93)	
HP	4.10 (-17.88, 26.14)		
Autoimmune ILD	10.22 (-3.21, 23.33)	6.68 (-3.88, 17.24)	
Other ILD	12.56 (-8.93, 34.41)	2.31 (-14.59, 19.22)	
Region			
Europe	6.46 (-12.57, 24.08)		
Asia	3.60 (-6.58, 13.70)	-0.10 (-8.94, 8.75)	
Canada and USA	9.41 (-14.25, 35.35)		
Rest of the World	-0.81 (-17.60, 16.33)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Nervous system disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.29 (0.82, 2.03)	1.20 (0.84, 1.70)	1.08 (0.60, 1.92)
Age			
<65 years	0.79 (0.35, 1.77)	1.11 (0.60, 2.02)	
>=65 years	1.66 (0.95, 2.91)	1.29 (0.83, 2.00)	
Sex			
Male	1.30 (0.69, 2.44)	1.01 (0.61, 1.69)	
Female	1.28 (0.66, 2.48)	1.41 (0.86, 2.31)	
Baseline FVC percent predicted			
<=70%	1.37 (0.70, 2.68)	1.14 (0.71, 1.81)	
>70%	1.19 (0.64, 2.22)	1.28 (0.74, 2.19)	
Baseline HRCT pattern			
UIP-like	1.51 (0.88, 2.59)	1.04 (0.66, 1.62)	
Other fibrotic patterns	0.88 (0.38, 2.05)	1.51 (0.85, 2.69)	
Underlying ILD diagnosis			
iNSIP	2.10 (0.52, 8.47)	1.26 (0.50, 3.16)	
Unclassifiable IIP	0.62 (0.19, 1.99)	1.28 (0.57, 2.88)	
HP	1.19 (0.45, 3.17)		
Autoimmune ILD	1.89 (0.82, 4.36)	1.56 (0.76, 3.17)	
Other ILD	1.95 (0.60, 6.33)	1.14 (0.43, 3.00)	
Region			
Europe	1.36 (0.55, 3.33)		
Asia	1.29 (0.63, 2.66)	0.99 (0.47, 2.09)	
Canada and USA	1.67 (0.42, 6.59)		
Rest of the World	0.95 (0.35, 2.63)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Psychiatric disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.07 (0.76, 1.49)	0.94 (0.63, 1.40)	1.14 (0.68, 1.92)	0.6182	
Age					
<65 years	1.00 (0.55, 1.80)	1.13 (0.61, 2.11)			
>=65 years	1.11 (0.74, 1.67)	0.81 (0.48, 1.37)			
Sex					
Male	0.87 (0.55, 1.38)	1.10 (0.60, 1.99)			
Female	1.34 (0.82, 2.20)	0.83 (0.48, 1.41)			
Baseline FVC percent predicted					
<=70%	0.92 (0.58, 1.45)	0.92 (0.57, 1.48)			
>70%	1.32 (0.79, 2.21)	0.96 (0.46, 1.99)			
Baseline HRCT pattern					
UIP-like	1.03 (0.68, 1.54)	1.10 (0.68, 1.77)			
Other fibrotic patterns	1.16 (0.64, 2.10)	0.67 (0.32, 1.38)			
Underlying ILD diagnosis					
iNSIP	0.66 (0.31, 1.40)	1.44 (0.51, 4.07)			
Unclassifiable IIP	1.41 (0.61, 3.26)	1.52 (0.57, 4.01)			
HP	0.65 (0.28, 1.53)				
Autoimmune ILD	1.22 (0.67, 2.22)	0.72 (0.34, 1.55)			
Other ILD	2.16 (0.88, 5.30)	1.12 (0.37, 3.39)			
Region					
Europe	0.81 (0.43, 1.53)				
Asia	0.99 (0.60, 1.63)	0.99 (0.46, 2.13)			
Canada and USA	1.76 (0.75, 4.18)				
Rest of the World	1.38 (0.56, 3.37)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Psychiatric disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	1.57 (-6.35, 9.48)	-0.76 (-5.35, 3.83)	2.33 (-6.82, 11.48)
Age			
<65 years	-0.03 (-12.21, 12.00)	1.52 (-6.00, 9.03)	
>=65 years	2.81 (-7.56, 13.18)	-2.32 (-8.13, 3.49)	
Sex			
Male	-3.34 (-14.33, 7.83)	0.92 (-5.03, 6.86)	
Female	6.79 (-4.54, 17.87)	-2.53 (-9.63, 4.57)	
Baseline FVC percent predicted			
<=70%	-2.12 (-13.62, 9.81)	-1.18 (-7.86, 5.50)	
>70%	5.92 (-4.90, 16.27)	-0.35 (-6.35, 5.64)	
Baseline HRCT pattern			
UIP-like	0.59 (-8.73, 9.93)	1.13 (-4.76, 7.02)	
Other fibrotic patterns	3.84 (-11.09, 18.46)	-4.16 (-11.48, 3.16)	
Underlying ILD diagnosis			
iNSIP	-9.32 (-26.61, 7.34)	3.46 (-6.03, 12.95)	
Unclassifiable IIP	8.06 (-11.25, 26.20)	5.31 (-6.56, 17.18)	
HP	-10.77 (-29.61, 10.41)		
Autoimmune ILD	4.59 (-9.37, 18.38)	-3.61 (-12.28, 5.05)	
Other ILD	19.33 (-2.57, 40.71)	1.32 (-11.73, 14.36)	
Region			
Europe	-6.08 (-24.50, 12.01)		
Asia	-0.21 (-11.41, 10.97)	-0.06 (-7.84, 7.71)	
Canada and USA	17.84 (-8.47, 43.41)		
Rest of the World	5.71 (-10.40, 21.91)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Psychiatric disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.09 (0.70, 1.69)	0.93 (0.59, 1.46)	1.18 (0.62, 2.21)
Age			
<65 years	1.00 (0.47, 2.10)	1.15 (0.57, 2.35)	
>=65 years	1.16 (0.67, 2.00)	0.79 (0.44, 1.43)	
Sex			
Male	0.83 (0.45, 1.53)	1.11 (0.57, 2.16)	
Female	1.47 (0.77, 2.78)	0.80 (0.43, 1.50)	
Baseline FVC percent predicted			
<=70%	0.90 (0.48, 1.66)	0.91 (0.52, 1.58)	
>70%	1.43 (0.75, 2.72)	0.95 (0.43, 2.13)	
Baseline HRCT pattern			
UIP-like	1.03 (0.61, 1.75)	1.11 (0.64, 1.93)	
Other fibrotic patterns	1.23 (0.55, 2.71)	0.64 (0.29, 1.42)	
Underlying ILD diagnosis			
iNSIP	0.59 (0.22, 1.55)	1.50 (0.48, 4.67)	
Unclassifiable IIP	1.57 (0.53, 4.62)	1.61 (0.54, 4.86)	
HP	0.56 (0.18, 1.73)		
Autoimmune ILD	1.29 (0.59, 2.83)	0.69 (0.29, 1.66)	
Other ILD	2.81 (0.85, 9.32)	1.14 (0.32, 4.01)	
Region			
Europe	0.75 (0.30, 1.83)		
Asia	0.99 (0.52, 1.88)	0.99 (0.41, 2.38)	
Canada and USA	2.30 (0.64, 8.31)		
Rest of the World	1.47 (0.50, 4.38)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Renal and urinary disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.62 (0.30, 1.28)	1.54 (0.92, 2.58)	0.40 (0.16, 0.98)	0.0439	
Age					0.9985
<65 years	0.63 (0.11, 3.67)	1.58 (0.62, 4.00)	0.40 (0.05, 2.92)	0.3652	
>=65 years	0.63 (0.29, 1.39)	1.58 (0.85, 2.94)	0.40 (0.15, 1.09)	0.0731	
Sex					0.0357
Male	0.44 (0.16, 1.20)	2.68 (1.23, 5.83)	0.16 (0.05, 0.58)	0.0052	
Female	0.97 (0.32, 2.92)	0.83 (0.40, 1.75)	1.17 (0.31, 4.40)	0.8195	
Baseline FVC percent predicted					0.6809
<=70%	0.41 (0.14, 1.23)	1.24 (0.64, 2.41)	0.33 (0.09, 1.19)	0.0910	
>70%	0.98 (0.34, 2.82)	2.01 (0.90, 4.49)	0.49 (0.13, 1.84)	0.2884	
Baseline HRCT pattern					0.0532
UIP-like	0.41 (0.16, 1.03)	1.93 (0.98, 3.77)	0.21 (0.07, 0.67)	0.0079	
Other fibrotic patterns	1.62 (0.40, 6.49)	1.09 (0.49, 2.43)	1.49 (0.30, 7.40)	0.6286	
Underlying ILD diagnosis					0.1088
iNSIP	0.18 (0.04, 0.81)	7.80 (0.94, 64.95)	0.02 (0.00, 0.31)	0.0045	
Unclassifiable IIP	2.71 (0.11, 64.43)	6.41 (0.71, 57.69)	0.42 (0.01, 19.97)	0.6612	
HP	1.30 (0.19, 8.70)				
Autoimmune ILD	0.51 (0.13, 1.95)	1.00 (0.42, 2.41)	0.51 (0.10, 2.53)	0.4070	
Other ILD	2.16 (0.39, 12.00)	1.58 (0.50, 4.97)	1.37 (0.17, 10.75)	0.7664	
Region					
Europe	0.25 (0.05, 1.18)				
Asia	0.50 (0.19, 1.27)	1.59 (0.68, 3.69)	0.31 (0.09, 1.10)	0.0710	
Canada and USA	8.61 (0.44, 169.58)				
Rest of the World	3.20 (0.13, 76.60)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Renal and urinary disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-3.11 (-7.97, 1.63)	3.25 (-0.58, 7.07)	-6.35 (-12.49, -0.22)
Age			
<65 years	-1.34 (-8.03, 4.78)	2.77 (-2.80, 8.34)	-4.11 (-12.60, 4.38)
>=65 years	-3.97 (-10.99, 3.02)	3.90 (-1.29, 9.09)	-7.87 (-16.59, 0.84)
Sex			
Male	-5.84 (-13.17, 1.24)	7.32 (2.05, 12.58)	-13.16 (-22.09, -4.23)
Female	-0.16 (-6.97, 6.56)	-1.32 (-6.80, 4.16)	1.17 (-7.54, 9.87)
Baseline FVC percent predicted			
<=70%	-6.00 (-13.23, 1.40)	1.68 (-3.46, 6.83)	-7.69 (-16.63, 1.26)
>70%	-0.12 (-7.01, 6.23)	5.09 (-0.66, 10.84)	-5.22 (-13.98, 3.55)
Baseline HRCT pattern			
UIP-like	-5.60 (-11.56, 0.08)	4.69 (0.01, 9.37)	-10.29 (-17.75, -2.82)
Other fibrotic patterns	2.89 (-6.38, 12.37)	0.69 (-5.96, 7.35)	2.19 (-9.30, 13.69)
Underlying ILD diagnosis			
iNSIP	-16.36 (-31.35, -3.49)	9.09 (1.74, 16.44)	-25.45 (-41.21, -9.70)
Unclassifiable IIP	2.50 (-7.36, 12.88)	8.70 (0.82, 16.58)	-6.20 (-19.03, 6.62)
HP	1.54 (-11.17, 16.66)		
Autoimmune ILD	-4.16 (-13.39, 4.66)	0.00 (-7.49, 7.50)	-4.17 (-15.90, 7.56)
Other ILD	6.44 (-8.38, 24.84)	5.27 (-7.70, 18.24)	1.18 (-19.90, 22.25)
Region			
Europe	-11.23 (-25.56, 0.76)		
Asia	-5.71 (-13.73, 1.99)	4.18 (-3.29, 11.66)	-9.90 (-20.75, 0.95)
Canada and USA	11.76 (-2.40, 34.34)		
Rest of the World	2.33 (-5.62, 12.06)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Renal and urinary disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.60 (0.27, 1.29)	1.60 (0.91, 2.80)	0.37 (0.14, 0.97)
Age			
<65 years	0.62 (0.10, 3.81)	1.62 (0.60, 4.41)	0.38 (0.05, 3.03)
>=65 years	0.60 (0.26, 1.43)	1.66 (0.84, 3.26)	0.37 (0.12, 1.09)
Sex			
Male	0.41 (0.14, 1.20)	2.90 (1.27, 6.59)	0.14 (0.04, 0.55)
Female	0.97 (0.30, 3.11)	0.82 (0.36, 1.85)	1.18 (0.29, 4.89)
Baseline FVC percent predicted			
<=70%	0.38 (0.12, 1.23)	1.26 (0.62, 2.59)	0.30 (0.08, 1.20)
>70%	0.98 (0.32, 3.00)	2.14 (0.87, 5.25)	0.46 (0.11, 1.92)
Baseline HRCT pattern			
UIP-like	0.39 (0.15, 1.02)	2.04 (0.98, 4.24)	0.19 (0.06, 0.64)
Other fibrotic patterns	1.67 (0.38, 7.28)	1.10 (0.46, 2.63)	1.52 (0.27, 8.46)
Underlying ILD diagnosis			
iNSIP	0.15 (0.03, 0.76)	8.69 (0.95, 79.57)	0.02 (0.00, 0.27)
Unclassifiable IIP	NC (NC, NC)	7.16 (0.76, 67.32)	
HP	1.32 (0.18, 9.97)		
Autoimmune ILD	0.49 (0.12, 2.02)	1.00 (0.36, 2.75)	0.48 (0.08, 2.79)
Other ILD	2.32 (0.36, 15.01)	1.68 (0.46, 6.04)	1.38 (0.14, 13.34)
Region			
Europe	0.22 (0.04, 1.17)		
Asia	0.47 (0.17, 1.29)	1.66 (0.65, 4.23)	0.28 (0.07, 1.12)
Canada and USA	NC (NC, NC)		
Rest of the World	NC (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Reproductive system and breast disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	2.52 (0.80, 7.92)	0.26 (0.08, 0.83)	9.87 (1.92, 50.91)	0.0062	
Age					0.9086
<65 years	4.24 (0.94, 19.07)	0.89 (0.15, 5.26)	4.77 (0.47, 48.84)	0.1884	
>=65 years	0.53 (0.05, 5.74)	0.14 (0.02, 0.77)	3.83 (0.20, 72.50)	0.3713	
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like					
Other fibrotic patterns					
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Reproductive system and breast disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	2.74 (-0.68, 6.52)	-2.72 (-4.87, -0.57)	5.46 (1.27, 9.66)
Age			
<65 years	7.82 (0.20, 16.08)	-0.19 (-3.16, 2.77)	8.01 (-0.47, 16.49)
>=65 years	-0.68 (-4.39, 2.88)	-4.23 (-7.20, -1.26)	3.55 (-1.15, 8.25)
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Reproductive system and breast disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	2.60 (0.80, 8.40)	0.25 (0.08, 0.81)	10.44 (1.97, 55.27)
Age			
<65 years	4.61 (0.97, 22.03)	0.89 (0.15, 5.40)	5.19 (0.48, 56.55)
>=65 years	0.52 (0.05, 5.84)	0.13 (0.02, 0.73)	3.95 (0.21, 75.49)
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.81, 1.26)	0.82 (0.71, 0.95)	1.22 (0.94, 1.60)	0.1379	
Age					
<65 years	0.85 (0.57, 1.28)	0.76 (0.60, 0.97)			
>=65 years	1.11 (0.85, 1.44)	0.87 (0.73, 1.04)			
Sex					
Male	1.11 (0.82, 1.51)	0.97 (0.81, 1.16)			
Female	0.91 (0.66, 1.26)	0.66 (0.51, 0.84)			
Baseline FVC percent predicted					
<=70%	1.07 (0.81, 1.42)	0.74 (0.62, 0.88)			
>70%	1.00 (0.70, 1.42)	0.98 (0.76, 1.27)			
Baseline HRCT pattern					
UIP-like	1.08 (0.82, 1.42)	0.83 (0.69, 0.99)			
Other fibrotic patterns	0.88 (0.60, 1.28)	0.82 (0.64, 1.05)			
Underlying ILD diagnosis					
iNSIP	1.21 (0.67, 2.18)	0.68 (0.44, 1.04)			
Unclassifiable IIP	1.13 (0.61, 2.07)	0.85 (0.64, 1.12)			
HP	0.75 (0.49, 1.14)				
Autoimmune ILD	1.05 (0.68, 1.64)	0.63 (0.44, 0.91)			
Other ILD	1.35 (0.83, 2.19)	1.20 (0.83, 1.73)			
Region					
Europe	1.11 (0.74, 1.68)				
Asia	0.95 (0.68, 1.31)	0.69 (0.53, 0.91)			
Canada and USA	1.93 (1.10, 3.38)				
Rest of the World	0.57 (0.28, 1.13)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.37 (-8.73, 9.47)	-9.48 (-16.66, -2.30)	9.85 (-1.74, 21.45)
Age			
<65 years	-5.60 (-19.58, 8.62)	-12.69 (-24.15, -1.23)	
>=65 years	4.52 (-7.23, 16.12)	-7.06 (-16.26, 2.15)	
Sex			
Male	4.49 (-8.23, 17.03)	-1.75 (-11.62, 8.12)	
Female	-3.92 (-16.74, 9.07)	-18.20 (-28.46, -7.95)	
Baseline FVC percent predicted			
<=70%	3.20 (-10.07, 16.34)	-16.42 (-25.84, -7.00)	
>70%	-0.09 (-12.48, 12.13)	-0.73 (-11.54, 10.08)	
Baseline HRCT pattern			
UIP-like	2.93 (-7.83, 13.62)	-9.35 (-18.29, -0.42)	
Other fibrotic patterns	-6.01 (-22.40, 10.83)	-9.78 (-21.82, 2.27)	
Underlying ILD diagnosis			
iNSIP	6.36 (-12.84, 24.16)	-14.76 (-30.56, 1.03)	
Unclassifiable IIP	4.17 (-16.88, 24.45)	-10.45 (-27.81, 6.90)	
HP	-16.67 (-37.76, 6.35)		
Autoimmune ILD	1.93 (-13.63, 17.39)	-16.96 (-30.01, -3.90)	
Other ILD	15.56 (-9.47, 37.86)	9.77 (-10.28, 29.82)	
Region			
Europe	5.33 (-14.63, 24.71)		
Asia	-2.26 (-15.17, 10.75)	-17.54 (-30.28, -4.80)	
Canada and USA	33.92 (4.25, 55.81)		
Rest of the World	-16.03 (-33.32, 2.90)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.02 (0.70, 1.48)	0.68 (0.51, 0.91)	1.49 (0.92, 2.40)
Age			
<65 years	0.78 (0.42, 1.47)	0.60 (0.38, 0.96)	
>=65 years	1.20 (0.74, 1.94)	0.75 (0.52, 1.09)	
Sex			
Male	1.20 (0.71, 2.04)	0.93 (0.62, 1.39)	
Female	0.85 (0.49, 1.47)	0.47 (0.31, 0.73)	
Baseline FVC percent predicted			
<=70%	1.14 (0.66, 1.95)	0.51 (0.34, 0.76)	
>70%	1.00 (0.58, 1.72)	0.97 (0.62, 1.51)	
Baseline HRCT pattern			
UIP-like	1.13 (0.72, 1.78)	0.69 (0.48, 0.99)	
Other fibrotic patterns	0.78 (0.39, 1.57)	0.68 (0.42, 1.10)	
Underlying ILD diagnosis			
iNSIP	1.33 (0.56, 3.19)	0.54 (0.27, 1.06)	
Unclassifiable IIP	1.20 (0.47, 3.08)	0.64 (0.30, 1.36)	
HP	0.50 (0.19, 1.33)		
Autoimmune ILD	1.09 (0.55, 2.16)	0.48 (0.27, 0.85)	
Other ILD	1.88 (0.67, 5.28)	1.49 (0.65, 3.44)	
Region			
Europe	1.24 (0.54, 2.82)		
Asia	0.91 (0.53, 1.57)	0.48 (0.28, 0.83)	
Canada and USA	4.15 (1.15, 14.92)		
Rest of the World	0.45 (0.18, 1.16)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Skin and subcutaneous tissue disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.93 (0.56, 1.56)	1.27 (0.94, 1.71)	0.74 (0.41, 1.33)	0.3123	
Age					
<65 years	1.06 (0.43, 2.62)	1.69 (1.02, 2.80)			
>=65 years	0.89 (0.48, 1.65)	1.07 (0.73, 1.57)			
Sex					
Male	0.72 (0.32, 1.62)	1.26 (0.82, 1.96)			
Female	1.11 (0.57, 2.16)	1.28 (0.85, 1.93)			
Baseline FVC percent predicted					
<=70%	1.60 (0.73, 3.48)	1.66 (1.12, 2.47)			
>70%	0.59 (0.30, 1.18)	0.85 (0.53, 1.37)			
Baseline HRCT pattern					
UIP-like	1.03 (0.57, 1.86)	1.16 (0.80, 1.69)			
Other fibrotic patterns	0.73 (0.27, 1.98)	1.48 (0.89, 2.45)			
Underlying ILD diagnosis					
iNSIP	1.21 (0.31, 4.78)	1.98 (0.88, 4.43)			
Unclassifiable IIP	0.45 (0.12, 1.67)	1.45 (0.72, 2.94)			
HP	0.65 (0.18, 2.39)				
Autoimmune ILD	1.69 (0.65, 4.40)	1.22 (0.74, 2.01)			
Other ILD	0.96 (0.30, 3.06)	1.68 (0.48, 5.87)			
Region					
Europe	0.65 (0.24, 1.78)				
Asia	1.07 (0.51, 2.24)	1.03 (0.65, 1.63)			
Canada and USA	0.25 (0.03, 1.88)				
Rest of the World	5.35 (0.65, 43.96)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Skin and subcutaneous tissue disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.80 (-6.89, 5.30)	4.48 (-1.17, 10.14)	-5.28 (-13.59, 3.04)
Age			
<65 years	0.59 (-8.93, 9.92)	9.67 (0.77, 18.57)	
>=65 years	-1.55 (-9.63, 6.63)	1.31 (-5.98, 8.60)	
Sex			
Male	-3.10 (-11.08, 4.90)	4.04 (-3.47, 11.56)	
Female	1.47 (-7.99, 10.87)	5.09 (-3.41, 13.60)	
Baseline FVC percent predicted			
<=70%	5.07 (-3.36, 14.16)	10.07 (2.42, 17.72)	
>70%	-6.67 (-15.89, 2.08)	-2.80 (-11.11, 5.52)	
Baseline HRCT pattern			
UIP-like	0.31 (-7.06, 7.74)	2.85 (-4.21, 9.91)	
Other fibrotic patterns	-3.41 (-14.77, 7.72)	7.43 (-2.02, 16.88)	
Underlying ILD diagnosis			
iNSIP	1.59 (-11.80, 13.17)	10.38 (-1.28, 22.04)	
Unclassifiable IIP	-9.17 (-25.16, 6.01)	8.08 (-6.55, 22.71)	
HP	-5.38 (-21.15, 12.23)		
Autoimmune ILD	5.84 (-5.00, 16.86)	4.43 (-7.06, 15.91)	
Other ILD	-0.67 (-18.66, 19.96)	5.00 (-7.06, 17.07)	
Region			
Europe	-6.18 (-21.84, 8.08)		
Asia	0.83 (-8.08, 9.72)	0.70 (-10.09, 11.50)	
Canada and USA	-17.45 (-35.70, 6.60)		
Rest of the World	9.45 (-1.81, 22.43)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Skin and subcutaneous tissue disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.93 (0.52, 1.65)	1.34 (0.92, 1.95)	0.69 (0.35, 1.37)
Age			
<65 years	1.07 (0.39, 2.91)	1.91 (1.03, 3.53)	
>=65 years	0.87 (0.43, 1.78)	1.09 (0.68, 1.75)	
Sex			
Male	0.70 (0.29, 1.71)	1.33 (0.78, 2.26)	
Female	1.13 (0.52, 2.45)	1.36 (0.81, 2.30)	
Baseline FVC percent predicted			
<=70%	1.69 (0.71, 4.05)	1.89 (1.15, 3.10)	
>70%	0.55 (0.25, 1.21)	0.82 (0.46, 1.47)	
Baseline HRCT pattern			
UIP-like	1.03 (0.52, 2.03)	1.20 (0.76, 1.91)	
Other fibrotic patterns	0.70 (0.23, 2.14)	1.62 (0.87, 3.03)	
Underlying ILD diagnosis			
iNSIP	1.23 (0.28, 5.49)	2.26 (0.87, 5.84)	
Unclassifiable IIP	0.41 (0.09, 1.76)	1.61 (0.66, 3.93)	
HP	0.61 (0.14, 2.67)		
Autoimmune ILD	1.81 (0.62, 5.27)	1.29 (0.67, 2.48)	
Other ILD	0.95 (0.24, 3.80)	1.76 (0.44, 7.04)	
Region			
Europe	0.60 (0.19, 1.95)		
Asia	1.08 (0.47, 2.50)	1.04 (0.55, 1.96)	
Canada and USA	0.21 (0.02, 1.84)		
Rest of the World	5.92 (0.66, 52.91)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Vascular disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.88 (0.50, 1.55)	0.89 (0.60, 1.34)	0.98 (0.49, 1.98)	0.9628	
Age					
<65 years	0.63 (0.23, 1.69)	0.86 (0.45, 1.64)			
>=65 years	1.05 (0.52, 2.12)	0.91 (0.55, 1.53)			
Sex					
Male	0.52 (0.23, 1.17)	0.85 (0.46, 1.57)			
Female	1.67 (0.68, 4.07)	0.93 (0.55, 1.59)			
Baseline FVC percent predicted					
<=70%	0.43 (0.18, 1.06)	0.75 (0.46, 1.24)			
>70%	1.96 (0.78, 4.91)	1.19 (0.60, 2.35)			
Baseline HRCT pattern					
UIP-like	0.89 (0.44, 1.81)	1.06 (0.62, 1.82)			
Other fibrotic patterns	0.85 (0.33, 2.20)	0.71 (0.39, 1.31)			
Underlying ILD diagnosis					
iNSIP	0.36 (0.12, 1.12)	0.77 (0.29, 2.03)			
Unclassifiable IIP	3.60 (0.42, 30.74)	0.69 (0.26, 1.85)			
HP	0.52 (0.11, 2.50)				
Autoimmune ILD	1.78 (0.54, 5.80)	0.88 (0.39, 2.03)			
Other ILD	0.86 (0.23, 3.29)	0.73 (0.27, 1.96)			
Region					
Europe	0.88 (0.32, 2.42)				
Asia	0.69 (0.27, 1.75)	2.62 (0.88, 7.77)			
Canada and USA	0.88 (0.09, 9.03)				
Rest of the World	1.07 (0.33, 3.44)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Vascular disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-1.27 (-6.92, 4.37)	-1.30 (-5.88, 3.27)	0.03 (-7.23, 7.30)
Age			
<65 years	-4.03 (-13.28, 4.82)	-1.75 (-9.15, 5.66)	
>=65 years	0.53 (-6.88, 8.08)	-1.05 (-6.94, 4.84)	
Sex			
Male	-6.59 (-14.81, 1.59)	-1.55 (-7.41, 4.31)	
Female	4.41 (-3.48, 12.40)	-0.96 (-8.11, 6.18)	
Baseline FVC percent predicted			
<=70%	-8.16 (-16.33, 0.35)	-3.68 (-10.16, 2.79)	
>70%	5.52 (-2.15, 12.97)	1.69 (-4.67, 8.05)	
Baseline HRCT pattern			
UIP-like	-1.05 (-7.61, 5.52)	0.58 (-4.83, 6.00)	
Other fibrotic patterns	-1.89 (-13.49, 9.53)	-4.66 (-13.00, 3.68)	
Underlying ILD diagnosis			
iNSIP	-12.73 (-28.13, 1.06)	-2.75 (-12.76, 7.26)	
Unclassifiable IIP	7.22 (-5.67, 20.47)	-4.36 (-16.05, 7.33)	
HP	-6.15 (-20.85, 10.18)		
Autoimmune ILD	4.37 (-5.09, 14.21)	-1.24 (-9.27, 6.79)	
Other ILD	-1.89 (-18.61, 17.69)	-4.70 (-18.93, 9.53)	
Region			
Europe	-1.79 (-17.36, 12.29)		
Asia	-2.89 (-10.71, 4.74)	6.26 (-0.21, 12.73)	
Canada and USA	-0.78 (-16.22, 20.86)		
Rest of the World	0.76 (-13.06, 15.00)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Vascular disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.87 (0.46, 1.63)	0.88 (0.56, 1.39)	0.98 (0.45, 2.14)
Age			
<65 years	0.60 (0.20, 1.77)	0.84 (0.41, 1.74)	
>=65 years	1.06 (0.48, 2.32)	0.90 (0.51, 1.61)	
Sex			
Male	0.49 (0.20, 1.18)	0.84 (0.43, 1.64)	
Female	1.75 (0.66, 4.63)	0.92 (0.50, 1.71)	
Baseline FVC percent predicted			
<=70%	0.40 (0.15, 1.05)	0.72 (0.41, 1.28)	
>70%	2.08 (0.77, 5.62)	1.21 (0.58, 2.54)	
Baseline HRCT pattern			
UIP-like	0.88 (0.40, 1.91)	1.07 (0.59, 1.94)	
Other fibrotic patterns	0.83 (0.28, 2.44)	0.68 (0.33, 1.37)	
Underlying ILD diagnosis			
iNSIP	0.31 (0.09, 1.13)	0.74 (0.25, 2.19)	
Unclassifiable IIP	3.89 (0.41, 36.54)	0.66 (0.21, 2.01)	
HP	0.49 (0.09, 2.70)		
Autoimmune ILD	1.86 (0.52, 6.67)	0.87 (0.35, 2.16)	
Other ILD	0.85 (0.18, 3.91)	0.68 (0.21, 2.19)	
Region			
Europe	0.86 (0.27, 2.80)		
Asia	0.67 (0.25, 1.84)	2.80 (0.88, 8.91)	
Canada and USA	0.88 (0.07, 10.43)		
Rest of the World	1.08 (0.29, 4.02)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Cardiac disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.51 (0.70, 3.30)	1.01 (0.59, 1.72)	1.50 (0.58, 3.85)	0.4006	
Age					
<65 years	1.26 (0.29, 5.45)	0.80 (0.20, 3.09)			
>=65 years	1.65 (0.66, 4.14)	1.13 (0.64, 2.00)			
Sex					
Male	2.35 (0.75, 7.42)	0.88 (0.48, 1.61)			
Female	0.97 (0.32, 2.92)	1.46 (0.49, 4.32)			
Baseline FVC percent predicted					
<=70%	1.23 (0.45, 3.38)	0.75 (0.37, 1.49)			
>70%	2.24 (0.61, 8.22)	1.56 (0.67, 3.63)			
Baseline HRCT pattern					
UIP-like	2.46 (0.89, 6.82)	1.14 (0.61, 2.12)			
Other fibrotic patterns	0.58 (0.14, 2.33)	0.76 (0.28, 2.05)			
Underlying ILD diagnosis					
iNSIP	3.66 (0.18, 74.23)	6.80 (0.80, 57.64)			
Unclassifiable IIP	1.35 (0.24, 7.63)	0.98 (0.30, 3.23)			
HP	1.95 (0.35, 10.94)				
Autoimmune ILD	1.52 (0.45, 5.16)	1.92 (0.59, 6.22)			
Other ILD	0.72 (0.07, 7.52)	0.42 (0.10, 1.67)			
Region					
Europe	0.75 (0.23, 2.43)				
Asia	1.49 (0.43, 5.12)	1.33 (0.49, 3.63)			
Canada and USA	1.76 (0.12, 26.45)				
Rest of the World	7.48 (0.40, 140.67)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Cardiac disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	2.31 (-2.14, 6.92)	0.07 (-3.59, 3.73)	2.24 (-3.58, 8.06)
Age			
<65 years	0.93 (-6.12, 7.91)	-0.67 (-4.53, 3.19)	
>=65 years	3.30 (-2.87, 9.80)	1.23 (-4.25, 6.72)	
Sex			
Male	4.66 (-1.68, 11.57)	-1.25 (-7.23, 4.73)	
Female	-0.16 (-6.97, 6.56)	1.42 (-2.53, 5.38)	
Baseline FVC percent predicted			
<=70%	1.36 (-5.53, 8.99)	-2.16 (-7.16, 2.85)	
>70%	3.57 (-2.56, 9.64)	2.90 (-2.52, 8.32)	
Baseline HRCT pattern			
UIP-like	4.63 (-0.57, 10.26)	1.01 (-3.80, 5.82)	
Other fibrotic patterns	-3.27 (-12.95, 5.87)	-1.56 (-7.12, 4.00)	
Underlying ILD diagnosis			
iNSIP	3.64 (-5.51, 12.32)	7.75 (0.80, 14.71)	
Unclassifiable IIP	1.94 (-11.57, 14.95)	-0.18 (-10.06, 9.71)	
HP	4.87 (-8.58, 20.93)		
Autoimmune ILD	2.94 (-6.26, 12.47)	3.79 (-2.49, 10.07)	
Other ILD	-1.56 (-14.57, 14.50)	-7.82 (-19.48, 3.84)	
Region			
Europe	-3.07 (-17.69, 9.84)		
Asia	1.83 (-4.46, 8.34)	1.87 (-4.49, 8.23)	
Canada and USA	2.55 (-11.64, 23.83)		
Rest of the World	6.98 (-1.99, 18.61)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Cardiac disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.55 (0.68, 3.53)	1.01 (0.57, 1.79)	1.53 (0.56, 4.17)
Age			
<65 years	1.27 (0.28, 5.85)	0.79 (0.20, 3.12)	
>=65 years	1.71 (0.64, 4.56)	1.15 (0.62, 2.15)	
Sex			
Male	2.47 (0.74, 8.27)	0.87 (0.45, 1.69)	
Female	0.97 (0.30, 3.11)	1.48 (0.49, 4.50)	
Baseline FVC percent predicted			
<=70%	1.25 (0.42, 3.69)	0.73 (0.35, 1.53)	
>70%	2.32 (0.60, 8.99)	1.61 (0.65, 3.97)	
Baseline HRCT pattern			
UIP-like	2.59 (0.89, 7.52)	1.15 (0.59, 2.25)	
Other fibrotic patterns	0.56 (0.13, 2.46)	0.74 (0.26, 2.14)	
Underlying ILD diagnosis			
iNSIP	NC (NC, NC)	7.50 (0.80, 70.01)	
Unclassifiable IIP	1.38 (0.22, 8.76)	0.98 (0.26, 3.61)	
HP	2.06 (0.32, 13.16)		
Autoimmune ILD	1.57 (0.42, 5.82)	2.00 (0.59, 6.73)	
Other ILD	0.71 (0.06, 8.26)	0.38 (0.08, 1.73)	
Region			
Europe	0.73 (0.20, 2.71)		
Asia	1.51 (0.42, 5.53)	1.36 (0.47, 3.94)	
Canada and USA	1.81 (0.11, 30.97)		
Rest of the World	NC (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: General disorders and administration site conditions

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.43 (0.24, 0.77)	0.38 (0.13, 1.09)	1.15 (0.34, 3.86)	0.8222	
Age					
<65 years	0.44 (0.17, 1.09)				
>=65 years	0.43 (0.21, 0.90)				
Sex					
Male	0.35 (0.15, 0.79)	0.38 (0.12, 1.28)			
Female	0.56 (0.24, 1.27)	0.42 (0.06, 2.90)			
Baseline FVC percent predicted					
<=70%	0.48 (0.25, 0.92)	0.52 (0.17, 1.61)			
>70%	0.48 (0.14, 1.59)	0.22 (0.03, 1.80)			
Baseline HRCT pattern					
UIP-like	0.35 (0.18, 0.70)				
Other fibrotic patterns	0.81 (0.26, 2.52)				
Underlying ILD diagnosis					
iNSIP	0.91 (0.26, 3.17)				
Unclassifiable IIP	0.68 (0.16, 2.81)				
HP	0.14 (0.02, 1.08)				
Autoimmune ILD	0.10 (0.01, 0.77)				
Other ILD	0.90 (0.33, 2.43)				
Region					
Europe	0.75 (0.23, 2.43)				
Asia	0.45 (0.21, 0.93)				
Canada and USA	0.59 (0.07, 5.22)				
Rest of the World	0.07 (0.00, 1.21)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: General disorders and administration site conditions

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-8.95 (-14.93, -3.06)	-2.00 (-4.14, 0.15)	-6.95 (-13.26, -0.64)
Age			
<65 years	-8.84 (-18.85, 0.76)		
>=65 years	-9.01 (-16.68, -1.39)		
Sex			
Male	-11.80 (-20.41, -3.25)	-2.81 (-6.34, 0.72)	
Female	-5.87 (-14.40, 2.42)	-1.14 (-3.60, 1.33)	
Baseline FVC percent predicted			
<=70%	-12.27 (-22.04, -1.86)	-1.97 (-5.30, 1.37)	
>70%	-3.50 (-10.31, 2.38)	-2.07 (-4.90, 0.76)	
Baseline HRCT pattern			
UIP-like	-11.86 (-19.23, -4.57)		
Other fibrotic patterns	-1.80 (-12.32, 8.47)		
Underlying ILD diagnosis			
iNSIP	-0.91 (-14.94, 11.19)		
Unclassifiable IIP	-3.61 (-18.64, 10.45)		
HP	-19.74 (-35.25, -2.81)		
Autoimmune ILD	-12.66 (-22.66, -3.83)		
Other ILD	-2.22 (-21.61, 19.60)		
Region			
Europe	-3.07 (-17.69, 9.84)		
Asia	-10.46 (-19.81, -1.18)		
Canada and USA	-4.12 (-20.47, 17.97)		
Rest of the World	-15.22 (-28.22, -4.01)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: General disorders and administration site conditions

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.39 (0.21, 0.74)	0.37 (0.12, 1.10)	1.06 (0.30, 3.75)
Age			
<65 years	0.39 (0.14, 1.09)		
>=65 years	0.39 (0.17, 0.88)		
Sex			
Male	0.30 (0.12, 0.75)	0.37 (0.11, 1.30)	
Female	0.52 (0.21, 1.30)	0.42 (0.06, 2.87)	
Baseline FVC percent predicted			
<=70%	0.42 (0.19, 0.89)	0.51 (0.16, 1.62)	
>70%	0.46 (0.13, 1.62)	0.21 (0.02, 1.80)	
Baseline HRCT pattern			
UIP-like	0.31 (0.14, 0.66)		
Other fibrotic patterns	0.79 (0.23, 2.74)		
Underlying ILD diagnosis			
iNSIP	0.90 (0.23, 3.59)		
Unclassifiable IIP	0.65 (0.13, 3.12)		
HP	0.11 (0.01, 0.97)		
Autoimmune ILD	0.09 (0.01, 0.71)		
Other ILD	0.88 (0.25, 3.07)		
Region			
Europe	0.73 (0.20, 2.71)		
Asia	0.39 (0.17, 0.91)		
Canada and USA	0.56 (0.05, 5.88)		
Rest of the World	0.00 (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Infections and infestations

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.79 (0.54, 1.17)	1.08 (0.76, 1.53)	0.74 (0.44, 1.24)	0.2479	
Age					
<65 years	0.50 (0.23, 1.12)	0.92 (0.49, 1.75)			
>=65 years	0.95 (0.61, 1.49)	1.20 (0.80, 1.80)			
Sex					
Male	0.84 (0.51, 1.41)	1.28 (0.81, 2.00)			
Female	0.74 (0.41, 1.34)	0.83 (0.48, 1.43)			
Baseline FVC percent predicted					
<=70%	0.81 (0.50, 1.30)	1.09 (0.72, 1.63)			
>70%	0.89 (0.46, 1.72)	1.04 (0.56, 1.96)			
Baseline HRCT pattern					
UIP-like	0.90 (0.57, 1.42)	1.09 (0.72, 1.64)			
Other fibrotic patterns	0.58 (0.27, 1.23)	1.07 (0.57, 2.01)			
Underlying ILD diagnosis					
iNSIP	1.21 (0.48, 3.06)	0.72 (0.31, 1.68)			
Unclassifiable IIP	0.68 (0.26, 1.76)	3.72 (0.98, 14.16)			
HP	0.65 (0.18, 2.39)				
Autoimmune ILD	0.68 (0.33, 1.40)	1.12 (0.65, 1.95)			
Other ILD	0.96 (0.46, 2.00)	0.69 (0.21, 2.22)			
Region					
Europe	1.81 (0.69, 4.73)				
Asia	0.63 (0.38, 1.04)	1.20 (0.69, 2.09)			
Canada and USA	0.71 (0.15, 3.25)				
Rest of the World	0.61 (0.19, 1.94)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Infections and infestations

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-4.35 (-11.64, 2.99)	1.14 (-4.00, 6.28)	-5.49 (-14.43, 3.45)
Age			
<65 years	-8.98 (-19.57, 1.39)	-0.91 (-8.30, 6.49)	
>=65 years	-1.05 (-10.92, 8.92)	3.14 (-3.84, 10.13)	
Sex			
Male	-3.49 (-13.94, 7.11)	4.05 (-3.31, 11.40)	
Female	-5.13 (-15.29, 5.04)	-2.43 (-9.47, 4.60)	
Baseline FVC percent predicted			
<=70%	-5.24 (-16.43, 6.49)	1.52 (-5.92, 8.96)	
>70%	-1.52 (-10.87, 7.40)	0.45 (-6.17, 7.07)	
Baseline HRCT pattern			
UIP-like	-2.07 (-10.80, 6.72)	1.33 (-5.29, 7.95)	
Other fibrotic patterns	-9.80 (-23.08, 3.67)	0.84 (-7.20, 8.87)	
Underlying ILD diagnosis			
iNSIP	3.18 (-13.00, 17.69)	-4.55 (-15.49, 6.39)	
Unclassifiable IIP	-7.22 (-24.96, 10.34)	12.44 (1.90, 22.99)	
HP	-5.38 (-21.15, 12.23)		
Autoimmune ILD	-6.84 (-19.40, 5.93)	2.29 (-8.59, 13.17)	
Other ILD	-1.33 (-23.37, 22.24)	-4.02 (-16.44, 8.40)	
Region			
Europe	10.14 (-6.28, 24.82)		
Asia	-10.54 (-21.59, 0.79)	3.36 (-6.65, 13.37)	
Canada and USA	-4.90 (-23.81, 19.52)		
Rest of the World	-5.92 (-20.09, 8.57)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Infections and infestations

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.75 (0.47, 1.21)	1.09 (0.73, 1.64)	0.69 (0.37, 1.29)
Age			
<65 years	0.45 (0.18, 1.13)	0.91 (0.44, 1.90)	
>=65 years	0.94 (0.53, 1.67)	1.25 (0.76, 2.03)	
Sex			
Male	0.81 (0.42, 1.54)	1.34 (0.78, 2.31)	
Female	0.70 (0.34, 1.42)	0.80 (0.43, 1.51)	
Baseline FVC percent predicted			
<=70%	0.75 (0.40, 1.42)	1.11 (0.67, 1.82)	
>70%	0.88 (0.41, 1.88)	1.05 (0.51, 2.17)	
Baseline HRCT pattern			
UIP-like	0.88 (0.50, 1.54)	1.10 (0.68, 1.80)	
Other fibrotic patterns	0.52 (0.21, 1.28)	1.08 (0.52, 2.21)	
Underlying ILD diagnosis			
iNSIP	1.26 (0.42, 3.80)	0.69 (0.27, 1.76)	
Unclassifiable IIP	0.62 (0.19, 1.99)	4.26 (1.03, 17.69)	
HP	0.61 (0.14, 2.67)		
Autoimmune ILD	0.62 (0.26, 1.50)	1.16 (0.58, 2.31)	
Other ILD	0.94 (0.32, 2.80)	0.65 (0.17, 2.52)	
Region			
Europe	2.05 (0.66, 6.38)		
Asia	0.55 (0.29, 1.05)	1.25 (0.64, 2.47)	
Canada and USA	0.67 (0.11, 3.88)		
Rest of the World	0.57 (0.15, 2.11)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.26 (0.51, 3.14)	0.89 (0.41, 1.94)	1.41 (0.43, 4.68)	0.5721	
Age					
<65 years	0.94 (0.20, 4.54)	1.26 (0.24, 6.50)			
>=65 years	1.47 (0.48, 4.53)	0.85 (0.36, 2.04)			
Sex					
Male	0.75 (0.24, 2.28)	1.11 (0.45, 2.74)			
Female	4.86 (0.58, 40.93)	0.52 (0.12, 2.31)			
Baseline FVC percent predicted					
<=70%	0.82 (0.14, 4.81)	0.81 (0.23, 2.77)			
>70%	1.34 (0.45, 3.98)	0.96 (0.37, 2.53)			
Baseline HRCT pattern					
UIP-like	1.64 (0.55, 4.91)	1.07 (0.46, 2.49)			
Other fibrotic patterns	0.65 (0.11, 3.74)	0.41 (0.06, 2.85)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.94 (-2.99, 4.97)	-0.37 (-2.97, 2.23)	1.31 (-3.44, 6.06)
Age			
<65 years	-0.21 (-7.06, 6.38)	0.46 (-2.76, 3.68)	
>=65 years	1.71 (-3.59, 7.33)	-0.68 (-4.44, 3.09)	
Sex			
Male	-1.53 (-7.96, 4.87)	0.47 (-3.69, 4.62)	
Female	3.64 (-1.31, 9.40)	-1.29 (-4.31, 1.73)	
Baseline FVC percent predicted			
<=70%	-0.46 (-5.36, 5.00)	-0.51 (-3.45, 2.42)	
>70%	1.64 (-5.09, 8.02)	-0.17 (-4.87, 4.53)	
Baseline HRCT pattern			
UIP-like	2.03 (-2.73, 7.08)	0.29 (-3.38, 3.95)	
Other fibrotic patterns	-1.66 (-10.16, 6.32)	-1.53 (-4.76, 1.70)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.27 (0.49, 3.29)	0.89 (0.40, 2.00)	1.43 (0.41, 4.98)
Age			
<65 years	0.94 (0.18, 4.80)	1.26 (0.24, 6.78)	
>=65 years	1.50 (0.46, 4.85)	0.85 (0.34, 2.12)	
Sex			
Male	0.73 (0.23, 2.39)	1.11 (0.43, 2.88)	
Female	5.05 (0.58, 43.95)	0.51 (0.11, 2.40)	
Baseline FVC percent predicted			
<=70%	0.82 (0.13, 4.98)	0.80 (0.23, 2.84)	
>70%	1.37 (0.43, 4.31)	0.96 (0.34, 2.69)	
Baseline HRCT pattern			
UIP-like	1.68 (0.54, 5.24)	1.07 (0.44, 2.61)	
Other fibrotic patterns	0.64 (0.10, 3.93)	0.40 (0.06, 2.84)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Nervous system disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	2.22 (0.78, 6.28)				
Age					
<65 years	1.89 (0.17, 20.42)				
>=65 years	2.37 (0.75, 7.51)				
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%	11.04 (0.60, 202.56)				
>70%	1.17 (0.38, 3.59)				
Baseline HRCT pattern					
UIP-like	2.74 (0.74, 10.12)				
Other fibrotic patterns	1.45 (0.25, 8.42)				
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	3.80 (0.19, 76.95)				
Asia	3.96 (0.86, 18.23)				
Canada and USA	5.17 (0.22, 120.26)				
Rest of the World	0.15 (0.01, 2.87)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Nervous system disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	2.75 (-0.89, 6.69)		
Age			
<65 years	1.07 (-4.49, 6.79)		
>=65 years	3.94 (-1.40, 9.84)		
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%	4.17 (0.12, 10.23)		
>70%	0.84 (-5.78, 7.03)		
Baseline HRCT pattern			
UIP-like	3.30 (-1.06, 8.18)		
Other fibrotic patterns	1.42 (-6.72, 9.72)		
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	3.77 (-5.40, 12.75)		
Asia	5.59 (-0.38, 12.32)		
Canada and USA	5.88 (-6.46, 26.98)		
Rest of the World	-6.52 (-17.50, 2.73)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Nervous system disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	2.28 (0.78, 6.69)		
Age			
<65 years	1.91 (0.17, 21.43)		
>=65 years	2.47 (0.74, 8.22)		
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%	NC (NC, NC)		
>70%	1.18 (0.36, 3.85)		
Baseline HRCT pattern			
UIP-like	2.83 (0.74, 10.88)		
Other fibrotic patterns	1.48 (0.24, 9.14)		
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	NC (NC, NC)		
Asia	4.20 (0.87, 20.27)		
Canada and USA	NC (NC, NC)		
Rest of the World	0.00 (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.64 (0.40, 1.05)	0.67 (0.51, 0.87)	0.97 (0.55, 1.69)	0.9095	
Age					
<65 years	0.47 (0.19, 1.20)	0.59 (0.35, 0.99)			
>=65 years	0.75 (0.42, 1.32)	0.73 (0.54, 1.00)			
Sex					
Male	0.73 (0.39, 1.38)	0.84 (0.60, 1.16)			
Female	0.55 (0.25, 1.18)	0.45 (0.28, 0.72)			
Baseline FVC percent predicted					
<=70%	0.61 (0.34, 1.10)	0.61 (0.45, 0.84)			
>70%	0.94 (0.38, 2.36)	0.79 (0.49, 1.30)			
Baseline HRCT pattern					
UIP-like	0.82 (0.44, 1.52)	0.62 (0.45, 0.85)			
Other fibrotic patterns	0.42 (0.19, 0.96)	0.79 (0.48, 1.30)			
Underlying ILD diagnosis					
iNSIP	2.18 (0.46, 10.26)	0.54 (0.27, 1.09)			
Unclassifiable IIP	1.08 (0.36, 3.24)	0.70 (0.44, 1.10)			
HP	0.24 (0.06, 0.99)				
Autoimmune ILD	0.56 (0.20, 1.60)	0.49 (0.25, 0.95)			
Other ILD	0.64 (0.22, 1.85)	0.84 (0.41, 1.71)			
Region					
Europe	0.38 (0.14, 1.02)				
Asia	0.99 (0.52, 1.88)	0.50 (0.32, 0.78)			
Canada and USA	0.19 (0.01, 3.35)				
Rest of the World	0.36 (0.08, 1.67)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-5.76 (-12.15, 0.62)	-9.32 (-15.41, -3.23)	3.55 (-5.27, 12.38)
Age			
<65 years	-7.64 (-17.48, 1.78)	-8.83 (-17.55, -0.10)	
>=65 years	-4.39 (-12.93, 4.27)	-8.44 (-16.68, -0.20)	
Sex			
Male	-4.63 (-13.95, 4.81)	-4.86 (-13.68, 3.97)	
Female	-6.84 (-15.74, 1.88)	-14.40 (-22.54, -6.26)	
Baseline FVC percent predicted			
<=70%	-9.15 (-19.32, 1.66)	-13.78 (-22.37, -5.18)	
>70%	-0.43 (-8.00, 6.60)	-3.75 (-11.89, 4.39)	
Baseline HRCT pattern			
UIP-like	-2.27 (-9.49, 4.98)	-11.94 (-19.73, -4.15)	
Other fibrotic patterns	-14.39 (-27.37, -1.17)	-4.55 (-14.14, 5.04)	
Underlying ILD diagnosis			
iNSIP	5.91 (-6.98, 17.41)	-11.61 (-24.52, 1.31)	
Unclassifiable IIP	1.11 (-15.66, 17.20)	-13.79 (-31.11, 3.53)	
HP	-21.54 (-37.84, -2.81)		
Autoimmune ILD	-5.53 (-16.04, 4.80)	-11.08 (-21.06, -1.09)	
Other ILD	-9.00 (-27.72, 12.78)	-4.45 (-22.13, 13.23)	
Region			
Europe	-15.57 (-31.67, -0.27)		
Asia	-0.14 (-9.89, 9.59)	-18.48 (-29.92, -7.04)	
Canada and USA	-13.33 (-29.68, 6.77)		
Rest of the World	-8.39 (-21.46, 4.44)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.60 (0.34, 1.06)	0.59 (0.42, 0.83)	1.02 (0.53, 1.98)
Age			
<65 years	0.43 (0.15, 1.21)	0.53 (0.28, 0.99)	
>=65 years	0.71 (0.36, 1.39)	0.65 (0.43, 0.99)	
Sex			
Male	0.69 (0.33, 1.45)	0.78 (0.50, 1.22)	
Female	0.51 (0.21, 1.20)	0.38 (0.21, 0.67)	
Baseline FVC percent predicted			
<=70%	0.55 (0.27, 1.11)	0.50 (0.33, 0.78)	
>70%	0.94 (0.35, 2.53)	0.76 (0.42, 1.38)	
Baseline HRCT pattern			
UIP-like	0.80 (0.40, 1.61)	0.53 (0.34, 0.80)	
Other fibrotic patterns	0.36 (0.14, 0.94)	0.75 (0.40, 1.38)	
Underlying ILD diagnosis			
iNSIP	2.33 (0.44, 12.18)	0.47 (0.20, 1.10)	
Unclassifiable IIP	1.09 (0.30, 3.95)	0.56 (0.26, 1.17)	
HP	0.18 (0.04, 0.90)		
Autoimmune ILD	0.53 (0.17, 1.67)	0.43 (0.20, 0.93)	
Other ILD	0.57 (0.15, 2.11)	0.79 (0.31, 2.03)	
Region			
Europe	0.31 (0.10, 1.00)		
Asia	0.99 (0.47, 2.10)	0.38 (0.20, 0.69)	
Canada and USA	0.00 (NC, NC)		
Rest of the World	0.33 (0.06, 1.71)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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M.3.2.4 Adverse events on PT level over the whole trial

Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.55 (1.09, 2.22)	2.79 (2.30, 3.38)	0.56 (0.37, 0.84)	0.0046	
Age					0.0219
<65 years	0.94 (0.51, 1.76)	3.36 (2.35, 4.81)	0.28 (0.14, 0.58)	0.0005	
>=65 years	2.01 (1.29, 3.14)	2.58 (2.05, 3.23)	0.78 (0.47, 1.29)	0.3330	
Sex					0.4597
Male	1.38 (0.84, 2.25)	2.86 (2.20, 3.72)	0.48 (0.28, 0.84)	0.0099	
Female	1.77 (1.05, 3.01)	2.71 (2.05, 3.58)	0.65 (0.36, 1.19)	0.1650	
Baseline FVC percent predicted					0.3919
<=70%	1.37 (0.87, 2.16)	2.78 (2.15, 3.58)	0.49 (0.29, 0.83)	0.0080	
>70%	2.00 (1.11, 3.62)	2.80 (2.09, 3.76)	0.71 (0.37, 1.38)	0.3172	
Baseline HRCT pattern					0.4635
UIP-like	1.69 (1.11, 2.55)	2.76 (2.18, 3.49)	0.61 (0.38, 0.98)	0.0421	
Other fibrotic patterns	1.23 (0.61, 2.51)	2.85 (2.04, 3.98)	0.43 (0.20, 0.95)	0.0369	
Underlying ILD diagnosis					0.4572
iNSIP	1.58 (0.66, 3.79)	3.26 (1.99, 5.36)	0.48 (0.18, 1.32)	0.1571	
Unclassifiable IIP	1.98 (0.76, 5.15)	4.14 (2.29, 7.48)	0.48 (0.16, 1.47)	0.1994	
HP	1.63 (0.73, 3.61)				
Autoimmune ILD	1.08 (0.58, 2.02)	2.47 (1.72, 3.55)	0.44 (0.21, 0.90)	0.0248	
Other ILD	2.88 (1.12, 7.41)	2.37 (1.41, 3.96)	1.22 (0.42, 3.57)	0.7198	
Region					
Europe	2.42 (0.97, 6.04)				
Asia	1.09 (0.64, 1.84)	2.75 (1.92, 3.94)	0.39 (0.21, 0.75)	0.0043	
Canada and USA	1.76 (0.75, 4.18)				
Rest of the World	2.50 (1.05, 5.91)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	9.71 (1.92, 17.36)	44.04 (37.70, 50.38)	-34.33 (-44.32, -24.35)
Age			
<65 years	-1.10 (-12.92, 10.60)	46.69 (36.94, 56.45)	-47.79 (-63.07, -32.51)
>=65 years	16.79 (6.51, 26.71)	43.21 (34.94, 51.47)	-26.42 (-39.47, -13.37)
Sex			
Male	7.16 (-3.72, 17.92)	45.68 (37.13, 54.23)	-38.52 (-52.31, -24.73)
Female	12.40 (1.24, 23.17)	42.21 (32.86, 51.56)	-29.81 (-44.22, -15.40)
Baseline FVC percent predicted			
<=70%	8.17 (-3.54, 19.95)	44.29 (35.80, 52.79)	-36.12 (-50.61, -21.62)
>70%	12.50 (2.22, 22.21)	43.71 (34.19, 53.23)	-31.21 (-45.01, -17.41)
Baseline HRCT pattern			
UIP-like	12.15 (2.70, 21.38)	44.63 (36.81, 52.46)	-32.48 (-44.67, -20.30)
Other fibrotic patterns	4.02 (-9.68, 17.48)	43.03 (32.29, 53.77)	-39.01 (-56.32, -21.69)
Underlying ILD diagnosis			
iNSIP	8.64 (-8.21, 23.62)	46.29 (31.96, 60.63)	-37.66 (-59.08, -16.23)
Unclassifiable IIP	13.61 (-5.04, 30.82)	55.80 (41.11, 70.48)	-42.19 (-65.36, -19.01)
HP	12.82 (-7.78, 33.18)		
Autoimmune ILD	1.73 (-11.91, 15.34)	36.63 (24.61, 48.65)	-34.90 (-53.07, -16.73)
Other ILD	26.11 (3.89, 46.89)	37.28 (19.05, 55.50)	-11.17 (-39.35, 17.02)
Region			
Europe	17.69 (0.39, 32.78)		
Asia	1.68 (-9.22, 12.53)	41.18 (30.23, 52.12)	-39.50 (-54.92, -24.07)
Canada and USA	17.84 (-8.47, 43.41)		
Rest of the World	19.51 (2.05, 35.97)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.76 (1.12, 2.77)	6.98 (5.01, 9.74)	0.25 (0.14, 0.44)
Age			
<65 years	0.93 (0.43, 2.01)	8.51 (4.85, 14.93)	0.11 (0.04, 0.28)
>=65 years	2.52 (1.42, 4.48)	6.55 (4.31, 9.95)	0.39 (0.19, 0.78)
Sex			
Male	1.51 (0.81, 2.83)	7.99 (5.00, 12.77)	0.19 (0.09, 0.41)
Female	2.08 (1.07, 4.05)	6.16 (3.84, 9.88)	0.34 (0.15, 0.76)
Baseline FVC percent predicted			
<=70%	1.53 (0.83, 2.84)	7.03 (4.53, 10.91)	0.22 (0.10, 0.46)
>70%	2.33 (1.15, 4.74)	6.91 (4.16, 11.47)	0.34 (0.14, 0.81)
Baseline HRCT pattern			
UIP-like	1.98 (1.16, 3.38)	7.35 (4.83, 11.20)	0.27 (0.14, 0.53)
Other fibrotic patterns	1.30 (0.54, 3.12)	6.46 (3.74, 11.19)	0.20 (0.07, 0.56)
Underlying ILD diagnosis			
iNSIP	1.75 (0.60, 5.10)	7.83 (3.65, 16.81)	0.22 (0.06, 0.83)
Unclassifiable IIP	2.35 (0.73, 7.59)	13.00 (5.36, 31.56)	0.18 (0.04, 0.79)
HP	1.94 (0.65, 5.74)		
Autoimmune ILD	1.11 (0.50, 2.46)	5.33 (2.83, 10.03)	0.21 (0.08, 0.57)
Other ILD	4.13 (1.20, 14.25)	4.55 (1.88, 11.02)	0.91 (0.20, 4.16)
Region			
Europe	3.03 (1.00, 9.14)		
Asia	1.11 (0.57, 2.15)	6.80 (3.61, 12.78)	0.16 (0.07, 0.41)
Canada and USA	2.30 (0.64, 8.31)		
Rest of the World	3.22 (1.10, 9.38)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Gastrooesophageal reflux disease

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.91 (0.38, 2.19)	1.84 (0.85, 4.01)	0.49 (0.15, 1.60)	0.2384	
Age					
<65 years	0.38 (0.08, 1.89)	2.95 (0.90, 9.75)			
>=65 years	1.47 (0.48, 4.53)	1.08 (0.37, 3.16)			
Sex					
Male	1.05 (0.35, 3.14)	1.89 (0.61, 5.86)			
Female	0.73 (0.17, 3.18)	1.74 (0.62, 4.89)			
Baseline FVC percent predicted					
<=70%	0.61 (0.12, 3.28)	0.99 (0.36, 2.67)			
>70%	0.98 (0.34, 2.82)	4.35 (1.10, 17.25)			
Baseline HRCT pattern					
UIP-like	0.88 (0.30, 2.56)	1.73 (0.61, 4.90)			
Other fibrotic patterns	0.97 (0.20, 4.63)	1.89 (0.61, 5.82)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	2.28 (0.10, 54.49)				
Asia	0.62 (0.21, 1.83)	1.76 (0.38, 8.18)			
Canada and USA	1.76 (0.12, 26.45)				
Rest of the World	2.14 (0.20, 22.75)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Gastrooesophageal reflux disease

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.41 (-4.48, 3.64)	2.16 (-0.54, 4.86)	-2.57 (-7.45, 2.30)
Age			
<65 years	-3.75 (-11.25, 2.85)	4.90 (-0.00, 9.81)	
>=65 years	1.71 (-3.59, 7.33)	0.23 (-2.87, 3.33)	
Sex			
Male	0.23 (-6.12, 6.74)	2.02 (-1.52, 5.57)	
Female	-1.02 (-6.84, 4.51)	2.31 (-1.92, 6.55)	
Baseline FVC percent predicted			
<=70%	-1.31 (-6.53, 4.29)	-0.05 (-3.63, 3.52)	
>70%	-0.12 (-7.01, 6.23)	5.02 (0.77, 9.26)	
Baseline HRCT pattern			
UIP-like	-0.53 (-5.44, 4.36)	1.69 (-1.44, 4.82)	
Other fibrotic patterns	-0.14 (-8.88, 8.42)	3.00 (-2.18, 8.17)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	1.89 (-7.01, 9.94)		
Asia	-2.87 (-10.03, 3.99)	1.65 (-2.74, 6.03)	
Canada and USA	2.55 (-11.64, 23.83)		
Rest of the World	2.48 (-7.28, 13.43)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Gastrooesophageal reflux disease

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.90 (0.36, 2.27)	1.89 (0.84, 4.23)	0.48 (0.14, 1.63)
Age			
<65 years	0.36 (0.07, 1.92)	3.11 (0.89, 10.82)	
>=65 years	1.50 (0.46, 4.85)	1.08 (0.36, 3.28)	
Sex			
Male	1.05 (0.33, 3.35)	1.93 (0.60, 6.23)	
Female	0.72 (0.16, 3.30)	1.79 (0.61, 5.25)	
Baseline FVC percent predicted			
<=70%	0.61 (0.11, 3.38)	0.99 (0.35, 2.77)	
>70%	0.98 (0.32, 3.00)	4.57 (1.09, 19.12)	
Baseline HRCT pattern			
UIP-like	0.87 (0.29, 2.66)	1.77 (0.60, 5.17)	
Other fibrotic patterns	0.97 (0.19, 4.98)	1.95 (0.60, 6.36)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	NC (NC, NC)		
Asia	0.60 (0.19, 1.90)	1.79 (0.36, 8.85)	
Canada and USA	1.81 (0.11, 30.97)		
Rest of the World	2.20 (0.19, 25.12)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.91 (0.87, 4.18)	2.98 (2.09, 4.26)	0.64 (0.27, 1.52)	0.3099	
Age					
<65 years	1.26 (0.29, 5.45)	3.34 (1.81, 6.15)			
>=65 years	2.28 (0.89, 5.83)	2.78 (1.79, 4.32)			
Sex					
Male	4.18 (0.91, 19.26)	2.75 (1.56, 4.85)			
Female	1.25 (0.48, 3.24)	3.14 (1.99, 4.93)			
Baseline FVC percent predicted					
<=70%	2.05 (0.77, 5.43)	2.71 (1.75, 4.19)			
>70%	1.96 (0.52, 7.38)	3.50 (1.89, 6.48)			
Baseline HRCT pattern					
UIP-like	3.33 (1.11, 10.00)	3.52 (2.14, 5.81)			
Other fibrotic patterns	0.78 (0.22, 2.76)	2.38 (1.43, 3.93)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	3.67 (-0.82, 8.38)	18.54 (13.13, 23.95)	-14.87 (-21.96, -7.77)
Age			
<65 years	0.93 (-6.12, 7.91)	19.80 (11.37, 28.23)	
>=65 years	5.53 (-0.70, 12.22)	17.76 (10.71, 24.82)	
Sex			
Male	5.48 (-0.10, 11.98)	13.02 (6.30, 19.74)	
Female	1.65 (-5.82, 9.15)	24.83 (16.36, 33.30)	
Baseline FVC percent predicted			
<=70%	5.33 (-1.93, 13.51)	19.35 (11.76, 26.93)	
>70%	2.76 (-3.23, 8.63)	17.60 (10.00, 25.20)	
Baseline HRCT pattern			
UIP-like	5.91 (0.79, 11.59)	18.55 (12.16, 24.94)	
Other fibrotic patterns	-1.75 (-11.67, 7.84)	18.32 (8.48, 28.16)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.98 (0.86, 4.55)	3.80 (2.49, 5.80)	0.52 (0.21, 1.32)
Age			
<65 years	1.27 (0.28, 5.85)	4.32 (2.13, 8.77)	
>=65 years	2.42 (0.89, 6.57)	3.50 (2.07, 5.92)	
Sex			
Male	4.43 (0.92, 21.33)	3.22 (1.69, 6.12)	
Female	1.27 (0.46, 3.55)	4.45 (2.53, 7.81)	
Baseline FVC percent predicted			
<=70%	2.17 (0.76, 6.21)	3.47 (2.05, 5.86)	
>70%	2.01 (0.51, 7.99)	4.45 (2.19, 9.05)	
Baseline HRCT pattern			
UIP-like	3.55 (1.13, 11.14)	4.51 (2.54, 8.01)	
Other fibrotic patterns	0.76 (0.19, 2.97)	2.99 (1.60, 5.58)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.50 (0.31, 0.82)				
Age					
<65 years	0.55 (0.27, 1.14)				
>=65 years	0.46 (0.24, 0.90)				
Sex					
Male	0.44 (0.23, 0.85)				
Female	0.61 (0.29, 1.28)				
Baseline FVC percent predicted					
<=70%	0.61 (0.34, 1.10)				
>70%	0.42 (0.18, 1.00)				
Baseline HRCT pattern					
UIP-like	0.42 (0.23, 0.76)				
Other fibrotic patterns	0.78 (0.33, 1.84)				
Underlying ILD diagnosis					
iNSIP	0.45 (0.16, 1.29)				
Unclassifiable IIP	0.72 (0.21, 2.48)				
HP	0.26 (0.06, 1.10)				
Autoimmune ILD	0.34 (0.11, 1.00)				
Other ILD	1.23 (0.47, 3.24)				
Region					
Europe	0.66 (0.26, 1.67)				
Asia	0.45 (0.21, 0.93)				
Canada and USA	0.44 (0.05, 3.64)				
Rest of the World	0.43 (0.14, 1.26)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-9.37 (-15.89, -2.86)		
Age			
<65 years	-9.12 (-20.24, 1.93)		
>=65 years	-9.65 (-17.73, -1.54)		
Sex			
Male	-12.50 (-21.94, -2.88)		
Female	-5.92 (-14.94, 2.95)		
Baseline FVC percent predicted			
<=70%	-9.15 (-19.32, 1.66)		
>70%	-7.82 (-16.20, -0.16)		
Baseline HRCT pattern			
UIP-like	-11.81 (-19.56, -4.04)		
Other fibrotic patterns	-3.50 (-15.79, 8.66)		
Underlying ILD diagnosis			
iNSIP	-10.91 (-26.54, 3.24)		
Unclassifiable IIP	-3.89 (-19.85, 11.32)		
HP	-18.97 (-35.15, -0.61)		
Autoimmune ILD	-11.19 (-22.11, -0.52)		
Other ILD	4.56 (-15.42, 26.27)		
Region			
Europe	-6.79 (-22.98, 8.23)		
Asia	-10.46 (-19.81, -1.18)		
Canada and USA	-7.45 (-24.50, 15.12)		
Rest of the World	-12.44 (-27.37, 3.09)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.45 (0.26, 0.79)		
Age			
<65 years	0.50 (0.21, 1.16)		
>=65 years	0.41 (0.20, 0.88)		
Sex			
Male	0.38 (0.18, 0.81)		
Female	0.57 (0.25, 1.32)		
Baseline FVC percent predicted			
<=70%	0.55 (0.27, 1.11)		
>70%	0.38 (0.15, 0.99)		
Baseline HRCT pattern			
UIP-like	0.36 (0.18, 0.72)		
Other fibrotic patterns	0.74 (0.27, 2.03)		
Underlying ILD diagnosis			
iNSIP	0.40 (0.12, 1.33)		
Unclassifiable IIP	0.69 (0.17, 2.79)		
HP	0.21 (0.04, 1.03)		
Autoimmune ILD	0.30 (0.09, 0.97)		
Other ILD	1.31 (0.38, 4.50)		
Region			
Europe	0.61 (0.20, 1.85)		
Asia	0.39 (0.17, 0.91)		
Canada and USA	0.41 (0.04, 3.96)		
Rest of the World	0.37 (0.11, 1.28)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Fatigue

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.83 (0.35, 1.95)	1.73 (1.03, 2.89)	0.48 (0.18, 1.31)	0.1499	
Age					
<65 years	0.63 (0.11, 3.67)	2.85 (1.10, 7.35)			
>=65 years	0.92 (0.34, 2.47)	1.31 (0.70, 2.47)			
Sex					
Male	1.05 (0.27, 4.08)	3.27 (1.37, 7.82)			
Female	0.69 (0.23, 2.12)	1.05 (0.54, 2.05)			
Baseline FVC percent predicted					
<=70%	0.61 (0.16, 2.39)	1.62 (0.81, 3.21)			
>70%	1.01 (0.32, 3.20)	1.87 (0.88, 4.00)			
Baseline HRCT pattern					
UIP-like	0.88 (0.30, 2.56)	1.89 (0.97, 3.68)			
Other fibrotic patterns	0.73 (0.17, 3.12)	1.48 (0.67, 3.27)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Fatigue

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.86 (-5.03, 3.25)	4.23 (0.37, 8.09)	-5.09 (-10.76, 0.57)
Age			
<65 years	-1.34 (-8.03, 4.78)	7.40 (1.44, 13.35)	
>=65 years	-0.45 (-6.31, 5.49)	2.21 (-2.83, 7.25)	
Sex			
Male	0.16 (-5.38, 5.85)	7.54 (2.56, 12.52)	
Female	-2.02 (-8.93, 4.61)	0.47 (-5.51, 6.45)	
Baseline FVC percent predicted			
<=70%	-1.96 (-7.89, 4.33)	3.72 (-1.37, 8.81)	
>70%	0.03 (-6.47, 6.01)	5.08 (-0.90, 11.07)	
Baseline HRCT pattern			
UIP-like	-0.53 (-5.44, 4.36)	4.65 (-0.05, 9.34)	
Other fibrotic patterns	-1.70 (-10.95, 7.14)	3.43 (-3.39, 10.25)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Fatigue

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.82 (0.33, 2.02)	1.81 (1.04, 3.15)	0.45 (0.16, 1.30)
Age			
<65 years	0.62 (0.10, 3.81)	3.09 (1.13, 8.42)	
>=65 years	0.92 (0.32, 2.60)	1.35 (0.68, 2.66)	
Sex			
Male	1.05 (0.26, 4.29)	3.54 (1.42, 8.84)	
Female	0.68 (0.21, 2.21)	1.06 (0.51, 2.20)	
Baseline FVC percent predicted			
<=70%	0.60 (0.15, 2.47)	1.68 (0.81, 3.49)	
>70%	1.01 (0.30, 3.40)	1.99 (0.87, 4.57)	
Baseline HRCT pattern			
UIP-like	0.87 (0.29, 2.66)	1.99 (0.97, 4.06)	
Other fibrotic patterns	0.71 (0.15, 3.33)	1.54 (0.65, 3.64)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Pyrexia

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.67 (0.33, 1.36)	0.91 (0.50, 1.64)	0.74 (0.30, 1.87)	0.5279	
Age					
<65 years	0.43 (0.16, 1.18)	0.83 (0.30, 2.28)			
>=65 years	1.05 (0.38, 2.92)	0.99 (0.48, 2.02)			
Sex					
Male	0.65 (0.22, 1.94)	0.95 (0.46, 1.93)			
Female	0.68 (0.27, 1.72)	0.79 (0.27, 2.30)			
Baseline FVC percent predicted					
<=70%	0.89 (0.37, 2.13)	0.99 (0.46, 2.11)			
>70%	0.48 (0.14, 1.59)	0.78 (0.31, 1.95)			
Baseline HRCT pattern					
UIP-like	0.82 (0.33, 2.02)	0.92 (0.46, 1.83)			
Other fibrotic patterns	0.48 (0.15, 1.53)	0.87 (0.28, 2.69)			
Underlying ILD diagnosis					
iNSIP	5.13 (0.27, 96.53)	1.62 (0.22, 12.11)			
Unclassifiable IIP	0.90 (0.13, 6.06)	0.94 (0.32, 2.77)			
HP	0.26 (0.01, 5.18)				
Autoimmune ILD	0.41 (0.13, 1.23)	0.24 (0.06, 0.99)			
Other ILD	1.08 (0.26, 4.41)	1.29 (0.38, 4.37)			
Region					
Europe	2.26 (0.24, 20.96)				
Asia	0.50 (0.21, 1.18)	0.80 (0.36, 1.81)			
Canada and USA	0.57 (0.02, 13.36)				
Rest of the World	1.07 (0.16, 7.26)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Pyrexia

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-2.65 (-7.57, 2.17)	-0.56 (-3.89, 2.77)	-2.09 (-7.99, 3.80)
Age			
<65 years	-7.57 (-17.08, 1.40)	-0.96 (-5.98, 4.07)	
>=65 years	0.27 (-5.42, 6.10)	-0.09 (-4.56, 4.38)	
Sex			
Male	-2.39 (-9.03, 4.15)	-0.39 (-5.56, 4.77)	
Female	-3.01 (-10.80, 4.53)	-0.87 (-4.87, 3.14)	
Baseline FVC percent predicted			
<=70%	-0.99 (-8.73, 7.32)	-0.09 (-4.65, 4.47)	
>70%	-3.50 (-10.31, 2.38)	-1.33 (-6.25, 3.58)	
Baseline HRCT pattern			
UIP-like	-1.13 (-6.68, 4.38)	-0.55 (-4.97, 3.87)	
Other fibrotic patterns	-6.44 (-17.35, 3.99)	-0.61 (-5.52, 4.29)	
Underlying ILD diagnosis			
iNSIP	5.45 (-4.01, 14.85)	1.29 (-4.01, 6.58)	
Unclassifiable IIP	-0.56 (-13.65, 11.63)	-0.59 (-11.35, 10.18)	
HP	-5.13 (-16.89, 6.81)		
Autoimmune ILD	-8.37 (-18.90, 1.84)	-6.49 (-12.66, -0.33)	
Other ILD	0.89 (-15.33, 20.06)	2.67 (-9.29, 14.63)	
Region			
Europe	3.16 (-7.87, 13.09)		
Asia	-6.67 (-15.10, 1.53)	-2.04 (-9.63, 5.56)	
Canada and USA	-3.33 (-16.67, 15.30)		
Rest of the World	0.30 (-10.42, 11.56)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Pyrexia

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.65 (0.31, 1.39)	0.90 (0.48, 1.69)	0.73 (0.27, 1.94)
Age			
<65 years	0.39 (0.13, 1.19)	0.82 (0.28, 2.36)	
>=65 years	1.06 (0.36, 3.10)	0.98 (0.46, 2.13)	
Sex			
Male	0.64 (0.20, 2.01)	0.94 (0.44, 2.03)	
Female	0.66 (0.24, 1.80)	0.78 (0.26, 2.39)	
Baseline FVC percent predicted			
<=70%	0.88 (0.34, 2.29)	0.98 (0.44, 2.21)	
>70%	0.46 (0.13, 1.62)	0.77 (0.29, 2.04)	
Baseline HRCT pattern			
UIP-like	0.81 (0.31, 2.11)	0.91 (0.44, 1.91)	
Other fibrotic patterns	0.45 (0.13, 1.58)	0.87 (0.27, 2.77)	
Underlying ILD diagnosis			
iNSIP	NC (NC, NC)	1.64 (0.20, 13.19)	
Unclassifiable IIP	0.89 (0.12, 6.70)	0.94 (0.28, 3.11)	
HP	0.00 (NC, NC)		
Autoimmune ILD	0.37 (0.11, 1.24)	0.22 (0.05, 0.95)	
Other ILD	1.09 (0.22, 5.36)	1.33 (0.35, 5.02)	
Region			
Europe	2.34 (0.23, 23.38)		
Asia	0.46 (0.18, 1.19)	0.79 (0.32, 1.92)	
Canada and USA	0.00 (NC, NC)		
Rest of the World	1.07 (0.14, 7.97)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Bronchitis

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.54, 1.89)	0.75 (0.53, 1.05)	1.35 (0.66, 2.75)	0.4135	
Age					
<65 years	1.51 (0.51, 4.43)	1.25 (0.73, 2.16)			
>=65 years	0.81 (0.37, 1.78)	0.53 (0.33, 0.84)			
Sex					
Male	1.05 (0.43, 2.54)	0.80 (0.49, 1.29)			
Female	0.97 (0.40, 2.35)	0.71 (0.44, 1.14)			
Baseline FVC percent predicted					
<=70%	1.23 (0.45, 3.38)	0.93 (0.62, 1.41)			
>70%	0.84 (0.38, 1.86)	0.50 (0.27, 0.91)			
Baseline HRCT pattern					
UIP-like	1.37 (0.59, 3.15)	0.72 (0.48, 1.10)			
Other fibrotic patterns	0.65 (0.24, 1.71)	0.81 (0.45, 1.45)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	0.69 (0.32, 1.45)				
Asia	0.40 (0.08, 2.00)	1.19 (0.51, 2.81)			
Canada and USA	7.06 (0.86, 58.16)				
Rest of the World	2.14 (0.20, 22.75)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Bronchitis

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.07 (-5.17, 5.34)	-4.39 (-9.54, 0.76)	4.46 (-2.89, 11.82)
Age			
<65 years	3.07 (-5.48, 11.62)	3.45 (-4.81, 11.72)	
>=65 years	-1.78 (-8.67, 5.17)	-9.42 (-15.90, -2.94)	
Sex			
Male	0.35 (-7.03, 7.87)	-3.25 (-10.23, 3.73)	
Female	-0.23 (-8.10, 7.54)	-5.62 (-13.25, 2.02)	
Baseline FVC percent predicted			
<=70%	1.36 (-5.53, 8.99)	-1.23 (-8.50, 6.04)	
>70%	-1.71 (-10.02, 6.09)	-8.51 (-15.62, -1.40)	
Baseline HRCT pattern			
UIP-like	2.10 (-3.70, 8.06)	-5.06 (-11.52, 1.41)	
Other fibrotic patterns	-4.97 (-16.59, 6.41)	-3.15 (-11.68, 5.39)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	-8.63 (-26.06, 8.27)		
Asia	-2.85 (-8.86, 2.56)	1.44 (-5.56, 8.45)	
Canada and USA	20.20 (0.88, 44.09)		
Rest of the World	2.48 (-7.28, 13.43)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Bronchitis

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.51, 2.00)	0.71 (0.47, 1.06)	1.43 (0.65, 3.16)
Age			
<65 years	1.56 (0.49, 4.98)	1.31 (0.68, 2.51)	
>=65 years	0.79 (0.34, 1.88)	0.47 (0.27, 0.80)	
Sex			
Male	1.05 (0.40, 2.75)	0.77 (0.44, 1.36)	
Female	0.97 (0.37, 2.55)	0.65 (0.37, 1.17)	
Baseline FVC percent predicted			
<=70%	1.25 (0.42, 3.69)	0.92 (0.55, 1.53)	
>70%	0.82 (0.34, 1.98)	0.44 (0.22, 0.89)	
Baseline HRCT pattern			
UIP-like	1.40 (0.57, 3.42)	0.68 (0.41, 1.12)	
Other fibrotic patterns	0.61 (0.20, 1.83)	0.78 (0.39, 1.54)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	0.61 (0.23, 1.63)		
Asia	0.38 (0.07, 2.03)	1.22 (0.47, 3.19)	
Canada and USA	8.92 (0.91, 87.84)		
Rest of the World	2.20 (0.19, 25.12)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: COVID-19

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.98 (0.62, 1.54)				
Age					
<65 years	0.63 (0.30, 1.32)				
>=65 years	1.30 (0.72, 2.35)				
Sex					
Male	0.80 (0.41, 1.57)				
Female	1.17 (0.62, 2.19)				
Baseline FVC percent predicted					
<=70%	0.56 (0.28, 1.12)				
>70%	1.76 (0.87, 3.57)				
Baseline HRCT pattern					
UIP-like	1.08 (0.60, 1.94)				
Other fibrotic patterns	0.82 (0.40, 1.70)				
Underlying ILD diagnosis					
iNSIP	0.62 (0.23, 1.71)				
Unclassifiable IIP	1.26 (0.44, 3.62)				
HP	0.93 (0.33, 2.64)				
Autoimmune ILD	1.16 (0.44, 3.02)				
Other ILD	1.20 (0.41, 3.50)				
Region					
Europe	0.75 (0.29, 1.98)				
Asia	0.83 (0.44, 1.55)				
Canada and USA	1.18 (0.39, 3.59)				
Rest of the World	5.35 (0.65, 43.96)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: COVID-19

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.32 (-6.89, 6.26)		
Age			
<65 years	-6.71 (-17.59, 4.03)		
>=65 years	3.68 (-4.67, 12.14)		
Sex			
Male	-2.94 (-11.87, 6.08)		
Female	2.36 (-7.43, 12.08)		
Baseline FVC percent predicted			
<=70%	-8.23 (-17.46, 1.54)		
>70%	7.32 (-1.78, 16.03)		
Baseline HRCT pattern			
UIP-like	0.96 (-6.48, 8.46)		
Other fibrotic patterns	-3.65 (-17.08, 9.79)		
Underlying ILD diagnosis			
iNSIP	-6.59 (-22.17, 7.40)		
Unclassifiable IIP	3.61 (-13.56, 20.04)		
HP	-1.28 (-18.71, 17.85)		
Autoimmune ILD	1.57 (-9.09, 12.34)		
Other ILD	3.33 (-15.53, 24.39)		
Region			
Europe	-4.29 (-20.20, 10.27)		
Asia	-2.96 (-12.80, 6.88)		
Canada and USA	3.53 (-18.71, 29.48)		
Rest of the World	9.45 (-1.81, 22.43)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: COVID-19

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.97 (0.57, 1.66)		
Age			
<65 years	0.58 (0.25, 1.38)		
>=65 years	1.36 (0.68, 2.70)		
Sex			
Male	0.77 (0.36, 1.68)		
Female	1.20 (0.57, 2.53)		
Baseline FVC percent predicted			
<=70%	0.51 (0.23, 1.13)		
>70%	1.92 (0.86, 4.28)		
Baseline HRCT pattern			
UIP-like	1.09 (0.56, 2.14)		
Other fibrotic patterns	0.78 (0.32, 1.91)		
Underlying ILD diagnosis			
iNSIP	0.58 (0.18, 1.87)		
Unclassifiable IIP	1.32 (0.38, 4.58)		
HP	0.91 (0.26, 3.23)		
Autoimmune ILD	1.18 (0.40, 3.45)		
Other ILD	1.25 (0.34, 4.65)		
Region			
Europe	0.72 (0.23, 2.24)		
Asia	0.80 (0.38, 1.68)		
Canada and USA	1.23 (0.29, 5.16)		
Rest of the World	5.92 (0.66, 52.91)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Influenza

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.49, 2.07)	0.82 (0.37, 1.81)	1.23 (0.42, 3.56)	0.7076	
Age					
<65 years	0.42 (0.13, 1.31)	0.83 (0.26, 2.68)			
>=65 years	2.11 (0.74, 6.00)	0.79 (0.28, 2.22)			
Sex					
Male	1.57 (0.45, 5.41)	1.46 (0.50, 4.32)			
Female	0.78 (0.32, 1.90)	0.42 (0.12, 1.45)			
Baseline FVC percent predicted					
<=70%	0.46 (0.13, 1.69)	1.08 (0.42, 2.79)			
>70%	1.54 (0.59, 4.02)	0.52 (0.13, 2.04)			
Baseline HRCT pattern					
UIP-like	0.94 (0.43, 2.07)	1.20 (0.49, 2.98)			
Other fibrotic patterns	1.45 (0.25, 8.42)	0.26 (0.04, 1.62)			
Underlying ILD diagnosis					
iNSIP	5.13 (0.27, 96.53)	0.23 (0.03, 1.85)			
Unclassifiable IIP	1.80 (0.17, 19.02)	0.58 (0.12, 2.80)			
HP	1.30 (0.08, 19.95)				
Autoimmune ILD	0.56 (0.20, 1.60)	2.59 (0.33, 20.27)			
Other ILD	1.44 (0.32, 6.56)	2.98 (0.33, 26.99)			
Region					
Europe	0.75 (0.16, 3.54)				
Asia	1.82 (0.70, 4.73)				
Canada and USA	1.72 (0.04, 83.12)				
Rest of the World	0.10 (0.01, 1.71)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Influenza

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.06 (-4.68, 4.81)	-0.64 (-3.22, 1.93)	0.70 (-4.70, 6.10)
Age			
<65 years	-6.30 (-15.23, 1.98)	-0.68 (-5.07, 3.72)	
>=65 years	3.98 (-1.70, 10.14)	-0.75 (-4.00, 2.50)	
Sex			
Male	1.96 (-3.90, 8.21)	1.30 (-2.29, 4.90)	
Female	-2.09 (-10.01, 5.64)	-2.75 (-6.51, 1.01)	
Baseline FVC percent predicted			
<=70%	-3.65 (-10.03, 2.90)	0.30 (-3.43, 4.04)	
>70%	3.10 (-4.24, 10.14)	-1.90 (-5.46, 1.66)	
Baseline HRCT pattern			
UIP-like	-0.45 (-6.52, 5.65)	0.72 (-2.74, 4.18)	
Other fibrotic patterns	1.42 (-6.72, 9.72)	-3.05 (-6.87, 0.77)	
Underlying ILD diagnosis			
iNSIP	5.45 (-4.01, 14.85)	-4.48 (-10.51, 1.55)	
Unclassifiable IIP	2.22 (-9.73, 13.95)	-2.71 (-10.69, 5.27)	
HP	0.77 (-10.20, 14.27)		
Autoimmune ILD	-5.53 (-16.04, 4.80)	2.08 (-1.83, 5.99)	
Other ILD	3.67 (-11.94, 22.43)	4.12 (-3.61, 11.86)	
Region			
Europe	-1.84 (-14.75, 9.04)		
Asia	4.62 (-2.96, 12.43)		
Canada and USA	0.00 (NC, NC)		
Rest of the World	-10.87 (-23.04, -0.63)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Influenza

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.47, 2.17)	0.82 (0.36, 1.84)	1.24 (0.41, 3.77)
Age			
<65 years	0.39 (0.12, 1.32)	0.82 (0.24, 2.83)	
>=65 years	2.20 (0.73, 6.61)	0.79 (0.28, 2.25)	
Sex			
Male	1.60 (0.44, 5.83)	1.48 (0.49, 4.51)	
Female	0.76 (0.29, 2.01)	0.41 (0.12, 1.43)	
Baseline FVC percent predicted			
<=70%	0.44 (0.11, 1.72)	1.08 (0.40, 2.93)	
>70%	1.59 (0.57, 4.46)	0.51 (0.14, 1.92)	
Baseline HRCT pattern			
UIP-like	0.94 (0.40, 2.19)	1.21 (0.47, 3.11)	
Other fibrotic patterns	1.48 (0.24, 9.14)	0.25 (0.04, 1.57)	
Underlying ILD diagnosis			
iNSIP	NC (NC, NC)	0.21 (0.02, 1.88)	
Unclassifiable IIP	1.84 (0.16, 21.22)	0.56 (0.10, 3.02)	
HP	1.31 (0.08, 21.84)		
Autoimmune ILD	0.53 (0.17, 1.67)	2.66 (0.34, 20.90)	
Other ILD	1.50 (0.28, 8.12)	3.27 (0.31, 34.41)	
Region			
Europe	0.74 (0.14, 3.88)		
Asia	1.91 (0.68, 5.37)		
Canada and USA	NC (NC, NC)		
Rest of the World	0.00 (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Nasopharyngitis

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.14 (0.68, 1.90)	1.10 (0.78, 1.57)	1.03 (0.55, 1.92)	0.9324	
Age					
<65 years	0.86 (0.38, 1.91)	1.07 (0.62, 1.83)			
>=65 years	1.38 (0.70, 2.72)	1.11 (0.70, 1.77)			
Sex					
Male	1.21 (0.60, 2.42)	0.89 (0.56, 1.43)			
Female	1.06 (0.49, 2.30)	1.45 (0.84, 2.48)			
Baseline FVC percent predicted					
<=70%	1.45 (0.68, 3.10)	1.27 (0.78, 2.07)			
>70%	0.90 (0.44, 1.83)	0.94 (0.57, 1.57)			
Baseline HRCT pattern					
UIP-like	0.86 (0.46, 1.62)	1.19 (0.78, 1.79)			
Other fibrotic patterns	2.13 (0.79, 5.80)	0.93 (0.47, 1.82)			
Underlying ILD diagnosis					
iNSIP	0.91 (0.26, 3.17)	1.20 (0.56, 2.54)			
Unclassifiable IIP	0.77 (0.29, 2.08)	1.21 (0.58, 2.52)			
HP	1.95 (0.60, 6.30)				
Autoimmune ILD	1.16 (0.44, 3.02)	0.86 (0.43, 1.72)			
Other ILD	1.44 (0.22, 9.55)	1.83 (0.25, 13.13)			
Region					
Europe	1.06 (0.36, 3.09)				
Asia	0.87 (0.45, 1.69)	0.86 (0.52, 1.40)			
Canada and USA	3.53 (0.34, 36.11)				
Rest of the World	2.14 (0.41, 11.09)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Nasopharyngitis

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	1.46 (-4.58, 7.53)	1.41 (-3.60, 6.42)	0.05 (-7.81, 7.91)
Age			
<65 years	-1.89 (-12.17, 8.18)	1.03 (-7.31, 9.38)	
>=65 years	3.53 (-4.08, 11.30)	1.43 (-4.87, 7.74)	
Sex			
Male	2.31 (-6.41, 11.15)	-1.71 (-8.75, 5.33)	
Female	0.63 (-7.96, 9.16)	4.95 (-2.20, 12.09)	
Baseline FVC percent predicted			
<=70%	4.22 (-4.34, 13.41)	3.16 (-3.36, 9.68)	
>70%	-1.21 (-10.12, 7.24)	-0.87 (-8.71, 6.97)	
Baseline HRCT pattern			
UIP-like	-1.64 (-8.78, 5.54)	2.69 (-3.84, 9.22)	
Other fibrotic patterns	8.85 (-2.77, 20.49)	-0.85 (-8.49, 6.80)	
Underlying ILD diagnosis			
iNSIP	-0.91 (-14.94, 11.19)	2.89 (-9.19, 14.97)	
Unclassifiable IIP	-4.44 (-21.93, 12.64)	3.66 (-10.53, 17.84)	
HP	9.74 (-7.22, 28.12)		
Autoimmune ILD	1.57 (-9.09, 12.34)	-1.98 (-11.13, 7.17)	
Other ILD	2.44 (-11.41, 19.88)	2.53 (-5.75, 10.82)	
Region			
Europe	0.71 (-14.45, 14.30)		
Asia	-2.01 (-11.53, 7.49)	-3.10 (-13.12, 6.92)	
Canada and USA	8.43 (-7.37, 31.17)		
Rest of the World	4.95 (-6.68, 17.65)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Nasopharyngitis

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.15 (0.64, 2.07)	1.12 (0.74, 1.71)	1.03 (0.50, 2.11)
Age			
<65 years	0.84 (0.34, 2.09)	1.08 (0.57, 2.05)	
>=65 years	1.43 (0.67, 3.08)	1.13 (0.66, 1.95)	
Sex			
Male	1.24 (0.56, 2.74)	0.87 (0.50, 1.53)	
Female	1.07 (0.45, 2.54)	1.54 (0.82, 2.88)	
Baseline FVC percent predicted			
<=70%	1.52 (0.65, 3.57)	1.32 (0.74, 2.32)	
>70%	0.89 (0.40, 1.99)	0.93 (0.51, 1.72)	
Baseline HRCT pattern			
UIP-like	0.85 (0.42, 1.72)	1.23 (0.75, 2.02)	
Other fibrotic patterns	2.36 (0.77, 7.23)	0.92 (0.43, 1.97)	
Underlying ILD diagnosis			
iNSIP	0.90 (0.23, 3.59)	1.24 (0.50, 3.04)	
Unclassifiable IIP	0.73 (0.22, 2.42)	1.26 (0.51, 3.14)	
HP	2.19 (0.56, 8.59)		
Autoimmune ILD	1.18 (0.40, 3.45)	0.84 (0.37, 1.89)	
Other ILD	1.48 (0.19, 11.26)	1.88 (0.24, 14.99)	
Region			
Europe	1.07 (0.31, 3.64)		
Asia	0.85 (0.39, 1.84)	0.81 (0.41, 1.60)	
Canada and USA	3.87 (0.32, 46.18)		
Rest of the World	2.26 (0.39, 13.00)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.07 (0.69, 1.66)	1.05 (0.69, 1.59)	1.02 (0.56, 1.86)	0.9504	
Age					
<65 years	0.75 (0.31, 1.82)	1.30 (0.65, 2.60)			
>=65 years	1.24 (0.75, 2.04)	0.94 (0.56, 1.60)			
Sex					
Male	1.05 (0.57, 1.90)	1.30 (0.76, 2.23)			
Female	1.10 (0.58, 2.09)	0.74 (0.38, 1.44)			
Baseline FVC percent predicted					
<=70%	1.00 (0.56, 1.78)	1.01 (0.62, 1.64)			
>70%	1.26 (0.64, 2.49)	1.15 (0.52, 2.56)			
Baseline HRCT pattern					
UIP-like	1.22 (0.71, 2.09)	1.06 (0.64, 1.74)			
Other fibrotic patterns	0.81 (0.38, 1.74)	1.04 (0.50, 2.19)			
Underlying ILD diagnosis					
iNSIP	2.00 (0.69, 5.83)	0.35 (0.11, 1.06)			
Unclassifiable IIP	1.50 (0.39, 5.84)	1.68 (0.58, 4.90)			
HP	1.73 (0.42, 7.17)				
Autoimmune ILD	0.94 (0.46, 1.91)	1.55 (0.76, 3.16)			
Other ILD	0.43 (0.13, 1.41)	1.27 (0.38, 4.21)			
Region					
Europe	2.26 (0.65, 7.83)				
Asia	0.78 (0.46, 1.34)	0.70 (0.37, 1.35)			
Canada and USA	2.65 (0.49, 14.31)				
Rest of the World	1.07 (0.29, 4.01)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	1.04 (-5.73, 7.82)	0.52 (-3.95, 4.98)	0.53 (-7.58, 8.64)
Age			
<65 years	-2.96 (-12.74, 6.54)	2.66 (-4.36, 9.68)	
>=65 years	3.91 (-5.36, 13.21)	-0.64 (-6.40, 5.13)	
Sex			
Male	0.70 (-8.87, 10.36)	3.17 (-3.28, 9.62)	
Female	1.45 (-8.25, 11.06)	-2.71 (-8.78, 3.36)	
Baseline FVC percent predicted			
<=70%	-0.09 (-10.21, 10.51)	0.15 (-6.45, 6.75)	
>70%	2.98 (-6.15, 11.69)	0.95 (-4.55, 6.45)	
Baseline HRCT pattern			
UIP-like	2.94 (-5.00, 10.92)	0.61 (-5.10, 6.32)	
Other fibrotic patterns	-3.60 (-16.67, 9.45)	0.39 (-6.70, 7.49)	
Underlying ILD diagnosis			
iNSIP	10.00 (-5.55, 23.76)	-9.76 (-19.59, 0.07)	
Unclassifiable IIP	4.17 (-11.05, 18.83)	5.72 (-5.41, 16.85)	
HP	5.64 (-9.32, 22.75)		
Autoimmune ILD	-1.17 (-13.85, 11.59)	5.76 (-3.56, 15.07)	
Other ILD	-15.78 (-33.79, 5.78)	2.40 (-9.58, 14.37)	
Region			
Europe	9.48 (-5.13, 22.68)		
Asia	-4.88 (-15.62, 5.94)	-4.73 (-13.77, 4.30)	
Canada and USA	10.98 (-7.62, 34.85)		
Rest of the World	0.61 (-12.31, 13.99)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.08 (0.65, 1.82)	1.06 (0.66, 1.69)	1.03 (0.51, 2.06)
Age			
<65 years	0.73 (0.27, 1.95)	1.34 (0.61, 2.90)	
>=65 years	1.30 (0.70, 2.40)	0.94 (0.51, 1.70)	
Sex			
Male	1.05 (0.52, 2.15)	1.36 (0.73, 2.52)	
Female	1.12 (0.53, 2.38)	0.72 (0.35, 1.50)	
Baseline FVC percent predicted			
<=70%	0.99 (0.49, 2.01)	1.01 (0.58, 1.78)	
>70%	1.30 (0.60, 2.85)	1.16 (0.48, 2.81)	
Baseline HRCT pattern			
UIP-like	1.26 (0.67, 2.37)	1.06 (0.60, 1.88)	
Other fibrotic patterns	0.77 (0.31, 1.94)	1.05 (0.46, 2.37)	
Underlying ILD diagnosis			
iNSIP	2.25 (0.66, 7.67)	0.31 (0.09, 1.05)	
Unclassifiable IIP	1.57 (0.35, 7.10)	1.80 (0.55, 5.89)	
HP	1.85 (0.38, 8.96)		
Autoimmune ILD	0.92 (0.39, 2.19)	1.66 (0.72, 3.78)	
Other ILD	0.35 (0.09, 1.45)	1.31 (0.33, 5.29)	
Region			
Europe	2.52 (0.64, 10.01)		
Asia	0.74 (0.38, 1.45)	0.67 (0.31, 1.43)	
Canada and USA	3.00 (0.45, 20.07)		
Rest of the World	1.08 (0.25, 4.60)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Respiratory tract infection

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.56 (0.75, 3.25)	1.17 (0.63, 2.15)	1.34 (0.51, 3.48)	0.5524	
Age					
<65 years	2.20 (0.59, 8.23)	2.02 (0.75, 5.40)			
>=65 years	1.32 (0.54, 3.23)	0.76 (0.33, 1.74)			
Sex					
Male	0.70 (0.26, 1.89)	1.29 (0.59, 2.81)			
Female	5.35 (1.21, 23.56)	0.97 (0.37, 2.57)			
Baseline FVC percent predicted					
<=70%	2.05 (0.50, 8.36)	1.36 (0.67, 2.75)			
>70%	1.26 (0.53, 2.96)	0.73 (0.23, 2.27)			
Baseline HRCT pattern					
UIP-like	1.60 (0.71, 3.58)	1.11 (0.48, 2.56)			
Other fibrotic patterns	1.45 (0.25, 8.42)	1.23 (0.51, 2.95)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	1.26 (0.32, 4.96)				
Asia	1.49 (0.43, 5.12)	0.68 (0.14, 3.37)			
Canada and USA	0.59 (0.07, 5.22)				
Rest of the World	5.35 (0.65, 43.96)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Respiratory tract infection

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	2.77 (-1.89, 7.59)	0.80 (-2.43, 4.04)	1.97 (-3.77, 7.71)
Age			
<65 years	4.34 (-3.30, 12.27)	4.06 (-1.36, 9.48)	
>=65 years	1.82 (-4.39, 8.27)	-1.32 (-5.28, 2.64)	
Sex			
Male	-2.35 (-9.32, 4.56)	1.58 (-3.24, 6.41)	
Female	8.20 (1.77, 15.42)	-0.13 (-4.45, 4.18)	
Baseline FVC percent predicted			
<=70%	2.67 (-2.86, 9.29)	2.18 (-2.75, 7.10)	
>70%	1.99 (-5.90, 9.47)	-1.05 (-5.06, 2.96)	
Baseline HRCT pattern			
UIP-like	3.39 (-2.58, 9.59)	0.44 (-3.26, 4.14)	
Other fibrotic patterns	1.42 (-6.72, 9.72)	1.46 (-4.75, 7.67)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	1.93 (-11.53, 13.82)		
Asia	1.83 (-4.46, 8.34)	-0.89 (-4.96, 3.18)	
Canada and USA	-4.12 (-20.47, 17.97)		
Rest of the World	9.45 (-1.81, 22.43)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Respiratory tract infection

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.61 (0.73, 3.51)	1.18 (0.61, 2.26)	1.37 (0.49, 3.78)
Age			
<65 years	2.30 (0.58, 9.23)	2.11 (0.74, 5.99)	
>=65 years	1.34 (0.51, 3.51)	0.75 (0.31, 1.80)	
Sex			
Male	0.68 (0.23, 1.98)	1.31 (0.57, 3.03)	
Female	5.84 (1.26, 27.00)	0.97 (0.35, 2.70)	
Baseline FVC percent predicted			
<=70%	2.11 (0.49, 9.05)	1.39 (0.65, 2.97)	
>70%	1.29 (0.50, 3.28)	0.72 (0.21, 2.45)	
Baseline HRCT pattern			
UIP-like	1.66 (0.69, 3.95)	1.11 (0.46, 2.70)	
Other fibrotic patterns	1.48 (0.24, 9.14)	1.25 (0.49, 3.20)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	1.28 (0.29, 5.72)		
Asia	1.51 (0.42, 5.53)	0.67 (0.12, 3.74)	
Canada and USA	0.56 (0.05, 5.88)		
Rest of the World	5.92 (0.66, 52.91)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Upper respiratory tract infection

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.71 (0.48, 1.06)	1.01 (0.62, 1.63)	0.71 (0.38, 1.32)	0.2784	
Age					
<65 years	0.63 (0.36, 1.10)	0.71 (0.34, 1.50)			
>=65 years	0.79 (0.45, 1.39)	1.26 (0.67, 2.37)			
Sex					
Male	0.46 (0.25, 0.87)	1.21 (0.56, 2.60)			
Female	1.02 (0.60, 1.74)	0.91 (0.49, 1.67)			
Baseline FVC percent predicted					
<=70%	0.47 (0.25, 0.88)	0.77 (0.38, 1.56)			
>70%	1.02 (0.59, 1.76)	1.27 (0.66, 2.46)			
Baseline HRCT pattern					
UIP-like	0.71 (0.45, 1.13)	0.84 (0.44, 1.60)			
Other fibrotic patterns	0.73 (0.33, 1.61)	1.25 (0.61, 2.55)			
Underlying ILD diagnosis					
iNSIP	0.73 (0.23, 2.35)	1.07 (0.39, 2.96)			
Unclassifiable IIP	1.26 (0.44, 3.62)	0.81 (0.19, 3.39)			
HP	0.13 (0.02, 0.96)				
Autoimmune ILD	1.01 (0.55, 1.87)	1.12 (0.50, 2.53)			
Other ILD	0.60 (0.24, 1.49)	1.04 (0.20, 5.35)			
Region					
Europe	0.19 (0.04, 0.84)				
Asia	0.88 (0.55, 1.41)	0.85 (0.39, 1.83)			
Canada and USA	0.98 (0.39, 2.45)				
Rest of the World	0.71 (0.13, 4.06)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Upper respiratory tract infection

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-6.17 (-13.38, 1.10)	0.07 (-3.92, 4.06)	-6.24 (-14.50, 2.03)
Age			
<65 years	-10.73 (-23.18, 1.99)	-2.95 (-9.55, 3.64)	
>=65 years	-3.63 (-12.25, 5.11)	1.85 (-3.20, 6.90)	
Sex			
Male	-12.47 (-22.07, -2.63)	1.17 (-3.65, 6.00)	
Female	0.37 (-10.37, 11.05)	-1.04 (-7.50, 5.42)	
Baseline FVC percent predicted			
<=70%	-13.12 (-22.94, -2.64)	-1.80 (-6.73, 3.13)	
>70%	0.28 (-10.05, 10.23)	2.40 (-4.13, 8.93)	
Baseline HRCT pattern			
UIP-like	-6.55 (-15.26, 2.29)	-1.23 (-5.87, 3.41)	
Other fibrotic patterns	-5.11 (-17.98, 7.73)	2.37 (-5.00, 9.74)	
Underlying ILD diagnosis			
iNSIP	-3.41 (-17.96, 9.22)	0.68 (-8.85, 10.21)	
Unclassifiable IIP	3.61 (-13.56, 20.04)	-1.24 (-9.69, 7.21)	
HP	-22.31 (-37.99, -4.97)		
Autoimmune ILD	0.32 (-13.42, 14.09)	1.09 (-6.90, 9.08)	
Other ILD	-13.33 (-33.10, 9.86)	0.20 (-8.90, 9.30)	
Region			
Europe	-16.23 (-31.23, -3.15)		
Asia	-3.05 (-14.55, 8.53)	-1.69 (-9.55, 6.17)	
Canada and USA	-0.59 (-24.67, 26.62)		
Rest of the World	-1.87 (-13.36, 9.75)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Upper respiratory tract infection

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.66 (0.41, 1.08)	1.01 (0.60, 1.71)	0.66 (0.32, 1.34)
Age			
<65 years	0.55 (0.27, 1.12)	0.69 (0.30, 1.57)	
>=65 years	0.76 (0.39, 1.47)	1.29 (0.65, 2.56)	
Sex			
Male	0.40 (0.19, 0.84)	1.22 (0.53, 2.82)	
Female	1.02 (0.52, 2.00)	0.90 (0.45, 1.77)	
Baseline FVC percent predicted			
<=70%	0.40 (0.19, 0.85)	0.76 (0.35, 1.62)	
>70%	1.02 (0.52, 2.00)	1.31 (0.62, 2.75)	
Baseline HRCT pattern			
UIP-like	0.66 (0.37, 1.16)	0.83 (0.41, 1.68)	
Other fibrotic patterns	0.68 (0.27, 1.76)	1.28 (0.58, 2.82)	
Underlying ILD diagnosis			
iNSIP	0.70 (0.19, 2.60)	1.08 (0.36, 3.29)	
Unclassifiable IIP	1.32 (0.38, 4.58)	0.80 (0.17, 3.71)	
HP	0.10 (0.01, 0.83)		
Autoimmune ILD	1.02 (0.46, 2.24)	1.14 (0.44, 2.94)	
Other ILD	0.50 (0.15, 1.66)	1.04 (0.17, 6.23)	
Region			
Europe	0.16 (0.03, 0.79)		
Asia	0.85 (0.46, 1.58)	0.83 (0.35, 1.97)	
Canada and USA	0.97 (0.26, 3.58)		
Rest of the World	0.70 (0.11, 4.40)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Urinary tract infection

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.84 (0.43, 1.63)	1.01 (0.58, 1.75)	0.83 (0.35, 1.96)	0.6731	
Age					
<65 years	0.47 (0.04, 5.10)	0.84 (0.30, 2.36)			
>=65 years	0.92 (0.47, 1.81)	1.11 (0.59, 2.10)			
Sex					
Male	1.05 (0.22, 5.07)	0.79 (0.27, 2.33)			
Female	0.78 (0.38, 1.58)	1.12 (0.60, 2.07)			
Baseline FVC percent predicted					
<=70%	1.23 (0.45, 3.38)	1.02 (0.50, 2.06)			
>70%	0.61 (0.25, 1.46)	1.00 (0.43, 2.33)			
Baseline HRCT pattern					
UIP-like	0.77 (0.33, 1.77)	0.83 (0.39, 1.78)			
Other fibrotic patterns	0.97 (0.33, 2.85)	1.24 (0.57, 2.71)			
Underlying ILD diagnosis					
iNSIP	0.73 (0.25, 2.09)	0.90 (0.20, 4.01)			
Unclassifiable IIP	0.30 (0.03, 2.76)	1.04 (0.27, 4.00)			
HP	0.98 (0.24, 4.03)				
Autoimmune ILD	1.35 (0.31, 5.82)	1.84 (0.68, 5.00)			
Other ILD	0.72 (0.07, 7.52)	0.15 (0.02, 1.18)			
Region					
Europe	2.64 (0.58, 12.04)				
Asia	0.17 (0.02, 1.35)	1.07 (0.27, 4.21)			
Canada and USA	0.59 (0.07, 5.22)				
Rest of the World	0.92 (0.33, 2.51)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Urinary tract infection

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-1.29 (-6.37, 3.76)	0.07 (-3.49, 3.64)	-1.36 (-7.56, 4.84)
Age			
<65 years	-1.27 (-7.30, 4.04)	-0.87 (-5.83, 4.09)	
>=65 years	-0.90 (-8.53, 6.81)	0.82 (-4.15, 5.79)	
Sex			
Male	0.12 (-4.95, 5.35)	-0.75 (-4.28, 2.78)	
Female	-3.14 (-12.28, 5.89)	1.16 (-5.26, 7.58)	
Baseline FVC percent predicted			
<=70%	1.36 (-5.53, 8.99)	0.13 (-4.76, 5.02)	
>70%	-4.13 (-12.14, 3.23)	0.00 (-5.29, 5.30)	
Baseline HRCT pattern			
UIP-like	-1.75 (-7.64, 4.09)	-0.97 (-5.03, 3.09)	
Other fibrotic patterns	-0.28 (-11.05, 10.33)	1.92 (-4.91, 8.75)	
Underlying ILD diagnosis			
iNSIP	-4.09 (-19.32, 9.41)	-0.48 (-7.28, 6.32)	
Unclassifiable IIP	-5.83 (-19.48, 5.90)	0.24 (-8.64, 9.11)	
HP	-0.26 (-15.10, 16.55)		
Autoimmune ILD	1.49 (-6.75, 10.03)	4.39 (-2.86, 11.64)	
Other ILD	-1.56 (-14.57, 14.50)	-12.10 (-22.56, -1.64)	
Region			
Europe	8.21 (-5.08, 20.39)		
Asia	-4.73 (-10.92, 0.44)	0.24 (-4.47, 4.96)	
Canada and USA	-4.12 (-20.47, 17.97)		
Rest of the World	-1.26 (-16.23, 14.09)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Urinary tract infection

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.83 (0.41, 1.69)	1.01 (0.56, 1.82)	0.82 (0.33, 2.06)
Age			
<65 years	0.47 (0.04, 5.23)	0.84 (0.29, 2.39)	
>=65 years	0.91 (0.43, 1.95)	1.12 (0.56, 2.24)	
Sex			
Male	1.05 (0.21, 5.30)	0.78 (0.25, 2.44)	
Female	0.75 (0.33, 1.69)	1.13 (0.57, 2.25)	
Baseline FVC percent predicted			
<=70%	1.25 (0.42, 3.69)	1.02 (0.48, 2.16)	
>70%	0.58 (0.23, 1.51)	1.00 (0.40, 2.50)	
Baseline HRCT pattern			
UIP-like	0.76 (0.31, 1.85)	0.82 (0.37, 1.85)	
Other fibrotic patterns	0.97 (0.29, 3.17)	1.27 (0.54, 2.98)	
Underlying ILD diagnosis			
iNSIP	0.69 (0.21, 2.33)	0.90 (0.19, 4.22)	
Unclassifiable IIP	0.28 (0.03, 2.84)	1.04 (0.24, 4.45)	
HP	0.97 (0.20, 4.71)		
Autoimmune ILD	1.37 (0.30, 6.37)	1.92 (0.64, 5.76)	
Other ILD	0.71 (0.06, 8.26)	0.12 (0.01, 1.11)	
Region			
Europe	2.89 (0.57, 14.74)		
Asia	0.16 (0.02, 1.33)	1.08 (0.25, 4.63)	
Canada and USA	0.56 (0.05, 5.88)		
Rest of the World	0.90 (0.28, 2.94)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Investigations
PT: C-reactive protein increased

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.85 (0.70, 4.91)				
Age					
<65 years					
>=65 years					
Sex					
Male	4.70 (1.04, 21.29)				
Female	0.49 (0.09, 2.60)				
Baseline FVC percent predicted					
<=70%	1.23 (0.37, 4.12)				
>70%	5.03 (0.62, 41.13)				
Baseline HRCT pattern					
UIP-like	2.05 (0.63, 6.67)				
Other fibrotic patterns	1.45 (0.25, 8.42)				
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	1.13 (0.20, 6.46)				
Asia	1.73 (0.52, 5.75)				
Canada and USA	1.72 (0.04, 83.12)				
Rest of the World	3.20 (0.13, 76.60)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Investigations
PT: C-reactive protein increased

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	2.30 (-1.47, 6.30)		
Age			
<65 years			
>=65 years			
Sex			
Male	6.38 (0.62, 13.09)		
Female	-1.94 (-7.63, 3.21)		
Baseline FVC percent predicted			
<=70%	0.97 (-5.10, 7.82)		
>70%	3.88 (-1.14, 9.25)		
Baseline HRCT pattern			
UIP-like	2.66 (-1.90, 7.63)		
Other fibrotic patterns	1.42 (-6.72, 9.72)		
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	0.66 (-11.43, 11.02)		
Asia	2.77 (-3.69, 9.52)		
Canada and USA	0.00 (NC, NC)		
Rest of the World	2.33 (-5.62, 12.06)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Investigations
PT: C-reactive protein increased

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.89 (0.69, 5.22)		
Age			
<65 years			
>=65 years			
Sex			
Male	5.03 (1.06, 23.82)		
Female	0.48 (0.09, 2.66)		
Baseline FVC percent predicted			
<=70%	1.24 (0.35, 4.42)		
>70%	5.24 (0.62, 44.22)		
Baseline HRCT pattern			
UIP-like	2.11 (0.62, 7.16)		
Other fibrotic patterns	1.48 (0.24, 9.14)		
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	1.14 (0.18, 7.17)		
Asia	1.79 (0.51, 6.29)		
Canada and USA	NC (NC, NC)		
Rest of the World	NC (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Investigations
PT: Weight decreased

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	2.08 (1.18, 3.67)	2.43 (1.51, 3.91)	0.86 (0.41, 1.79)	0.6793	
Age					
<65 years	1.89 (0.59, 6.03)	5.34 (1.73, 16.51)			
>=65 years	2.19 (1.15, 4.18)	1.93 (1.13, 3.31)			
Sex					
Male	1.81 (0.90, 3.62)	2.80 (1.41, 5.53)			
Female	2.72 (1.02, 7.30)	2.11 (1.08, 4.11)			
Baseline FVC percent predicted					
<=70%	1.42 (0.71, 2.83)	1.88 (1.02, 3.47)			
>70%	5.03 (1.52, 16.61)	3.46 (1.60, 7.49)			
Baseline HRCT pattern					
UIP-like	2.43 (1.24, 4.73)	3.77 (1.89, 7.52)			
Other fibrotic patterns	1.36 (0.45, 4.06)	1.38 (0.70, 2.74)			
Underlying ILD diagnosis					
iNSIP	1.82 (0.37, 8.90)	3.09 (1.08, 8.80)			
Unclassifiable IIP	4.95 (1.18, 20.85)	1.53 (0.63, 3.68)			
HP	0.33 (0.04, 2.76)				
Autoimmune ILD	2.54 (0.83, 7.71)	3.50 (1.09, 11.21)			
Other ILD	2.16 (0.68, 6.87)	3.46 (0.67, 17.90)			
Region					
Europe	3.02 (0.35, 25.98)				
Asia	1.89 (0.96, 3.73)	2.00 (1.02, 3.94)			
Canada and USA	2.94 (0.80, 10.81)				
Rest of the World	3.21 (0.35, 29.69)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Investigations
PT: Weight decreased

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	7.79 (1.93, 13.77)	8.59 (4.25, 12.93)	-0.80 (-8.14, 6.54)
Age			
<65 years	4.27 (-3.94, 12.64)	10.98 (4.97, 16.99)	
>=65 years	10.31 (2.09, 18.66)	7.40 (1.46, 13.34)	
Sex			
Male	7.63 (-1.28, 16.69)	9.70 (3.77, 15.64)	
Female	8.13 (0.41, 16.16)	7.33 (0.99, 13.67)	
Baseline FVC percent predicted			
<=70%	4.61 (-4.50, 14.27)	6.12 (0.39, 11.84)	
>70%	11.63 (4.29, 19.14)	11.85 (5.20, 18.49)	
Baseline HRCT pattern			
UIP-like	9.92 (2.73, 17.28)	11.31 (6.08, 16.53)	
Other fibrotic patterns	2.79 (-7.87, 13.46)	3.62 (-4.01, 11.24)	
Underlying ILD diagnosis			
iNSIP	4.09 (-8.51, 15.18)	12.64 (2.11, 23.16)	
Unclassifiable IIP	21.94 (4.97, 37.80)	6.37 (-6.38, 19.12)	
HP	-6.92 (-20.52, 7.78)		
Autoimmune ILD	8.65 (-1.53, 19.27)	8.29 (1.15, 15.43)	
Other ILD	12.89 (-6.03, 33.44)	8.36 (-1.96, 18.69)	
Region			
Europe	5.05 (-6.30, 15.56)		
Asia	9.25 (-0.44, 18.88)	9.86 (0.81, 18.90)	
Canada and USA	19.41 (-3.04, 44.02)		
Rest of the World	4.80 (-5.44, 16.57)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Investigations
PT: Weight decreased

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	2.27 (1.21, 4.26)	2.67 (1.58, 4.51)	0.85 (0.37, 1.93)
Age			
<65 years	1.98 (0.57, 6.82)	5.99 (1.78, 20.11)	
>=65 years	2.47 (1.19, 5.16)	2.10 (1.15, 3.84)	
Sex			
Male	1.97 (0.89, 4.36)	3.12 (1.48, 6.56)	
Female	2.98 (1.03, 8.58)	2.28 (1.09, 4.78)	
Baseline FVC percent predicted			
<=70%	1.50 (0.67, 3.32)	2.02 (1.03, 3.96)	
>70%	5.72 (1.63, 20.00)	3.91 (1.67, 9.12)	
Baseline HRCT pattern			
UIP-like	2.71 (1.29, 5.71)	4.25 (2.02, 8.95)	
Other fibrotic patterns	1.40 (0.42, 4.66)	1.44 (0.66, 3.14)	
Underlying ILD diagnosis			
iNSIP	1.90 (0.35, 10.33)	3.57 (1.12, 11.39)	
Unclassifiable IIP	6.45 (1.32, 31.49)	1.64 (0.59, 4.58)	
HP	0.30 (0.03, 2.85)		
Autoimmune ILD	2.79 (0.83, 9.37)	3.80 (1.07, 13.52)	
Other ILD	2.53 (0.63, 10.11)	4.31 (0.63, 29.70)	
Region			
Europe	3.18 (0.34, 29.65)		
Asia	2.11 (0.96, 4.63)	2.24 (1.03, 4.91)	
Canada and USA	3.75 (0.77, 18.29)		
Rest of the World	3.38 (0.34, 33.76)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.52, 1.97)	2.46 (1.55, 3.89)	0.41 (0.18, 0.92)	0.0314	
Age					0.3448
<65 years	1.57 (0.39, 6.37)	8.67 (2.30, 32.75)	0.18 (0.03, 1.25)	0.0828	
>=65 years	0.89 (0.41, 1.92)	1.75 (1.06, 2.92)	0.51 (0.20, 1.27)	0.1487	
Sex					0.9959
Male	0.87 (0.27, 2.77)	2.20 (1.18, 4.09)	0.40 (0.11, 1.47)	0.1673	
Female	1.07 (0.47, 2.41)	2.71 (1.38, 5.34)	0.39 (0.14, 1.14)	0.0852	
Baseline FVC percent predicted					0.5388
<=70%	0.92 (0.41, 2.10)	2.52 (1.38, 4.62)	0.37 (0.13, 1.01)	0.0534	
>70%	1.47 (0.44, 4.88)	2.34 (1.17, 4.67)	0.63 (0.16, 2.51)	0.5099	
Baseline HRCT pattern					0.4477
UIP-like	0.94 (0.43, 2.07)	2.83 (1.59, 5.04)	0.33 (0.13, 0.88)	0.0272	
Other fibrotic patterns	1.21 (0.34, 4.31)	1.83 (0.86, 3.90)	0.66 (0.15, 2.89)	0.5822	
Underlying ILD diagnosis					0.2981
iNSIP	1.45 (0.28, 7.56)	3.32 (1.04, 10.62)	0.44 (0.06, 3.29)	0.4217	
Unclassifiable IIP	0.45 (0.09, 2.31)	3.09 (1.00, 9.56)	0.15 (0.02, 1.07)	0.0577	
HP	0.43 (0.05, 3.96)				
Autoimmune ILD	1.01 (0.31, 3.35)	12.56 (2.22, 70.98)	0.08 (0.01, 0.66)	0.0191	
Other ILD	2.88 (0.57, 14.54)	2.67 (0.82, 8.73)	1.08 (0.15, 8.02)	0.9408	
Region					
Europe	2.26 (0.24, 20.96)				
Asia	0.72 (0.30, 1.72)	2.72 (1.29, 5.73)	0.26 (0.08, 0.83)	0.0231	
Canada and USA	0.44 (0.05, 3.64)				
Rest of the World	9.61 (0.53, 173.44)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.07 (-4.93, 5.08)	9.29 (4.86, 13.72)	-9.22 (-15.91, -2.54)
Age			
<65 years	2.07 (-5.17, 9.40)	13.53 (7.49, 19.57)	-11.46 (-20.93, -1.99)
>=65 years	-1.02 (-8.02, 6.06)	6.93 (0.82, 13.03)	-7.94 (-17.26, 1.37)
Sex			
Male	-0.67 (-6.88, 5.59)	8.31 (2.19, 14.43)	-8.98 (-17.72, -0.25)
Female	0.66 (-7.65, 8.90)	10.21 (3.76, 16.66)	-9.55 (-20.04, 0.94)
Baseline FVC percent predicted			
<=70%	-0.79 (-8.85, 7.82)	9.91 (3.92, 15.91)	-10.71 (-20.97, -0.44)
>70%	1.80 (-4.53, 7.82)	8.61 (1.97, 15.24)	-6.81 (-15.87, 2.25)
Baseline HRCT pattern			
UIP-like	-0.45 (-6.52, 5.65)	11.12 (5.50, 16.73)	-11.57 (-19.85, -3.29)
Other fibrotic patterns	1.33 (-8.42, 11.06)	5.99 (-1.26, 13.24)	-4.66 (-16.80, 7.48)
Underlying ILD diagnosis			
iNSIP	2.27 (-10.05, 12.90)	11.45 (1.70, 21.21)	-9.18 (-24.24, 5.87)
Unclassifiable IIP	-6.11 (-20.77, 7.20)	13.50 (1.93, 25.08)	-19.62 (-37.77, -1.46)
HP	-4.36 (-17.28, 9.90)		
Autoimmune ILD	0.10 (-9.23, 9.50)	15.09 (7.68, 22.51)	-14.99 (-26.94, -3.05)
Other ILD	10.44 (-5.39, 29.53)	11.81 (-1.69, 25.31)	-1.37 (-23.43, 20.70)
Region			
Europe	3.16 (-7.87, 13.09)		
Asia	-2.90 (-11.02, 5.07)	12.93 (4.43, 21.44)	-15.83 (-27.54, -4.13)
Canada and USA	-7.45 (-24.50, 15.12)		
Rest of the World	9.30 (-0.24, 21.60)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.49, 2.07)	2.74 (1.65, 4.54)	0.37 (0.15, 0.89)
Age			
<65 years	1.61 (0.37, 6.94)	10.03 (2.52, 39.88)	0.16 (0.02, 1.20)
>=65 years	0.88 (0.38, 2.04)	1.90 (1.07, 3.39)	0.46 (0.17, 1.28)
Sex			
Male	0.86 (0.26, 2.92)	2.41 (1.22, 4.76)	0.36 (0.09, 1.45)
Female	1.08 (0.44, 2.65)	3.06 (1.45, 6.48)	0.35 (0.11, 1.13)
Baseline FVC percent predicted			
<=70%	0.91 (0.37, 2.27)	2.81 (1.45, 5.46)	0.32 (0.11, 1.00)
>70%	1.50 (0.43, 5.26)	2.60 (1.21, 5.61)	0.57 (0.13, 2.51)
Baseline HRCT pattern			
UIP-like	0.94 (0.40, 2.19)	3.22 (1.71, 6.08)	0.29 (0.10, 0.84)
Other fibrotic patterns	1.23 (0.31, 4.80)	1.96 (0.85, 4.52)	0.63 (0.13, 3.10)
Underlying ILD diagnosis			
iNSIP	1.49 (0.26, 8.56)	3.78 (1.08, 13.21)	0.39 (0.05, 3.39)
Unclassifiable IIP	0.42 (0.07, 2.45)	3.60 (1.04, 12.40)	0.12 (0.01, 1.01)
HP	0.41 (0.04, 4.19)		
Autoimmune ILD	1.02 (0.28, 3.67)	14.64 (2.37, 90.46)	0.07 (0.01, 0.64)
Other ILD	3.24 (0.54, 19.25)	3.06 (0.81, 11.51)	1.06 (0.11, 9.76)
Region			
Europe	2.34 (0.23, 23.38)		
Asia	0.70 (0.27, 1.81)	3.28 (1.39, 7.72)	0.21 (0.06, 0.77)
Canada and USA	0.41 (0.04, 3.96)		
Rest of the World	NC (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.23 (0.62, 2.42)	0.54 (0.28, 1.02)	2.28 (0.89, 5.80)	0.0844	
Age					
<65 years	1.18 (0.33, 4.24)	0.70 (0.28, 1.76)			
>=65 years	1.26 (0.57, 2.83)	0.43 (0.17, 1.04)			
Sex					
Male	1.05 (0.41, 2.69)	0.57 (0.26, 1.23)			
Female	1.46 (0.54, 3.96)	0.51 (0.17, 1.51)			
Baseline FVC percent predicted					
<=70%	2.46 (0.87, 6.95)	0.38 (0.16, 0.92)			
>70%	0.65 (0.25, 1.69)	0.87 (0.34, 2.18)			
Baseline HRCT pattern					
UIP-like	1.03 (0.44, 2.40)	0.73 (0.33, 1.62)			
Other fibrotic patterns	1.70 (0.52, 5.52)	0.35 (0.12, 1.02)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	1.66 (0.63, 4.40)				
Asia	0.50 (0.09, 2.65)	0.67 (0.18, 2.42)			
Canada and USA	0.59 (0.07, 5.22)				
Rest of the World	1.60 (0.28, 9.14)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	1.42 (-3.49, 6.40)	-3.19 (-6.43, 0.05)	4.61 (-1.30, 10.52)
Age			
<65 years	0.86 (-6.78, 8.39)	-2.09 (-7.67, 3.49)	
>=65 years	1.90 (-4.83, 8.83)	-4.04 (-8.03, -0.06)	
Sex			
Male	0.31 (-6.75, 7.52)	-3.68 (-8.62, 1.27)	
Female	2.60 (-4.65, 9.95)	-2.59 (-6.73, 1.55)	
Baseline FVC percent predicted			
<=70%	6.18 (-0.88, 14.25)	-5.01 (-9.43, -0.59)	
>70%	-3.01 (-10.56, 3.85)	-0.78 (-5.68, 4.12)	
Baseline HRCT pattern			
UIP-like	0.16 (-5.57, 5.96)	-1.54 (-5.43, 2.35)	
Other fibrotic patterns	4.36 (-5.91, 14.78)	-6.11 (-11.98, -0.25)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	8.25 (-7.93, 22.78)		
Asia	-1.90 (-7.60, 3.32)	-1.59 (-6.73, 3.55)	
Canada and USA	-4.12 (-20.47, 17.97)		
Rest of the World	2.63 (-8.54, 14.68)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.24 (0.60, 2.59)	0.52 (0.27, 1.02)	2.39 (0.88, 6.48)
Age			
<65 years	1.19 (0.31, 4.59)	0.69 (0.26, 1.84)	
>=65 years	1.29 (0.54, 3.10)	0.41 (0.16, 1.03)	
Sex			
Male	1.05 (0.38, 2.90)	0.54 (0.24, 1.24)	
Female	1.50 (0.51, 4.37)	0.50 (0.16, 1.53)	
Baseline FVC percent predicted			
<=70%	2.63 (0.87, 7.97)	0.36 (0.14, 0.91)	
>70%	0.63 (0.23, 1.76)	0.86 (0.33, 2.26)	
Baseline HRCT pattern			
UIP-like	1.03 (0.42, 2.54)	0.71 (0.31, 1.67)	
Other fibrotic patterns	1.78 (0.49, 6.40)	0.33 (0.11, 1.00)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	1.83 (0.58, 5.78)		
Asia	0.49 (0.09, 2.71)	0.66 (0.17, 2.52)	
Canada and USA	0.56 (0.05, 5.88)		
Rest of the World	1.65 (0.26, 10.39)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Musculoskeletal and connective tissue disorders
PT: Back pain

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	2.45 (1.04, 5.79)	1.01 (0.61, 1.66)	2.43 (0.90, 6.56)	0.0799	
Age					
<65 years	5.66 (0.70, 46.01)	1.17 (0.54, 2.54)			
>=65 years	1.93 (0.73, 5.07)	0.90 (0.47, 1.70)			
Sex					
Male	3.66 (0.78, 17.23)	0.73 (0.35, 1.53)			
Female	1.94 (0.69, 5.50)	1.34 (0.68, 2.65)			
Baseline FVC percent predicted					
<=70%	11.06 (1.43, 85.79)	1.13 (0.56, 2.29)			
>70%	1.12 (0.40, 3.12)	0.90 (0.45, 1.79)			
Baseline HRCT pattern					
UIP-like	2.22 (0.87, 5.70)	0.93 (0.49, 1.76)			
Other fibrotic patterns	3.88 (0.45, 33.77)	1.13 (0.53, 2.42)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	2.52 (0.74, 8.55)				
Asia	1.98 (0.51, 7.72)	0.48 (0.18, 1.26)			
Canada and USA	0.57 (0.02, 13.36)				
Rest of the World	3.20 (0.13, 76.60)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Musculoskeletal and connective tissue disorders
PT: Back pain

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	4.57 (0.28, 9.17)	0.07 (-3.80, 3.94)	4.51 (-1.38, 10.40)
Age			
<65 years	5.61 (-0.83, 12.95)	1.35 (-5.02, 7.72)	
>=65 years	4.02 (-1.98, 10.43)	-0.84 (-5.76, 4.08)	
Sex			
Male	4.58 (-0.82, 10.85)	-2.13 (-7.17, 2.90)	
Female	4.46 (-2.70, 11.86)	2.62 (-3.37, 8.61)	
Baseline FVC percent predicted			
<=70%	8.53 (2.74, 16.05)	0.86 (-4.02, 5.74)	
>70%	0.68 (-6.31, 7.23)	-0.96 (-7.26, 5.33)	
Baseline HRCT pattern			
UIP-like	4.64 (-0.82, 10.48)	-0.56 (-5.23, 4.12)	
Other fibrotic patterns	4.50 (-3.21, 13.11)	1.16 (-5.81, 8.12)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	11.37 (-3.51, 24.79)		
Asia	2.78 (-3.20, 9.15)	-5.25 (-12.09, 1.59)	
Canada and USA	-3.33 (-16.67, 15.30)		
Rest of the World	2.33 (-5.62, 12.06)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Musculoskeletal and connective tissue disorders
PT: Back pain

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	2.57 (1.04, 6.33)	1.01 (0.59, 1.74)	2.55 (0.89, 7.29)
Age			
<65 years	6.00 (0.71, 50.95)	1.19 (0.51, 2.76)	
>=65 years	2.02 (0.72, 5.61)	0.89 (0.44, 1.79)	
Sex			
Male	3.84 (0.78, 18.88)	0.72 (0.32, 1.58)	
Female	2.04 (0.67, 6.18)	1.38 (0.66, 2.92)	
Baseline FVC percent predicted			
<=70%	12.10 (1.51, 97.32)	1.14 (0.54, 2.44)	
>70%	1.13 (0.38, 3.36)	0.89 (0.41, 1.91)	
Baseline HRCT pattern			
UIP-like	2.34 (0.86, 6.31)	0.92 (0.46, 1.85)	
Other fibrotic patterns	4.06 (0.44, 37.39)	1.15 (0.50, 2.64)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	2.87 (0.73, 11.21)		
Asia	2.04 (0.50, 8.38)	0.45 (0.16, 1.28)	
Canada and USA	0.00 (NC, NC)		
Rest of the World	NC (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Nervous system disorders
PT: Headache

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.55, 1.85)	1.41 (0.88, 2.25)	0.72 (0.33, 1.54)	0.3938	
Age					
<65 years	0.47 (0.17, 1.32)	1.07 (0.54, 2.11)			
>=65 years	1.64 (0.73, 3.66)	1.72 (0.91, 3.25)			
Sex					
Male	1.05 (0.43, 2.54)	1.91 (0.75, 4.86)			
Female	0.97 (0.42, 2.24)	1.26 (0.74, 2.14)			
Baseline FVC percent predicted					
<=70%	1.23 (0.56, 2.71)	1.46 (0.77, 2.77)			
>70%	0.84 (0.33, 2.16)	1.34 (0.68, 2.63)			
Baseline HRCT pattern					
UIP-like	1.20 (0.57, 2.50)	1.48 (0.79, 2.75)			
Other fibrotic patterns	0.69 (0.23, 2.07)	1.31 (0.65, 2.63)			
Underlying ILD diagnosis					
iNSIP	0.36 (0.03, 3.87)	1.17 (0.35, 3.91)			
Unclassifiable IIP	0.23 (0.03, 1.92)	2.63 (0.83, 8.32)			
HP	1.63 (0.48, 5.54)				
Autoimmune ILD	1.35 (0.49, 3.70)	2.04 (0.65, 6.43)			
Other ILD	1.92 (0.47, 7.84)	6.34 (0.83, 48.52)			
Region					
Europe	1.01 (0.38, 2.67)				
Asia	0.62 (0.21, 1.83)	0.67 (0.18, 2.52)			
Canada and USA	0.88 (0.09, 9.03)				
Rest of the World	1.78 (0.45, 7.01)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Nervous system disorders
PT: Headache

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.08 (-5.29, 5.46)	3.05 (-1.05, 7.15)	-2.97 (-9.73, 3.78)
Age			
<65 years	-6.37 (-15.67, 2.41)	0.69 (-6.32, 7.70)	
>=65 years	4.13 (-2.68, 11.22)	4.46 (-0.65, 9.58)	
Sex			
Male	0.35 (-7.03, 7.87)	3.04 (-1.21, 7.29)	
Female	-0.26 (-8.44, 7.83)	3.21 (-3.97, 10.38)	
Baseline FVC percent predicted			
<=70%	2.14 (-6.11, 11.01)	3.24 (-2.14, 8.61)	
>70%	-1.24 (-8.69, 5.63)	2.77 (-3.60, 9.15)	
Baseline HRCT pattern			
UIP-like	1.50 (-4.84, 7.94)	3.10 (-1.75, 7.95)	
Other fibrotic patterns	-3.36 (-14.21, 7.17)	2.95 (-4.57, 10.47)	
Underlying ILD diagnosis			
iNSIP	-3.18 (-14.78, 5.41)	1.09 (-7.18, 9.36)	
Unclassifiable IIP	-8.61 (-22.96, 3.75)	10.56 (-0.56, 21.67)	
HP	6.41 (-9.85, 24.41)		
Autoimmune ILD	2.98 (-7.40, 13.53)	4.29 (-2.19, 10.76)	
Other ILD	7.67 (-8.89, 27.10)	11.11 (0.51, 21.71)	
Region			
Europe	0.09 (-15.73, 14.45)		
Asia	-2.87 (-10.03, 3.99)	-1.58 (-6.56, 3.40)	
Canada and USA	-0.78 (-16.22, 20.86)		
Rest of the World	5.11 (-7.68, 18.65)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Nervous system disorders
PT: Headache

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.52, 1.96)	1.46 (0.87, 2.44)	0.69 (0.30, 1.60)
Age			
<65 years	0.44 (0.14, 1.35)	1.08 (0.50, 2.32)	
>=65 years	1.71 (0.72, 4.11)	1.81 (0.91, 3.60)	
Sex			
Male	1.05 (0.40, 2.75)	1.98 (0.74, 5.26)	
Female	0.97 (0.39, 2.43)	1.31 (0.71, 2.42)	
Baseline FVC percent predicted			
<=70%	1.26 (0.52, 3.04)	1.52 (0.75, 3.05)	
>70%	0.83 (0.30, 2.29)	1.38 (0.65, 2.92)	
Baseline HRCT pattern			
UIP-like	1.22 (0.54, 2.72)	1.53 (0.78, 3.00)	
Other fibrotic patterns	0.67 (0.20, 2.22)	1.36 (0.62, 2.96)	
Underlying ILD diagnosis			
iNSIP	0.35 (0.03, 4.02)	1.19 (0.32, 4.33)	
Unclassifiable IIP	0.21 (0.02, 1.93)	2.96 (0.84, 10.42)	
HP	1.75 (0.43, 7.18)		
Autoimmune ILD	1.40 (0.46, 4.26)	2.14 (0.64, 7.12)	
Other ILD	2.10 (0.43, 10.31)	6.99 (0.83, 59.27)	
Region			
Europe	1.01 (0.32, 3.18)		
Asia	0.60 (0.19, 1.90)	0.67 (0.18, 2.49)	
Canada and USA	0.88 (0.07, 10.43)		
Rest of the World	1.89 (0.42, 8.42)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Anxiety

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.13 (0.68, 1.87)				
Age					
<65 years	1.11 (0.53, 2.35)				
>=65 years	1.13 (0.57, 2.25)				
Sex					
Male	0.70 (0.35, 1.38)				
Female	2.22 (0.95, 5.18)				
Baseline FVC percent predicted					
<=70%	1.14 (0.56, 2.31)				
>70%	1.14 (0.55, 2.38)				
Baseline HRCT pattern					
UIP-like	0.97 (0.54, 1.75)				
Other fibrotic patterns	1.75 (0.62, 4.93)				
Underlying ILD diagnosis					
iNSIP	0.48 (0.15, 1.61)				
Unclassifiable IIP	0.90 (0.24, 3.34)				
HP	0.98 (0.24, 4.03)				
Autoimmune ILD	1.78 (0.79, 3.96)				
Other ILD	1.44 (0.32, 6.56)				
Region					
Europe	0.66 (0.26, 1.67)				
Asia	0.90 (0.40, 2.03)				
Canada and USA	2.21 (0.68, 7.12)				
Rest of the World	3.21 (0.68, 15.05)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Anxiety

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	1.47 (-4.67, 7.62)		
Age			
<65 years	1.52 (-9.21, 12.06)		
>=65 years	1.29 (-6.22, 8.95)		
Sex			
Male	-4.71 (-13.62, 4.29)		
Female	8.08 (-0.33, 16.61)		
Baseline FVC percent predicted			
<=70%	1.68 (-7.25, 11.16)		
>70%	1.52 (-7.19, 9.80)		
Baseline HRCT pattern			
UIP-like	-0.32 (-7.77, 7.17)		
Other fibrotic patterns	5.82 (-5.33, 17.03)		
Underlying ILD diagnosis			
iNSIP	-7.73 (-22.47, 5.03)		
Unclassifiable IIP	-1.11 (-16.55, 13.56)		
HP	-0.26 (-15.10, 16.55)		
Autoimmune ILD	8.73 (-3.43, 20.84)		
Other ILD	3.67 (-11.94, 22.43)		
Region			
Europe	-6.79 (-22.98, 8.23)		
Asia	-1.03 (-9.41, 7.29)		
Canada and USA	16.08 (-6.89, 41.12)		
Rest of the World	9.61 (-2.98, 23.28)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Anxiety

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.15 (0.65, 2.04)		
Age			
<65 years	1.13 (0.48, 2.70)		
>=65 years	1.14 (0.53, 2.47)		
Sex			
Male	0.66 (0.30, 1.44)		
Female	2.43 (0.96, 6.18)		
Baseline FVC percent predicted			
<=70%	1.16 (0.52, 2.61)		
>70%	1.16 (0.51, 2.66)		
Baseline HRCT pattern			
UIP-like	0.97 (0.50, 1.90)		
Other fibrotic patterns	1.86 (0.59, 5.90)		
Underlying ILD diagnosis			
iNSIP	0.44 (0.12, 1.69)		
Unclassifiable IIP	0.89 (0.21, 3.85)		
HP	0.97 (0.20, 4.71)		
Autoimmune ILD	1.97 (0.77, 5.04)		
Other ILD	1.50 (0.28, 8.12)		
Region			
Europe	0.61 (0.20, 1.85)		
Asia	0.89 (0.36, 2.19)		
Canada and USA	2.71 (0.62, 11.92)		
Rest of the World	3.57 (0.68, 18.74)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Depression

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.94 (0.57, 1.55)	0.90 (0.38, 2.15)	1.04 (0.38, 2.83)	0.9400	
Age					
<65 years	1.35 (0.54, 3.37)	0.68 (0.17, 2.76)			
>=65 years	0.80 (0.44, 1.47)	1.08 (0.37, 3.16)			
Sex					
Male	0.58 (0.28, 1.20)	0.99 (0.22, 4.38)			
Female	1.56 (0.74, 3.27)	0.87 (0.31, 2.44)			
Baseline FVC percent predicted					
<=70%	0.91 (0.48, 1.71)	0.83 (0.27, 2.56)			
>70%	1.12 (0.49, 2.55)	1.01 (0.28, 3.71)			
Baseline HRCT pattern					
UIP-like	0.86 (0.46, 1.62)	0.79 (0.31, 2.02)			
Other fibrotic patterns	1.08 (0.47, 2.48)	1.69 (0.22, 13.07)			
Underlying ILD diagnosis					
iNSIP	0.36 (0.07, 1.89)				
Unclassifiable IIP	0.90 (0.28, 2.86)				
HP	0.87 (0.27, 2.80)				
Autoimmune ILD	1.13 (0.49, 2.60)				
Other ILD	1.80 (0.54, 6.05)				
Region					
Europe	0.86 (0.34, 2.18)				
Asia	0.91 (0.44, 1.91)	1.00 (0.06, 17.11)			
Canada and USA	2.35 (0.60, 9.29)				
Rest of the World	0.43 (0.09, 2.09)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Depression

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.79 (-6.98, 5.40)	-0.28 (-2.62, 2.06)	-0.52 (-7.13, 6.10)
Age			
<65 years	2.93 (-6.51, 12.28)	-1.04 (-4.83, 2.76)	
>=65 years	-2.99 (-11.22, 5.35)	0.23 (-2.87, 3.33)	
Sex			
Male	-6.51 (-15.19, 2.21)	-0.02 (-2.63, 2.60)	
Female	5.24 (-3.67, 14.15)	-0.55 (-4.64, 3.55)	
Baseline FVC percent predicted			
<=70%	-1.52 (-11.08, 8.56)	-0.52 (-3.73, 2.69)	
>70%	1.02 (-7.05, 8.65)	0.04 (-3.53, 3.61)	
Baseline HRCT pattern			
UIP-like	-1.64 (-8.78, 5.54)	-0.84 (-4.17, 2.49)	
Other fibrotic patterns	1.09 (-11.42, 13.46)	0.75 (-2.13, 3.63)	
Underlying ILD diagnosis			
iNSIP	-6.36 (-19.68, 4.22)		
Unclassifiable IIP	-1.39 (-17.75, 14.30)		
HP	-2.05 (-18.49, 16.21)		
Autoimmune ILD	1.61 (-9.97, 13.25)		
Other ILD	8.89 (-9.16, 29.16)		
Region			
Europe	-2.41 (-18.57, 12.42)		
Asia	-1.05 (-9.97, 7.83)	0.00 (-2.32, 2.32)	
Canada and USA	13.53 (-7.43, 38.15)		
Rest of the World	-6.22 (-18.84, 6.21)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Depression

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.93 (0.53, 1.64)	0.90 (0.37, 2.19)	1.03 (0.36, 2.98)
Age			
<65 years	1.39 (0.50, 3.85)	0.67 (0.16, 2.82)	
>=65 years	0.78 (0.39, 1.56)	1.08 (0.36, 3.28)	
Sex			
Male	0.54 (0.24, 1.23)	0.99 (0.22, 4.49)	
Female	1.65 (0.71, 3.83)	0.87 (0.30, 2.54)	
Baseline FVC percent predicted			
<=70%	0.89 (0.42, 1.88)	0.83 (0.26, 2.63)	
>70%	1.13 (0.46, 2.80)	1.01 (0.27, 3.85)	
Baseline HRCT pattern			
UIP-like	0.85 (0.42, 1.72)	0.78 (0.29, 2.08)	
Other fibrotic patterns	1.09 (0.41, 2.89)	1.71 (0.21, 14.20)	
Underlying ILD diagnosis			
iNSIP	0.34 (0.06, 1.95)		
Unclassifiable IIP	0.89 (0.23, 3.35)		
HP	0.85 (0.22, 3.32)		
Autoimmune ILD	1.15 (0.44, 3.02)		
Other ILD	2.00 (0.48, 8.35)		
Region			
Europe	0.84 (0.28, 2.54)		
Asia	0.90 (0.39, 2.08)	1.00 (0.06, 17.56)	
Canada and USA	2.77 (0.54, 14.23)		
Rest of the World	0.40 (0.07, 2.18)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Insomnia

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.59 (0.63, 4.02)	0.93 (0.50, 1.72)	1.71 (0.56, 5.19)	0.3476	
Age					
<65 years	0.94 (0.20, 4.54)	1.69 (0.61, 4.67)			
>=65 years	2.11 (0.65, 6.83)	0.62 (0.27, 1.41)			
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%	0.74 (0.18, 3.01)	0.99 (0.47, 2.04)			
>70%	3.35 (0.73, 15.45)	0.81 (0.27, 2.39)			
Baseline HRCT pattern					
UIP-like	1.44 (0.47, 4.43)	1.29 (0.64, 2.60)			
Other fibrotic patterns	1.94 (0.37, 10.22)	0.32 (0.08, 1.35)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	3.80 (0.19, 76.95)				
Asia	1.59 (0.54, 4.69)	0.86 (0.39, 1.86)			
Canada and USA	5.17 (0.22, 120.26)				
Rest of the World	0.21 (0.01, 4.33)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Insomnia

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	1.85 (-2.04, 5.91)	-0.38 (-3.60, 2.84)	2.22 (-2.89, 7.34)
Age			
<65 years	-0.21 (-7.06, 6.38)	2.76 (-2.40, 7.93)	
>=65 years	3.18 (-2.03, 8.90)	-2.38 (-6.47, 1.70)	
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%	-1.11 (-6.80, 5.04)	-0.10 (-4.82, 4.63)	
>70%	4.53 (-1.23, 10.46)	-0.81 (-5.05, 3.44)	
Baseline HRCT pattern			
UIP-like	1.38 (-3.27, 6.27)	1.55 (-2.80, 5.89)	
Other fibrotic patterns	2.94 (-5.48, 11.74)	-3.82 (-8.38, 0.74)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	3.77 (-5.40, 12.75)		
Asia	2.76 (-4.13, 9.87)	-1.50 (-9.16, 6.15)	
Canada and USA	5.88 (-6.46, 26.98)		
Rest of the World	-4.35 (-14.53, 4.44)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Insomnia

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.62 (0.61, 4.25)	0.93 (0.48, 1.78)	1.75 (0.54, 5.60)
Age			
<65 years	0.94 (0.18, 4.80)	1.74 (0.60, 5.09)	
>=65 years	2.18 (0.64, 7.41)	0.61 (0.26, 1.44)	
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%	0.73 (0.17, 3.13)	0.98 (0.45, 2.15)	
>70%	3.52 (0.73, 16.94)	0.80 (0.26, 2.52)	
Baseline HRCT pattern			
UIP-like	1.46 (0.45, 4.69)	1.31 (0.62, 2.79)	
Other fibrotic patterns	2.00 (0.35, 11.32)	0.31 (0.07, 1.34)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	NC (NC, NC)		
Asia	1.63 (0.52, 5.16)	0.84 (0.35, 2.04)	
Canada and USA	NC (NC, NC)		
Rest of the World	0.00 (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.22 (0.80, 1.86)	0.76 (0.53, 1.09)	1.61 (0.92, 2.80)	0.0944	
Age					
<65 years	1.46 (0.73, 2.93)	0.65 (0.39, 1.09)			
>=65 years	1.10 (0.65, 1.88)	0.84 (0.50, 1.38)			
Sex					
Male	1.53 (0.84, 2.80)	0.93 (0.57, 1.52)			
Female	0.97 (0.54, 1.77)	0.60 (0.35, 1.04)			
Baseline FVC percent predicted					
<=70%	1.52 (0.85, 2.71)	0.68 (0.43, 1.08)			
>70%	1.00 (0.54, 1.84)	0.90 (0.50, 1.61)			
Baseline HRCT pattern					
UIP-like	0.90 (0.53, 1.53)	0.90 (0.56, 1.46)			
Other fibrotic patterns	2.18 (1.02, 4.66)	0.60 (0.34, 1.06)			
Underlying ILD diagnosis					
iNSIP	1.16 (0.41, 3.29)	0.55 (0.19, 1.56)			
Unclassifiable IIP	1.08 (0.36, 3.24)	0.99 (0.47, 2.11)			
HP	1.16 (0.51, 2.64)				
Autoimmune ILD	1.12 (0.51, 2.46)	0.39 (0.13, 1.15)			
Other ILD	2.52 (0.82, 7.70)	1.01 (0.44, 2.30)			
Region					
Europe	1.51 (0.67, 3.39)				
Asia	0.92 (0.47, 1.82)	0.71 (0.29, 1.75)			
Canada and USA	4.71 (1.44, 15.41)				
Rest of the World	0.53 (0.17, 1.65)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	3.32 (-3.64, 10.27)	-3.76 (-8.76, 1.25)	7.07 (-1.49, 15.64)
Age			
<65 years	6.07 (-5.22, 17.10)	-7.10 (-15.81, 1.60)	
>=65 years	1.60 (-7.30, 10.58)	-2.16 (-8.19, 3.87)	
Sex			
Male	6.89 (-2.80, 16.61)	-0.98 (-7.92, 5.95)	
Female	-0.47 (-10.57, 9.58)	-6.77 (-13.98, 0.43)	
Baseline FVC percent predicted			
<=70%	7.47 (-2.83, 18.10)	-5.79 (-12.69, 1.11)	
>70%	-0.06 (-9.78, 9.25)	-1.32 (-8.47, 5.83)	
Baseline HRCT pattern			
UIP-like	-1.54 (-9.53, 6.50)	-1.23 (-7.19, 4.73)	
Other fibrotic patterns	14.77 (0.93, 28.00)	-8.29 (-17.18, 0.59)	
Underlying ILD diagnosis			
iNSIP	2.05 (-13.25, 15.63)	-5.50 (-15.03, 4.03)	
Unclassifiable IIP	1.11 (-15.66, 17.20)	-0.10 (-14.09, 13.89)	
HP	3.59 (-16.13, 24.20)		
Autoimmune ILD	1.63 (-10.36, 13.66)	-6.35 (-13.36, 0.66)	
Other ILD	16.89 (-2.86, 37.58)	0.11 (-15.73, 15.95)	
Region			
Europe	8.92 (-8.65, 24.73)		
Asia	-1.07 (-10.48, 8.32)	-2.45 (-9.23, 4.32)	
Canada and USA	37.06 (10.97, 59.99)		
Rest of the World	-8.09 (-22.56, 6.75)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.27 (0.77, 2.11)	0.73 (0.48, 1.11)	1.75 (0.91, 3.37)
Age			
<65 years	1.57 (0.69, 3.58)	0.60 (0.32, 1.12)	
>=65 years	1.12 (0.59, 2.13)	0.81 (0.46, 1.44)	
Sex			
Male	1.66 (0.81, 3.40)	0.92 (0.52, 1.64)	
Female	0.97 (0.47, 1.98)	0.56 (0.30, 1.04)	
Baseline FVC percent predicted			
<=70%	1.66 (0.82, 3.37)	0.63 (0.37, 1.09)	
>70%	1.00 (0.48, 2.05)	0.88 (0.45, 1.73)	
Baseline HRCT pattern			
UIP-like	0.89 (0.48, 1.65)	0.89 (0.52, 1.54)	
Other fibrotic patterns	2.63 (1.05, 6.57)	0.55 (0.28, 1.06)	
Underlying ILD diagnosis			
iNSIP	1.19 (0.36, 3.96)	0.51 (0.16, 1.65)	
Unclassifiable IIP	1.09 (0.30, 3.95)	0.99 (0.39, 2.54)	
HP	1.21 (0.40, 3.64)		
Autoimmune ILD	1.14 (0.45, 2.88)	0.36 (0.11, 1.13)	
Other ILD	3.11 (0.80, 12.09)	1.01 (0.36, 2.84)	
Region			
Europe	1.69 (0.61, 4.69)		
Asia	0.91 (0.42, 2.00)	0.69 (0.25, 1.89)	
Canada and USA	8.00 (1.74, 36.81)		
Rest of the World	0.49 (0.14, 1.75)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.37 (0.75, 2.48)	0.91 (0.65, 1.28)	1.50 (0.75, 2.99)	0.2492	
Age					
<65 years	1.13 (0.36, 3.57)	1.16 (0.62, 2.14)			
>=65 years	1.49 (0.74, 3.00)	0.83 (0.55, 1.26)			
Sex					
Male	2.30 (0.83, 6.41)	1.18 (0.77, 1.81)			
Female	0.97 (0.46, 2.07)	0.59 (0.33, 1.06)			
Baseline FVC percent predicted					
<=70%	1.33 (0.64, 2.78)	0.67 (0.44, 1.02)			
>70%	1.68 (0.59, 4.75)	1.65 (0.89, 3.04)			
Baseline HRCT pattern					
UIP-like	2.05 (0.90, 4.66)	1.23 (0.79, 1.91)			
Other fibrotic patterns	0.75 (0.30, 1.90)	0.56 (0.31, 0.99)			
Underlying ILD diagnosis					
iNSIP	0.73 (0.23, 2.35)	0.96 (0.31, 2.99)			
Unclassifiable IIP	2.70 (0.29, 24.81)	1.21 (0.52, 2.84)			
HP	1.63 (0.48, 5.54)				
Autoimmune ILD	1.01 (0.31, 3.35)	0.85 (0.41, 1.74)			
Other ILD	3.60 (0.76, 17.10)	0.93 (0.44, 1.97)			
Region					
Europe	1.89 (0.64, 5.58)				
Asia	0.62 (0.21, 1.83)	1.18 (0.35, 4.00)			
Canada and USA	2.21 (0.68, 7.12)				
Rest of the World	3.21 (0.35, 29.69)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	2.80 (-2.65, 8.32)	-1.40 (-6.50, 3.70)	4.20 (-3.29, 11.69)
Age			
<65 years	0.79 (-7.38, 8.83)	1.80 (-5.77, 9.36)	
>=65 years	4.25 (-3.25, 11.93)	-3.07 (-9.88, 3.74)	
Sex			
Male	5.60 (-1.28, 12.99)	2.89 (-4.64, 10.42)	
Female	-0.31 (-9.05, 8.34)	-6.22 (-12.94, 0.51)	
Baseline FVC percent predicted			
<=70%	3.37 (-5.32, 12.66)	-7.00 (-14.24, 0.25)	
>70%	3.26 (-3.72, 9.98)	5.75 (-1.20, 12.70)	
Baseline HRCT pattern			
UIP-like	5.33 (-0.71, 11.65)	2.95 (-3.28, 9.18)	
Other fibrotic patterns	-3.46 (-15.30, 8.22)	-9.23 (-18.05, -0.40)	
Underlying ILD diagnosis			
iNSIP	-3.41 (-17.96, 9.22)	-0.33 (-8.99, 8.32)	
Unclassifiable IIP	4.72 (-7.69, 17.30)	3.01 (-9.93, 15.94)	
HP	6.41 (-9.85, 24.41)		
Autoimmune ILD	0.10 (-9.23, 9.50)	-2.05 (-10.92, 6.83)	
Other ILD	14.44 (-2.37, 33.99)	-1.64 (-18.32, 15.05)	
Region			
Europe	8.87 (-6.59, 22.74)		
Asia	-2.87 (-10.03, 3.99)	0.72 (-4.51, 5.95)	
Canada and USA	16.08 (-6.89, 41.12)		
Rest of the World	4.80 (-5.44, 16.57)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.41 (0.73, 2.71)	0.89 (0.59, 1.35)	1.58 (0.73, 3.41)
Age			
<65 years	1.14 (0.33, 3.89)	1.18 (0.58, 2.41)	
>=65 years	1.56 (0.72, 3.42)	0.80 (0.48, 1.32)	
Sex			
Male	2.44 (0.82, 7.27)	1.22 (0.72, 2.07)	
Female	0.97 (0.41, 2.26)	0.54 (0.28, 1.06)	
Baseline FVC percent predicted			
<=70%	1.38 (0.60, 3.19)	0.61 (0.36, 1.02)	
>70%	1.74 (0.57, 5.25)	1.77 (0.88, 3.58)	
Baseline HRCT pattern			
UIP-like	2.17 (0.90, 5.24)	1.28 (0.76, 2.16)	
Other fibrotic patterns	0.73 (0.25, 2.08)	0.50 (0.25, 0.98)	
Underlying ILD diagnosis			
iNSIP	0.70 (0.19, 2.60)	0.95 (0.28, 3.27)	
Unclassifiable IIP	2.84 (0.28, 28.59)	1.26 (0.46, 3.42)	
HP	1.75 (0.43, 7.18)		
Autoimmune ILD	1.02 (0.28, 3.67)	0.82 (0.36, 1.91)	
Other ILD	4.25 (0.75, 23.98)	0.91 (0.34, 2.43)	
Region			
Europe	2.09 (0.60, 7.24)		
Asia	0.60 (0.19, 1.90)	1.19 (0.33, 4.34)	
Canada and USA	2.71 (0.62, 11.92)		
Rest of the World	3.38 (0.34, 33.76)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Interstitial lung disease

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.64 (0.25, 1.63)	0.48 (0.32, 0.71)	1.34 (0.49, 3.69)	0.5676	
Age					
<65 years	0.19 (0.02, 1.58)	0.24 (0.11, 0.52)			
>=65 years	1.05 (0.35, 3.18)	0.65 (0.41, 1.04)			
Sex					
Male	0.15 (0.02, 1.19)	0.51 (0.30, 0.86)			
Female	1.46 (0.42, 5.02)	0.45 (0.25, 0.81)			
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like	0.68 (0.25, 1.88)	0.46 (0.29, 0.72)			
Other fibrotic patterns	0.48 (0.05, 5.22)	0.54 (0.24, 1.24)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	0.38 (0.04, 4.02)				
Asia	0.66 (0.19, 2.27)	0.45 (0.28, 0.74)			
Canada and USA	1.76 (0.12, 26.45)				
Rest of the World	0.53 (0.05, 5.69)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Interstitial lung disease

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-1.77 (-5.82, 2.12)	-9.29 (-14.16, -4.41)	7.51 (1.23, 13.80)
Age			
<65 years	-4.89 (-12.26, 1.19)	-13.99 (-21.27, -6.72)	
>=65 years	0.23 (-5.14, 5.76)	-6.11 (-12.61, 0.39)	
Sex			
Male	-5.13 (-11.08, -0.06)	-9.05 (-15.88, -2.22)	
Female	1.73 (-4.54, 8.14)	-9.40 (-16.21, -2.59)	
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like	-1.80 (-7.01, 3.30)	-11.67 (-18.21, -5.12)	
Other fibrotic patterns	-1.61 (-9.28, 5.35)	-5.05 (-11.67, 1.58)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	-3.11 (-14.72, 5.72)		
Asia	-1.92 (-8.47, 4.35)	-18.34 (-29.36, -7.32)	
Canada and USA	2.55 (-11.64, 23.83)		
Rest of the World	-2.02 (-12.38, 8.21)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Interstitial lung disease

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.63 (0.24, 1.66)	0.43 (0.27, 0.67)	1.47 (0.51, 4.26)
Age			
<65 years	0.18 (0.02, 1.57)	0.19 (0.08, 0.47)	
>=65 years	1.06 (0.33, 3.36)	0.61 (0.35, 1.04)	
Sex			
Male	0.14 (0.02, 1.17)	0.46 (0.25, 0.84)	
Female	1.49 (0.41, 5.42)	0.40 (0.20, 0.79)	
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like	0.67 (0.23, 1.93)	0.40 (0.24, 0.68)	
Other fibrotic patterns	0.48 (0.04, 5.39)	0.50 (0.20, 1.26)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	0.37 (0.03, 4.18)		
Asia	0.65 (0.18, 2.36)	0.35 (0.18, 0.66)	
Canada and USA	1.81 (0.11, 30.97)		
Rest of the World	0.52 (0.05, 5.99)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Vascular disorders
PT: Hypertension

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.11 (0.48, 2.56)	1.15 (0.59, 2.25)	0.97 (0.33, 2.82)	0.9511	
Age					
<65 years	0.71 (0.16, 3.07)	1.18 (0.47, 2.99)			
>=65 years	1.40 (0.50, 3.94)	1.05 (0.41, 2.71)			
Sex					
Male	0.35 (0.07, 1.69)	1.14 (0.41, 3.23)			
Female	2.19 (0.69, 6.89)	1.16 (0.49, 2.73)			
Baseline FVC percent predicted					
<=70%	0.77 (0.26, 2.27)	0.99 (0.43, 2.27)			
>70%	2.52 (0.52, 12.20)	1.43 (0.48, 4.30)			
Baseline HRCT pattern					
UIP-like	1.17 (0.44, 3.15)	1.04 (0.41, 2.67)			
Other fibrotic patterns	0.97 (0.20, 4.63)	1.26 (0.50, 3.20)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Vascular disorders
PT: Hypertension

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.50 (-3.71, 4.75)	0.62 (-2.35, 3.60)	-0.13 (-5.29, 5.04)
Age			
<65 years	-1.41 (-8.69, 5.39)	0.99 (-4.45, 6.43)	
>=65 years	1.74 (-3.88, 7.66)	0.18 (-3.30, 3.66)	
Sex			
Male	-3.37 (-9.17, 1.95)	0.48 (-3.21, 4.16)	
Female	4.48 (-2.26, 11.56)	0.87 (-3.99, 5.73)	
Baseline FVC percent predicted			
<=70%	-1.57 (-8.29, 5.64)	-0.07 (-4.27, 4.13)	
>70%	2.92 (-2.56, 8.41)	1.45 (-2.79, 5.69)	
Baseline HRCT pattern			
UIP-like	0.76 (-4.34, 6.00)	0.15 (-3.17, 3.47)	
Other fibrotic patterns	-0.14 (-8.88, 8.42)	1.47 (-4.43, 7.37)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Vascular disorders
PT: Hypertension

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.12 (0.46, 2.68)	1.16 (0.57, 2.32)	0.97 (0.31, 2.96)
Age			
<65 years	0.70 (0.15, 3.21)	1.19 (0.45, 3.19)	
>=65 years	1.43 (0.48, 4.24)	1.05 (0.40, 2.80)	
Sex			
Male	0.34 (0.07, 1.70)	1.15 (0.39, 3.37)	
Female	2.30 (0.68, 7.69)	1.17 (0.48, 2.87)	
Baseline FVC percent predicted			
<=70%	0.76 (0.24, 2.39)	0.98 (0.41, 2.37)	
>70%	2.59 (0.51, 13.13)	1.45 (0.47, 4.48)	
Baseline HRCT pattern			
UIP-like	1.18 (0.42, 3.34)	1.04 (0.40, 2.73)	
Other fibrotic patterns	0.97 (0.19, 4.98)	1.28 (0.47, 3.46)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.43 (0.23, 0.83)				
Age					
<65 years	0.51 (0.20, 1.33)				
>=65 years	0.37 (0.15, 0.91)				
Sex					
Male	0.33 (0.14, 0.80)				
Female	0.65 (0.24, 1.76)				
Baseline FVC percent predicted					
<=70%	0.53 (0.27, 1.07)				
>70%	0.34 (0.07, 1.69)				
Baseline HRCT pattern					
UIP-like	0.31 (0.14, 0.71)				
Other fibrotic patterns	0.97 (0.29, 3.19)				
Underlying ILD diagnosis					
iNSIP	0.55 (0.13, 2.30)				
Unclassifiable IIP	1.35 (0.24, 7.63)				
HP	0.19 (0.02, 1.43)				
Autoimmune ILD	0.13 (0.02, 0.99)				
Other ILD	0.82 (0.27, 2.52)				
Region					
Europe	0.75 (0.23, 2.43)				
Asia	0.43 (0.19, 1.01)				
Canada and USA	0.25 (0.01, 4.50)				
Rest of the World	0.12 (0.01, 2.14)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-7.16 (-12.68, -1.80)		
Age			
<65 years	-6.43 (-16.09, 2.80)		
>=65 years	-7.68 (-14.61, -0.98)		
Sex			
Male	-10.97 (-19.29, -2.82)		
Female	-2.99 (-10.46, 4.19)		
Baseline FVC percent predicted			
<=70%	-9.07 (-18.39, 0.78)		
>70%	-3.19 (-9.27, 1.72)		
Baseline HRCT pattern			
UIP-like	-10.01 (-16.76, -3.51)		
Other fibrotic patterns	-0.24 (-10.40, 9.76)		
Underlying ILD diagnosis			
iNSIP	-4.55 (-18.08, 6.63)		
Unclassifiable IIP	1.94 (-11.57, 14.95)		
HP	-14.62 (-29.59, 1.46)		
Autoimmune ILD	-9.84 (-19.33, -1.56)		
Other ILD	-3.44 (-21.75, 17.58)		
Region			
Europe	-3.07 (-17.69, 9.84)		
Asia	-8.55 (-17.24, -0.10)		
Canada and USA	-10.00 (-25.62, 9.56)		
Rest of the World	-8.70 (-20.32, 1.05)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.40 (0.20, 0.81)		
Age			
<65 years	0.48 (0.17, 1.36)		
>=65 years	0.34 (0.13, 0.90)		
Sex			
Male	0.29 (0.11, 0.76)		
Female	0.63 (0.22, 1.83)		
Baseline FVC percent predicted			
<=70%	0.48 (0.22, 1.07)		
>70%	0.32 (0.06, 1.71)		
Baseline HRCT pattern			
UIP-like	0.28 (0.12, 0.67)		
Other fibrotic patterns	0.97 (0.27, 3.51)		
Underlying ILD diagnosis			
iNSIP	0.52 (0.11, 2.46)		
Unclassifiable IIP	1.38 (0.22, 8.76)		
HP	0.16 (0.02, 1.36)		
Autoimmune ILD	0.11 (0.01, 0.94)		
Other ILD	0.79 (0.20, 3.05)		
Region			
Europe	0.73 (0.20, 2.71)		
Asia	0.39 (0.15, 1.00)		
Canada and USA	0.00 (NC, NC)		
Rest of the World	0.00 (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.97 (0.55, 1.68)	1.28 (0.74, 2.20)	0.76 (0.35, 1.64)	0.4779	
Age					
<65 years	0.94 (0.28, 3.14)	1.71 (0.63, 4.66)			
>=65 years	0.99 (0.54, 1.85)	1.16 (0.60, 2.23)			
Sex					
Male	0.87 (0.39, 1.93)	1.46 (0.74, 2.89)			
Female	1.06 (0.49, 2.30)	0.98 (0.41, 2.32)			
Baseline FVC percent predicted					
<=70%	1.23 (0.63, 2.39)	1.12 (0.59, 2.12)			
>70%	0.73 (0.28, 1.96)	1.75 (0.63, 4.87)			
Baseline HRCT pattern					
UIP-like	1.03 (0.51, 2.08)	1.13 (0.60, 2.13)			
Other fibrotic patterns	0.86 (0.35, 2.10)	1.72 (0.62, 4.82)			
Underlying ILD diagnosis					
iNSIP	1.64 (0.54, 4.94)	0.63 (0.19, 2.08)			
Unclassifiable IIP	1.35 (0.24, 7.63)	5.51 (0.60, 50.42)			
HP	0.65 (0.06, 6.83)				
Autoimmune ILD	0.71 (0.29, 1.76)	1.42 (0.63, 3.19)			
Other ILD	0.58 (0.12, 2.74)	0.72 (0.16, 3.21)			
Region					
Europe	2.64 (0.58, 12.04)				
Asia	0.74 (0.37, 1.49)	0.88 (0.39, 2.03)			
Canada and USA	0.88 (0.09, 9.03)				
Rest of the World	0.71 (0.13, 4.06)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.36 (-6.11, 5.40)	1.62 (-1.98, 5.22)	-1.98 (-8.76, 4.81)
Age			
<65 years	-0.34 (-8.34, 7.39)	2.87 (-2.39, 8.13)	
>=65 years	-0.07 (-8.16, 8.12)	1.10 (-3.73, 5.93)	
Sex			
Male	-1.34 (-9.31, 6.71)	2.91 (-2.36, 8.18)	
Female	0.63 (-7.96, 9.16)	-0.12 (-4.94, 4.69)	
Baseline FVC percent predicted			
<=70%	2.91 (-6.41, 12.76)	0.95 (-4.38, 6.29)	
>70%	-2.05 (-9.39, 4.65)	2.39 (-2.09, 6.88)	
Baseline HRCT pattern			
UIP-like	0.23 (-6.31, 6.83)	0.88 (-3.82, 5.58)	
Other fibrotic patterns	-1.94 (-14.01, 9.99)	2.99 (-2.55, 8.54)	
Underlying ILD diagnosis			
iNSIP	6.36 (-8.69, 19.71)	-3.39 (-11.91, 5.14)	
Unclassifiable IIP	1.94 (-11.57, 14.95)	7.25 (-0.20, 14.70)	
HP	-1.79 (-13.87, 12.05)		
Autoimmune ILD	-4.08 (-15.24, 7.07)	3.60 (-4.77, 11.97)	
Other ILD	-5.89 (-21.75, 12.79)	-2.13 (-11.61, 7.35)	
Region			
Europe	8.21 (-5.08, 20.39)		
Asia	-3.88 (-13.17, 5.37)	-1.07 (-8.45, 6.31)	
Canada and USA	-0.78 (-16.22, 20.86)		
Rest of the World	-1.87 (-13.36, 9.75)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.2.4: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.96 (0.52, 1.78)	1.30 (0.72, 2.34)	0.74 (0.31, 1.73)
Age			
<65 years	0.94 (0.26, 3.37)	1.76 (0.60, 5.14)	
>=65 years	0.99 (0.49, 2.02)	1.18 (0.58, 2.41)	
Sex			
Male	0.86 (0.35, 2.07)	1.52 (0.70, 3.29)	
Female	1.07 (0.45, 2.54)	0.98 (0.39, 2.45)	
Baseline FVC percent predicted			
<=70%	1.27 (0.59, 2.75)	1.13 (0.56, 2.27)	
>70%	0.72 (0.25, 2.05)	1.81 (0.57, 5.72)	
Baseline HRCT pattern			
UIP-like	1.03 (0.47, 2.24)	1.14 (0.57, 2.29)	
Other fibrotic patterns	0.84 (0.30, 2.34)	1.78 (0.60, 5.28)	
Underlying ILD diagnosis			
iNSIP	1.76 (0.50, 6.18)	0.61 (0.17, 2.15)	
Unclassifiable IIP	1.38 (0.22, 8.76)	6.09 (0.63, 58.70)	
HP	0.64 (0.06, 7.39)		
Autoimmune ILD	0.68 (0.24, 1.89)	1.48 (0.59, 3.71)	
Other ILD	0.54 (0.10, 3.03)	0.70 (0.14, 3.65)	
Region			
Europe	2.89 (0.57, 14.74)		
Asia	0.71 (0.32, 1.58)	0.87 (0.35, 2.20)	
Canada and USA	0.88 (0.07, 10.43)		
Rest of the World	0.70 (0.11, 4.40)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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M.3.3 Further analysis

M.3.3.1 Further safety analysis

Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.18 (0.95, 1.46)	1.73 (1.53, 1.94)	0.68 (0.54, 0.87)	0.0024	
Age					0.0198
<65 years	0.86 (0.59, 1.25)	1.89 (1.53, 2.35)	0.46 (0.30, 0.70)	0.0004	
>=65 years	1.41 (1.08, 1.84)	1.66 (1.44, 1.91)	0.85 (0.63, 1.15)	0.2904	
Sex					0.7831
Male	1.19 (0.87, 1.62)	1.68 (1.44, 1.98)	0.70 (0.50, 1.00)	0.0496	
Female	1.17 (0.87, 1.58)	1.78 (1.50, 2.12)	0.66 (0.47, 0.93)	0.0173	
Baseline FVC percent predicted					0.5458
<=70%	1.13 (0.83, 1.53)	1.56 (1.35, 1.80)	0.72 (0.51, 1.02)	0.0612	
>70%	1.24 (0.91, 1.68)	2.00 (1.63, 2.44)	0.62 (0.43, 0.89)	0.0104	
Baseline HRCT pattern					0.2310
UIP-like	1.28 (0.99, 1.65)	1.69 (1.47, 1.96)	0.75 (0.56, 1.01)	0.0589	
Other fibrotic patterns	0.97 (0.64, 1.46)	1.79 (1.46, 2.19)	0.54 (0.34, 0.86)	0.0085	
Underlying ILD diagnosis					0.1942
iNSIP	1.12 (0.63, 1.97)	2.54 (1.72, 3.76)	0.44 (0.22, 0.88)	0.0196	
Unclassifiable IIP	1.18 (0.74, 1.89)	2.27 (1.63, 3.16)	0.52 (0.29, 0.92)	0.0256	
HP	0.99 (0.58, 1.71)				
Autoimmune ILD	1.23 (0.85, 1.79)	1.66 (1.33, 2.08)	0.74 (0.48, 1.15)	0.1792	
Other ILD	1.54 (0.92, 2.59)	1.45 (1.09, 1.93)	1.06 (0.59, 1.92)	0.8368	
Region					
Europe	1.39 (0.82, 2.38)				
Asia	1.10 (0.82, 1.47)	1.75 (1.42, 2.14)	0.63 (0.44, 0.90)	0.0113	
Canada and USA	0.99 (0.57, 1.74)				
Rest of the World	1.56 (0.88, 2.76)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	7.18 (-2.04, 16.23)	34.56 (28.18, 40.93)	-27.38 (-38.52, -16.24)
Age			
<65 years	-5.81 (-20.00, 8.67)	37.52 (27.08, 47.96)	-43.32 (-61.06, -25.59)
>=65 years	15.66 (3.79, 26.93)	33.40 (25.41, 41.39)	-17.74 (-31.80, -3.68)
Sex			
Male	7.11 (-5.63, 19.56)	33.17 (24.41, 41.93)	-26.05 (-41.39, -10.72)
Female	7.11 (-6.10, 19.98)	36.41 (27.16, 45.66)	-29.29 (-45.28, -13.30)
Baseline FVC percent predicted			
<=70%	5.16 (-8.03, 18.19)	29.37 (20.87, 37.87)	-24.22 (-39.84, -8.59)
>70%	9.12 (-3.76, 21.50)	41.05 (31.51, 50.59)	-31.93 (-47.76, -16.10)
Baseline HRCT pattern			
UIP-like	10.74 (-0.26, 21.39)	33.70 (25.82, 41.57)	-22.96 (-36.34, -9.57)
Other fibrotic patterns	-1.28 (-17.73, 15.25)	36.08 (25.30, 46.86)	-37.36 (-57.06, -17.66)
Underlying ILD diagnosis			
iNSIP	3.86 (-15.38, 21.99)	45.33 (30.68, 59.98)	-41.47 (-65.22, -17.72)
Unclassifiable IIP	8.06 (-13.86, 28.89)	51.39 (36.76, 66.02)	-43.33 (-69.23, -17.43)
HP	-0.26 (-22.46, 22.31)		
Autoimmune ILD	9.13 (-7.10, 24.72)	31.77 (20.01, 43.53)	-22.64 (-42.42, -2.85)
Other ILD	21.11 (-4.09, 42.89)	25.48 (7.74, 43.21)	-4.36 (-33.79, 25.07)
Region			
Europe	12.78 (-7.19, 30.95)		
Asia	4.27 (-8.97, 17.29)	36.45 (25.75, 47.15)	-32.19 (-49.13, -15.24)
Canada and USA	-0.39 (-27.84, 26.66)		
Rest of the World	15.93 (-3.91, 34.25)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.34 (0.92, 1.96)	5.24 (3.72, 7.37)	0.26 (0.15, 0.43)
Age			
<65 years	0.78 (0.42, 1.45)	5.48 (3.23, 9.31)	0.14 (0.06, 0.32)
>=65 years	1.89 (1.16, 3.06)	5.32 (3.38, 8.38)	0.35 (0.18, 0.69)
Sex			
Male	1.34 (0.79, 2.28)	4.98 (3.10, 8.01)	0.27 (0.13, 0.55)
Female	1.33 (0.78, 2.29)	5.66 (3.44, 9.31)	0.24 (0.11, 0.49)
Baseline FVC percent predicted			
<=70%	1.23 (0.72, 2.13)	4.19 (2.66, 6.59)	0.29 (0.15, 0.60)
>70%	1.45 (0.86, 2.47)	6.83 (4.06, 11.51)	0.21 (0.10, 0.45)
Baseline HRCT pattern			
UIP-like	1.55 (0.99, 2.43)	5.21 (3.38, 8.03)	0.30 (0.16, 0.56)
Other fibrotic patterns	0.95 (0.47, 1.91)	5.33 (3.04, 9.34)	0.18 (0.07, 0.44)
Underlying ILD diagnosis			
iNSIP	1.19 (0.50, 2.80)	7.10 (3.39, 14.88)	0.17 (0.05, 0.52)
Unclassifiable IIP	1.38 (0.56, 3.41)	17.00 (6.01, 48.10)	0.08 (0.02, 0.32)
HP	0.99 (0.38, 2.59)		
Autoimmune ILD	1.45 (0.74, 2.83)	4.81 (2.48, 9.34)	0.30 (0.12, 0.77)
Other ILD	2.36 (0.83, 6.69)	3.40 (1.32, 8.78)	0.69 (0.17, 2.84)
Region			
Europe	1.72 (0.73, 4.04)		
Asia	1.19 (0.69, 2.04)	7.87 (3.83, 16.17)	0.15 (0.06, 0.37)
Canada and USA	0.98 (0.30, 3.24)		
Rest of the World	2.01 (0.83, 4.84)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.41 (0.46, 4.38)	3.54 (1.80, 6.98)	0.40 (0.11, 1.49)	0.1720	
Age					
<65 years	0.94 (0.06, 14.84)	4.03 (1.25, 12.96)			
>=65 years	1.58 (0.46, 5.47)	3.18 (1.41, 7.19)			
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like	1.23 (0.38, 3.95)	6.52 (2.10, 20.26)			
Other fibrotic patterns	2.91 (0.12, 70.15)	2.01 (0.86, 4.70)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.93 (-2.41, 4.41)	7.22 (3.75, 10.69)	-6.29 (-11.16, -1.42)
Age			
<65 years	-0.07 (-5.46, 5.05)	7.59 (2.21, 12.97)	
>=65 years	1.67 (-3.27, 6.98)	6.99 (2.39, 11.58)	
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like	0.73 (-3.81, 5.43)	8.02 (4.05, 11.99)	
Other fibrotic patterns	1.52 (-4.28, 8.10)	5.71 (-0.95, 12.37)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.43 (0.45, 4.56)	3.83 (1.89, 7.77)	0.37 (0.10, 1.45)
Age			
<65 years	0.94 (0.06, 15.32)	4.37 (1.29, 14.73)	
>=65 years	1.61 (0.44, 5.83)	3.43 (1.46, 8.08)	
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like	1.24 (0.37, 4.15)	7.10 (2.21, 22.75)	
Other fibrotic patterns	NC (NC, NC)	2.14 (0.85, 5.36)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain upper

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.33, 3.08)	4.93 (2.25, 10.79)	0.20 (0.05, 0.80)	0.0227	
Age					
<65 years					
>=65 years					
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like					
Other fibrotic patterns					
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain upper

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.02 (-3.38, 3.45)	7.95 (4.61, 11.28)	-7.92 (-12.69, -3.15)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain upper

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.32, 3.18)	5.36 (2.39, 12.03)	0.19 (0.05, 0.77)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.55 (1.09, 2.22)	2.79 (2.30, 3.38)	0.56 (0.37, 0.84)	0.0046	
Age					0.0219
<65 years	0.94 (0.51, 1.76)	3.36 (2.35, 4.81)	0.28 (0.14, 0.58)	0.0005	
>=65 years	2.01 (1.29, 3.14)	2.58 (2.05, 3.23)	0.78 (0.47, 1.29)	0.3330	
Sex					0.4597
Male	1.38 (0.84, 2.25)	2.86 (2.20, 3.72)	0.48 (0.28, 0.84)	0.0099	
Female	1.77 (1.05, 3.01)	2.71 (2.05, 3.58)	0.65 (0.36, 1.19)	0.1650	
Baseline FVC percent predicted					0.3919
<=70%	1.37 (0.87, 2.16)	2.78 (2.15, 3.58)	0.49 (0.29, 0.83)	0.0080	
>70%	2.00 (1.11, 3.62)	2.80 (2.09, 3.76)	0.71 (0.37, 1.38)	0.3172	
Baseline HRCT pattern					0.4635
UIP-like	1.69 (1.11, 2.55)	2.76 (2.18, 3.49)	0.61 (0.38, 0.98)	0.0421	
Other fibrotic patterns	1.23 (0.61, 2.51)	2.85 (2.04, 3.98)	0.43 (0.20, 0.95)	0.0369	
Underlying ILD diagnosis					0.4572
iNSIP	1.58 (0.66, 3.79)	3.26 (1.99, 5.36)	0.48 (0.18, 1.32)	0.1571	
Unclassifiable IIP	1.98 (0.76, 5.15)	4.14 (2.29, 7.48)	0.48 (0.16, 1.47)	0.1994	
HP	1.63 (0.73, 3.61)				
Autoimmune ILD	1.08 (0.58, 2.02)	2.47 (1.72, 3.55)	0.44 (0.21, 0.90)	0.0248	
Other ILD	2.88 (1.12, 7.41)	2.37 (1.41, 3.96)	1.22 (0.42, 3.57)	0.7198	
Region					
Europe	2.42 (0.97, 6.04)				
Asia	1.09 (0.64, 1.84)	2.75 (1.92, 3.94)	0.39 (0.21, 0.75)	0.0043	
Canada and USA	1.76 (0.75, 4.18)				
Rest of the World	2.50 (1.05, 5.91)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	9.71 (1.92, 17.36)	44.04 (37.70, 50.38)	-34.33 (-44.32, -24.35)
Age			
<65 years	-1.10 (-12.92, 10.60)	46.69 (36.94, 56.45)	-47.79 (-63.07, -32.51)
>=65 years	16.79 (6.51, 26.71)	43.21 (34.94, 51.47)	-26.42 (-39.47, -13.37)
Sex			
Male	7.16 (-3.72, 17.92)	45.68 (37.13, 54.23)	-38.52 (-52.31, -24.73)
Female	12.40 (1.24, 23.17)	42.21 (32.86, 51.56)	-29.81 (-44.22, -15.40)
Baseline FVC percent predicted			
<=70%	8.17 (-3.54, 19.95)	44.29 (35.80, 52.79)	-36.12 (-50.61, -21.62)
>70%	12.50 (2.22, 22.21)	43.71 (34.19, 53.23)	-31.21 (-45.01, -17.41)
Baseline HRCT pattern			
UIP-like	12.15 (2.70, 21.38)	44.63 (36.81, 52.46)	-32.48 (-44.67, -20.30)
Other fibrotic patterns	4.02 (-9.68, 17.48)	43.03 (32.29, 53.77)	-39.01 (-56.32, -21.69)
Underlying ILD diagnosis			
iNSIP	8.64 (-8.21, 23.62)	46.29 (31.96, 60.63)	-37.66 (-59.08, -16.23)
Unclassifiable IIP	13.61 (-5.04, 30.82)	55.80 (41.11, 70.48)	-42.19 (-65.36, -19.01)
HP	12.82 (-7.78, 33.18)		
Autoimmune ILD	1.73 (-11.91, 15.34)	36.63 (24.61, 48.65)	-34.90 (-53.07, -16.73)
Other ILD	26.11 (3.89, 46.89)	37.28 (19.05, 55.50)	-11.17 (-39.35, 17.02)
Region			
Europe	17.69 (0.39, 32.78)		
Asia	1.68 (-9.22, 12.53)	41.18 (30.23, 52.12)	-39.50 (-54.92, -24.07)
Canada and USA	17.84 (-8.47, 43.41)		
Rest of the World	19.51 (2.05, 35.97)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.76 (1.12, 2.77)	6.98 (5.01, 9.74)	0.25 (0.14, 0.44)
Age			
<65 years	0.93 (0.43, 2.01)	8.51 (4.85, 14.93)	0.11 (0.04, 0.28)
>=65 years	2.52 (1.42, 4.48)	6.55 (4.31, 9.95)	0.39 (0.19, 0.78)
Sex			
Male	1.51 (0.81, 2.83)	7.99 (5.00, 12.77)	0.19 (0.09, 0.41)
Female	2.08 (1.07, 4.05)	6.16 (3.84, 9.88)	0.34 (0.15, 0.76)
Baseline FVC percent predicted			
<=70%	1.53 (0.83, 2.84)	7.03 (4.53, 10.91)	0.22 (0.10, 0.46)
>70%	2.33 (1.15, 4.74)	6.91 (4.16, 11.47)	0.34 (0.14, 0.81)
Baseline HRCT pattern			
UIP-like	1.98 (1.16, 3.38)	7.35 (4.83, 11.20)	0.27 (0.14, 0.53)
Other fibrotic patterns	1.30 (0.54, 3.12)	6.46 (3.74, 11.19)	0.20 (0.07, 0.56)
Underlying ILD diagnosis			
iNSIP	1.75 (0.60, 5.10)	7.83 (3.65, 16.81)	0.22 (0.06, 0.83)
Unclassifiable IIP	2.35 (0.73, 7.59)	13.00 (5.36, 31.56)	0.18 (0.04, 0.79)
HP	1.94 (0.65, 5.74)		
Autoimmune ILD	1.11 (0.50, 2.46)	5.33 (2.83, 10.03)	0.21 (0.08, 0.57)
Other ILD	4.13 (1.20, 14.25)	4.55 (1.88, 11.02)	0.91 (0.20, 4.16)
Region			
Europe	3.03 (1.00, 9.14)		
Asia	1.11 (0.57, 2.15)	6.80 (3.61, 12.78)	0.16 (0.07, 0.41)
Canada and USA	2.30 (0.64, 8.31)		
Rest of the World	3.22 (1.10, 9.38)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.91 (0.87, 4.18)	2.98 (2.09, 4.26)	0.64 (0.27, 1.52)	0.3099	
Age					
<65 years	1.26 (0.29, 5.45)	3.34 (1.81, 6.15)			
>=65 years	2.28 (0.89, 5.83)	2.78 (1.79, 4.32)			
Sex					
Male	4.18 (0.91, 19.26)	2.75 (1.56, 4.85)			
Female	1.25 (0.48, 3.24)	3.14 (1.99, 4.93)			
Baseline FVC percent predicted					
<=70%	2.05 (0.77, 5.43)	2.71 (1.75, 4.19)			
>70%	1.96 (0.52, 7.38)	3.50 (1.89, 6.48)			
Baseline HRCT pattern					
UIP-like	3.33 (1.11, 10.00)	3.52 (2.14, 5.81)			
Other fibrotic patterns	0.78 (0.22, 2.76)	2.38 (1.43, 3.93)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	3.67 (-0.82, 8.38)	18.54 (13.13, 23.95)	-14.87 (-21.96, -7.77)
Age			
<65 years	0.93 (-6.12, 7.91)	19.80 (11.37, 28.23)	
>=65 years	5.53 (-0.70, 12.22)	17.76 (10.71, 24.82)	
Sex			
Male	5.48 (-0.10, 11.98)	13.02 (6.30, 19.74)	
Female	1.65 (-5.82, 9.15)	24.83 (16.36, 33.30)	
Baseline FVC percent predicted			
<=70%	5.33 (-1.93, 13.51)	19.35 (11.76, 26.93)	
>70%	2.76 (-3.23, 8.63)	17.60 (10.00, 25.20)	
Baseline HRCT pattern			
UIP-like	5.91 (0.79, 11.59)	18.55 (12.16, 24.94)	
Other fibrotic patterns	-1.75 (-11.67, 7.84)	18.32 (8.48, 28.16)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.98 (0.86, 4.55)	3.80 (2.49, 5.80)	0.52 (0.21, 1.32)
Age			
<65 years	1.27 (0.28, 5.85)	4.32 (2.13, 8.77)	
>=65 years	2.42 (0.89, 6.57)	3.50 (2.07, 5.92)	
Sex			
Male	4.43 (0.92, 21.33)	3.22 (1.69, 6.12)	
Female	1.27 (0.46, 3.55)	4.45 (2.53, 7.81)	
Baseline FVC percent predicted			
<=70%	2.17 (0.76, 6.21)	3.47 (2.05, 5.86)	
>70%	2.01 (0.51, 7.99)	4.45 (2.19, 9.05)	
Baseline HRCT pattern			
UIP-like	3.55 (1.13, 11.14)	4.51 (2.54, 8.01)	
Other fibrotic patterns	0.76 (0.19, 2.97)	2.99 (1.60, 5.58)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Vomiting

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.30 (0.49, 3.42)	3.95 (2.37, 6.58)	0.33 (0.11, 0.98)	0.0464	
Age					0.0662
<65 years	0.24 (0.03, 2.07)	4.24 (1.71, 10.53)	0.06 (0.01, 0.59)	0.0161	
>=65 years	2.81 (0.76, 10.36)	3.80 (2.07, 6.99)	0.74 (0.17, 3.12)	0.6801	
Sex					0.1851
Male	2.09 (0.39, 11.18)	2.40 (1.10, 5.22)	0.87 (0.14, 5.53)	0.8837	
Female	0.97 (0.29, 3.26)	5.32 (2.71, 10.47)	0.18 (0.05, 0.73)	0.0162	
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					0.4317
UIP-like	0.88 (0.30, 2.56)	3.09 (1.70, 5.60)	0.28 (0.08, 0.97)	0.0441	
Other fibrotic patterns	6.79 (0.36, 128.91)	6.26 (2.35, 16.64)	1.09 (0.05, 24.13)	0.9587	
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	0.75 (0.05, 11.70)				
Asia	2.31 (0.61, 8.70)	6.99 (1.74, 28.05)	0.33 (0.05, 2.26)	0.2591	
Canada and USA	0.34 (0.02, 6.78)				
Rest of the World	1.07 (0.07, 16.57)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Vomiting

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.94 (-2.81, 4.79)	13.94 (9.44, 18.44)	-13.00 (-18.89, -7.11)
Age			
<65 years	-3.68 (-10.67, 2.13)	12.96 (6.24, 19.67)	-16.64 (-25.92, -7.36)
>=65 years	3.90 (-1.07, 9.53)	14.77 (8.72, 20.81)	-10.86 (-18.90, -2.83)
Sex			
Male	1.88 (-2.99, 7.32)	6.10 (0.94, 11.25)	-4.22 (-11.51, 3.07)
Female	-0.13 (-6.54, 6.17)	23.00 (15.57, 30.42)	-23.13 (-32.90, -13.35)
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like	-0.53 (-5.44, 4.36)	11.82 (6.24, 17.41)	-12.36 (-19.79, -4.93)
Other fibrotic patterns	4.55 (-1.86, 12.53)	17.64 (10.04, 25.23)	-13.09 (-23.55, -2.63)
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	-0.61 (-11.11, 7.70)		
Asia	3.71 (-2.44, 10.33)	12.41 (5.67, 19.15)	-8.70 (-17.98, 0.59)
Canada and USA	-6.67 (-21.32, 12.38)		
Rest of the World	0.15 (-9.21, 10.05)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Vomiting

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.31 (0.48, 3.58)	4.63 (2.66, 8.06)	0.28 (0.09, 0.89)
Age			
<65 years	0.23 (0.02, 2.07)	4.91 (1.86, 12.93)	0.05 (0.00, 0.52)
>=65 years	2.92 (0.76, 11.27)	4.50 (2.31, 8.79)	0.65 (0.14, 2.93)
Sex			
Male	2.13 (0.38, 11.87)	2.57 (1.12, 5.90)	0.83 (0.12, 5.60)
Female	0.97 (0.27, 3.46)	7.03 (3.33, 14.83)	0.14 (0.03, 0.60)
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like	0.87 (0.29, 2.66)	3.54 (1.85, 6.78)	0.25 (0.07, 0.90)
Other fibrotic patterns	NC (NC, NC)	7.42 (2.56, 21.53)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	0.75 (0.05, 12.37)		
Asia	2.40 (0.60, 9.56)	7.95 (1.84, 34.46)	0.30 (0.04, 2.26)
Canada and USA	0.00 (NC, NC)		
Rest of the World	1.07 (0.06, 17.68)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.14 (0.45, 2.89)	3.87 (2.15, 6.97)	0.29 (0.10, 0.88)	0.0295	
Age					0.8205
<65 years	1.89 (0.35, 10.03)	8.30 (2.11, 32.64)	0.23 (0.03, 1.97)	0.1789	
>=65 years	0.88 (0.27, 2.81)	2.88 (1.49, 5.55)	0.30 (0.08, 1.16)	0.0813	
Sex					0.6854
Male	0.87 (0.27, 2.77)	3.28 (1.59, 6.79)	0.27 (0.07, 1.04)	0.0572	
Female	1.94 (0.36, 10.40)	4.50 (1.76, 11.52)	0.43 (0.06, 2.95)	0.3921	
Baseline FVC percent predicted					0.7643
<=70%	0.92 (0.21, 4.02)	3.80 (1.81, 8.00)	0.24 (0.05, 1.26)	0.0922	
>70%	1.26 (0.36, 4.34)	3.68 (1.48, 9.14)	0.34 (0.07, 1.59)	0.1714	
Baseline HRCT pattern					0.9560
UIP-like	1.03 (0.37, 2.86)	3.21 (1.63, 6.32)	0.32 (0.09, 1.09)	0.0690	
Other fibrotic patterns	1.94 (0.18, 20.87)	5.59 (1.79, 17.45)	0.35 (0.02, 4.84)	0.4313	
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	1.51 (0.14, 16.07)				
Asia	0.99 (0.36, 2.73)	6.72 (2.80, 16.12)	0.15 (0.04, 0.56)	0.0050	
Canada and USA	1.72 (0.04, 83.12)				
Rest of the World	1.07 (0.02, 52.68)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.49 (-3.37, 4.41)	10.68 (6.72, 14.64)	-10.19 (-15.74, -4.64)
Age			
<65 years	2.14 (-4.43, 8.93)	12.87 (7.16, 18.58)	-10.73 (-19.52, -1.94)
>=65 years	-0.53 (-5.77, 4.78)	9.32 (3.98, 14.66)	-9.85 (-17.36, -2.34)
Sex			
Male	-0.67 (-6.88, 5.59)	10.43 (4.68, 16.18)	-11.10 (-19.58, -2.62)
Female	1.78 (-3.45, 7.34)	10.91 (5.47, 16.35)	-9.13 (-16.79, -1.47)
Baseline FVC percent predicted			
<=70%	-0.26 (-5.67, 5.76)	11.50 (6.03, 16.97)	-11.76 (-19.68, -3.85)
>70%	0.99 (-5.21, 6.80)	9.55 (3.81, 15.29)	-8.56 (-16.86, -0.25)
Baseline HRCT pattern			
UIP-like	0.12 (-4.89, 5.19)	9.94 (4.92, 14.96)	-9.82 (-16.94, -2.71)
Other fibrotic patterns	1.47 (-5.65, 8.94)	11.95 (5.48, 18.43)	-10.49 (-20.24, -0.73)
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	1.27 (-9.46, 10.49)		
Asia	-0.06 (-7.28, 7.13)	28.86 (19.61, 38.12)	-28.93 (-40.65, -17.20)
Canada and USA	0.00 (NC, NC)		
Rest of the World	0.00 (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.14 (0.43, 3.01)	4.43 (2.37, 8.28)	0.26 (0.08, 0.82)
Age			
<65 years	1.93 (0.34, 10.82)	9.69 (2.43, 38.71)	0.20 (0.02, 1.82)
>=65 years	0.87 (0.26, 2.93)	3.25 (1.59, 6.65)	0.27 (0.07, 1.10)
Sex			
Male	0.86 (0.26, 2.92)	3.78 (1.69, 8.47)	0.23 (0.05, 0.98)
Female	1.98 (0.36, 11.05)	5.02 (1.94, 13.00)	0.39 (0.06, 2.81)
Baseline FVC percent predicted			
<=70%	0.92 (0.20, 4.21)	4.31 (1.97, 9.43)	0.21 (0.04, 1.18)
>70%	1.27 (0.35, 4.63)	4.33 (1.59, 11.78)	0.29 (0.06, 1.51)
Baseline HRCT pattern			
UIP-like	1.03 (0.35, 3.00)	3.66 (1.77, 7.58)	0.28 (0.08, 1.03)
Other fibrotic patterns	1.97 (0.17, 22.26)	6.47 (1.96, 21.35)	0.30 (0.02, 4.54)
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	1.53 (0.13, 17.48)		
Asia	0.99 (0.33, 2.93)	9.64 (3.67, 25.35)	0.10 (0.02, 0.44)
Canada and USA	NC (NC, NC)		
Rest of the World	NC (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders
PT: Hepatic function abnormal

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.26, 3.98)	4.76 (1.92, 11.81)	0.21 (0.04, 1.10)	0.0650	
Age					
<65 years					
>=65 years					
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like					
Other fibrotic patterns					
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders
PT: Hepatic function abnormal

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.02 (-2.94, 2.99)	5.80 (2.96, 8.63)	-5.78 (-9.88, -1.68)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders
PT: Hepatic function abnormal

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.25, 4.09)	5.34 (2.04, 14.01)	0.19 (0.03, 1.03)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.52, 1.97)	2.46 (1.55, 3.89)	0.41 (0.18, 0.92)	0.0314	
Age					0.3448
<65 years	1.57 (0.39, 6.37)	8.67 (2.30, 32.75)	0.18 (0.03, 1.25)	0.0828	
>=65 years	0.89 (0.41, 1.92)	1.75 (1.06, 2.92)	0.51 (0.20, 1.27)	0.1487	
Sex					0.9959
Male	0.87 (0.27, 2.77)	2.20 (1.18, 4.09)	0.40 (0.11, 1.47)	0.1673	
Female	1.07 (0.47, 2.41)	2.71 (1.38, 5.34)	0.39 (0.14, 1.14)	0.0852	
Baseline FVC percent predicted					0.5388
<=70%	0.92 (0.41, 2.10)	2.52 (1.38, 4.62)	0.37 (0.13, 1.01)	0.0534	
>70%	1.47 (0.44, 4.88)	2.34 (1.17, 4.67)	0.63 (0.16, 2.51)	0.5099	
Baseline HRCT pattern					0.4477
UIP-like	0.94 (0.43, 2.07)	2.83 (1.59, 5.04)	0.33 (0.13, 0.88)	0.0272	
Other fibrotic patterns	1.21 (0.34, 4.31)	1.83 (0.86, 3.90)	0.66 (0.15, 2.89)	0.5822	
Underlying ILD diagnosis					0.2981
iNSIP	1.45 (0.28, 7.56)	3.32 (1.04, 10.62)	0.44 (0.06, 3.29)	0.4217	
Unclassifiable IIP	0.45 (0.09, 2.31)	3.09 (1.00, 9.56)	0.15 (0.02, 1.07)	0.0577	
HP	0.43 (0.05, 3.96)				
Autoimmune ILD	1.01 (0.31, 3.35)	12.56 (2.22, 70.98)	0.08 (0.01, 0.66)	0.0191	
Other ILD	2.88 (0.57, 14.54)	2.67 (0.82, 8.73)	1.08 (0.15, 8.02)	0.9408	
Region					
Europe	2.26 (0.24, 20.96)				
Asia	0.72 (0.30, 1.72)	2.72 (1.29, 5.73)	0.26 (0.08, 0.83)	0.0231	
Canada and USA	0.44 (0.05, 3.64)				
Rest of the World	9.61 (0.53, 173.44)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.07 (-4.93, 5.08)	9.29 (4.86, 13.72)	-9.22 (-15.91, -2.54)
Age			
<65 years	2.07 (-5.17, 9.40)	13.53 (7.49, 19.57)	-11.46 (-20.93, -1.99)
>=65 years	-1.02 (-8.02, 6.06)	6.93 (0.82, 13.03)	-7.94 (-17.26, 1.37)
Sex			
Male	-0.67 (-6.88, 5.59)	8.31 (2.19, 14.43)	-8.98 (-17.72, -0.25)
Female	0.66 (-7.65, 8.90)	10.21 (3.76, 16.66)	-9.55 (-20.04, 0.94)
Baseline FVC percent predicted			
<=70%	-0.79 (-8.85, 7.82)	9.91 (3.92, 15.91)	-10.71 (-20.97, -0.44)
>70%	1.80 (-4.53, 7.82)	8.61 (1.97, 15.24)	-6.81 (-15.87, 2.25)
Baseline HRCT pattern			
UIP-like	-0.45 (-6.52, 5.65)	11.12 (5.50, 16.73)	-11.57 (-19.85, -3.29)
Other fibrotic patterns	1.33 (-8.42, 11.06)	5.99 (-1.26, 13.24)	-4.66 (-16.80, 7.48)
Underlying ILD diagnosis			
iNSIP	2.27 (-10.05, 12.90)	11.45 (1.70, 21.21)	-9.18 (-24.24, 5.87)
Unclassifiable IIP	-6.11 (-20.77, 7.20)	13.50 (1.93, 25.08)	-19.62 (-37.77, -1.46)
HP	-4.36 (-17.28, 9.90)		
Autoimmune ILD	0.10 (-9.23, 9.50)	15.09 (7.68, 22.51)	-14.99 (-26.94, -3.05)
Other ILD	10.44 (-5.39, 29.53)	11.81 (-1.69, 25.31)	-1.37 (-23.43, 20.70)
Region			
Europe	3.16 (-7.87, 13.09)		
Asia	-2.90 (-11.02, 5.07)	12.93 (4.43, 21.44)	-15.83 (-27.54, -4.13)
Canada and USA	-7.45 (-24.50, 15.12)		
Rest of the World	9.30 (-0.24, 21.60)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.49, 2.07)	2.74 (1.65, 4.54)	0.37 (0.15, 0.89)
Age			
<65 years	1.61 (0.37, 6.94)	10.03 (2.52, 39.88)	0.16 (0.02, 1.20)
>=65 years	0.88 (0.38, 2.04)	1.90 (1.07, 3.39)	0.46 (0.17, 1.28)
Sex			
Male	0.86 (0.26, 2.92)	2.41 (1.22, 4.76)	0.36 (0.09, 1.45)
Female	1.08 (0.44, 2.65)	3.06 (1.45, 6.48)	0.35 (0.11, 1.13)
Baseline FVC percent predicted			
<=70%	0.91 (0.37, 2.27)	2.81 (1.45, 5.46)	0.32 (0.11, 1.00)
>70%	1.50 (0.43, 5.26)	2.60 (1.21, 5.61)	0.57 (0.13, 2.51)
Baseline HRCT pattern			
UIP-like	0.94 (0.40, 2.19)	3.22 (1.71, 6.08)	0.29 (0.10, 0.84)
Other fibrotic patterns	1.23 (0.31, 4.80)	1.96 (0.85, 4.52)	0.63 (0.13, 3.10)
Underlying ILD diagnosis			
iNSIP	1.49 (0.26, 8.56)	3.78 (1.08, 13.21)	0.39 (0.05, 3.39)
Unclassifiable IIP	0.42 (0.07, 2.45)	3.60 (1.04, 12.40)	0.12 (0.01, 1.01)
HP	0.41 (0.04, 4.19)		
Autoimmune ILD	1.02 (0.28, 3.67)	14.64 (2.37, 90.46)	0.07 (0.01, 0.64)
Other ILD	3.24 (0.54, 19.25)	3.06 (0.81, 11.51)	1.06 (0.11, 9.76)
Region			
Europe	2.34 (0.23, 23.38)		
Asia	0.70 (0.27, 1.81)	3.28 (1.39, 7.72)	0.21 (0.06, 0.77)
Canada and USA	0.41 (0.04, 3.96)		
Rest of the World	NC (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 2 Indirect treatment comparison for the proportion of patients with specific serious AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.33, 3.08)	2.49 (1.01, 6.17)	0.40 (0.10, 1.70)	0.2176	
Age					
<65 years					
>=65 years					
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like					
Other fibrotic patterns					
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 2 Indirect treatment comparison for the proportion of patients with specific serious AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.02 (-3.38, 3.45)	2.62 (0.15, 5.08)	-2.59 (-6.80, 1.62)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 2 Indirect treatment comparison for the proportion of patients with specific serious AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.32, 3.18)	2.56 (1.01, 6.49)	0.39 (0.09, 1.73)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 2 Indirect treatment comparison for the proportion of patients with specific serious AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.25 (0.03, 2.24)	2.79 (0.95, 8.17)	0.09 (0.01, 1.03)	0.0528	
Age					
<65 years					
>=65 years					
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like					
Other fibrotic patterns					
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 2 Indirect treatment comparison for the proportion of patients with specific serious AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-1.35 (-4.11, 1.00)	2.17 (0.01, 4.32)	-3.51 (-6.85, -0.17)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 2 Indirect treatment comparison for the proportion of patients with specific serious AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.25 (0.03, 2.24)	2.85 (0.95, 8.56)	0.09 (0.01, 1.02)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 3 Indirect treatment comparison for the proportion of patients with Diarrhoea with CTCAE grade <3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.55 (1.09, 2.22)	2.59 (2.11, 3.18)	0.60 (0.40, 0.91)	0.0150	
Age					0.0107
<65 years	0.94 (0.51, 1.76)	3.42 (2.32, 5.05)	0.28 (0.13, 0.58)	0.0006	
>=65 years	2.01 (1.29, 3.14)	2.28 (1.79, 2.91)	0.88 (0.53, 1.47)	0.6318	
Sex					0.4096
Male	1.38 (0.84, 2.25)	2.71 (2.05, 3.58)	0.51 (0.29, 0.89)	0.0187	
Female	1.77 (1.05, 3.01)	2.46 (1.82, 3.33)	0.72 (0.39, 1.33)	0.2925	
Baseline FVC percent predicted					0.2315
<=70%	1.37 (0.87, 2.16)	2.76 (2.09, 3.65)	0.50 (0.29, 0.85)	0.0104	
>70%	2.00 (1.11, 3.62)	2.39 (1.76, 3.24)	0.84 (0.43, 1.63)	0.6018	
Baseline HRCT pattern					0.3248
UIP-like	1.69 (1.11, 2.55)	2.45 (1.91, 3.15)	0.69 (0.42, 1.11)	0.1279	
Other fibrotic patterns	1.23 (0.61, 2.51)	2.87 (2.00, 4.12)	0.43 (0.19, 0.95)	0.0380	
Underlying ILD diagnosis					0.4774
iNSIP	1.58 (0.66, 3.79)	3.15 (1.86, 5.33)	0.50 (0.18, 1.39)	0.1849	
Unclassifiable IIP	1.98 (0.76, 5.15)	3.56 (1.95, 6.50)	0.56 (0.18, 1.72)	0.3101	
HP	1.63 (0.73, 3.61)				
Autoimmune ILD	1.08 (0.58, 2.02)	2.53 (1.70, 3.77)	0.43 (0.20, 0.89)	0.0239	
Other ILD	2.88 (1.12, 7.41)	2.37 (1.37, 4.10)	1.21 (0.41, 3.61)	0.7286	
Region					
Europe	2.42 (0.97, 6.04)				
Asia	1.09 (0.64, 1.84)	2.58 (1.79, 3.71)	0.42 (0.22, 0.80)	0.0082	
Canada and USA	1.76 (0.75, 4.18)				
Rest of the World	2.50 (1.05, 5.91)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 3 Indirect treatment comparison for the proportion of patients with Diarrhoea with CTCAE grade <3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	9.71 (1.92, 17.36)	36.53 (30.01, 43.05)	-26.82 (-36.93, -16.72)
Age			
<65 years	-1.10 (-12.92, 10.60)	42.42 (32.57, 52.27)	-43.51 (-58.85, -28.17)
>=65 years	16.79 (6.51, 26.71)	33.42 (24.82, 42.01)	-16.63 (-29.89, -3.37)
Sex			
Male	7.16 (-3.72, 17.92)	39.25 (30.45, 48.05)	-32.09 (-46.03, -18.14)
Female	12.40 (1.24, 23.17)	33.54 (23.94, 43.14)	-21.14 (-35.71, -6.56)
Baseline FVC percent predicted			
<=70%	8.17 (-3.54, 19.95)	38.71 (30.09, 47.33)	-30.53 (-45.10, -15.96)
>70%	12.50 (2.22, 22.21)	33.65 (23.70, 43.61)	-21.15 (-35.26, -7.04)
Baseline HRCT pattern			
UIP-like	12.15 (2.70, 21.38)	35.04 (26.88, 43.20)	-22.89 (-35.29, -10.49)
Other fibrotic patterns	4.02 (-9.68, 17.48)	39.25 (28.44, 50.06)	-35.23 (-52.58, -17.87)
Underlying ILD diagnosis			
iNSIP	8.64 (-8.21, 23.62)	40.87 (26.36, 55.37)	-32.23 (-53.77, -10.69)
Unclassifiable IIP	13.61 (-5.04, 30.82)	45.48 (30.04, 60.92)	-31.87 (-55.53, -8.20)
HP	12.82 (-7.78, 33.18)		
Autoimmune ILD	1.73 (-11.91, 15.34)	33.90 (21.85, 45.95)	-32.17 (-50.36, -13.98)
Other ILD	26.11 (3.89, 46.89)	34.69 (16.28, 53.10)	-8.58 (-36.89, 19.73)
Region			
Europe	17.69 (0.39, 32.78)		
Asia	1.68 (-9.22, 12.53)	37.14 (25.94, 48.33)	-35.45 (-51.06, -19.84)
Canada and USA	17.84 (-8.47, 43.41)		
Rest of the World	19.51 (2.05, 35.97)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 3 Indirect treatment comparison for the proportion of patients with Diarrhoea with CTCAE grade <3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.76 (1.12, 2.77)	5.03 (3.63, 6.95)	0.35 (0.20, 0.61)
Age			
<65 years	0.93 (0.43, 2.01)	7.28 (4.14, 12.79)	0.13 (0.05, 0.33)
>=65 years	2.52 (1.42, 4.48)	4.21 (2.81, 6.30)	0.60 (0.30, 1.21)
Sex			
Male	1.51 (0.81, 2.83)	5.88 (3.73, 9.28)	0.26 (0.12, 0.56)
Female	2.08 (1.07, 4.05)	4.34 (2.73, 6.91)	0.48 (0.21, 1.08)
Baseline FVC percent predicted			
<=70%	1.53 (0.83, 2.84)	5.61 (3.62, 8.67)	0.27 (0.13, 0.58)
>70%	2.33 (1.15, 4.74)	4.38 (2.69, 7.13)	0.53 (0.23, 1.26)
Baseline HRCT pattern			
UIP-like	1.98 (1.16, 3.38)	4.70 (3.14, 7.04)	0.42 (0.22, 0.82)
Other fibrotic patterns	1.30 (0.54, 3.12)	5.67 (3.27, 9.82)	0.23 (0.08, 0.64)
Underlying ILD diagnosis			
iNSIP	1.75 (0.60, 5.10)	6.34 (2.96, 13.59)	0.28 (0.07, 1.03)
Unclassifiable IIP	2.35 (0.73, 7.59)	7.99 (3.39, 18.84)	0.29 (0.07, 1.26)
HP	1.94 (0.65, 5.74)		
Autoimmune ILD	1.11 (0.50, 2.46)	4.82 (2.56, 9.08)	0.23 (0.08, 0.64)
Other ILD	4.13 (1.20, 14.25)	4.16 (1.72, 10.04)	0.99 (0.22, 4.54)
Region			
Europe	3.03 (1.00, 9.14)		
Asia	1.11 (0.57, 2.15)	5.56 (3.00, 10.28)	0.20 (0.08, 0.49)
Canada and USA	2.30 (0.64, 8.31)		
Rest of the World	3.22 (1.10, 9.38)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 4 Indirect treatment comparison for the proportion of patients with Diarrhoea with CTCAE grade >=3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.02, 50.63)	5.28 (2.30, 12.12)	0.19 (0.00, 10.47)	0.4179	
Age					
<65 years					
>=65 years					
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like					
Other fibrotic patterns					
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 4 Indirect treatment comparison for the proportion of patients with Diarrhoea with CTCAE grade >=3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.00 (NC, NC)	7.49 (4.26, 10.72)	
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.3.3.1: 4 Indirect treatment comparison for the proportion of patients with Diarrhoea with CTCAE grade >=3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	NC (NC, NC)	5.73 (2.42, 13.53)	
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on a meta-analysis of studies 1199-0247 and 1199-0434.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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3.2 Indirekter Vergleich von FIBRONEER®-ILD und INBUILD®

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M.1 Nerandomilast 18mg versus Nintedanib (1199.247)

M.1.1 Efficacy Analysis

M.1.1.1 Time to event analyses

M.1.1.1.1 Analyses of composite endpoints

M.1.1.1.1.1 Time to first confirmed acute ILD exacerbation or death

Table M.1.1.1.1.1: 1 Indirect treatment comparison for the time to first confirmed acute ILD exacerbation or death over the whole trial

Subgroup Category	Nera 18mg vs Placebo Hazard ratio (95% CI)	Nin 150bid vs Placebo Hazard ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Hazard ratio (95% CI)	p-value	Interaction p-value
Overall	0.57 (0.35, 0.92)	0.67 (0.46, 0.98)	0.84 (0.46, 1.55)	0.5852	
Age					0.1994
<65 years	0.82 (0.34, 1.94)	0.53 (0.25, 1.14)	1.53 (0.48, 4.84)	0.4735	
>=65 years	0.48 (0.27, 0.85)	0.77 (0.50, 1.18)	0.62 (0.30, 1.29)	0.2035	
Sex					0.1744
Male	0.48 (0.25, 0.94)	0.80 (0.51, 1.26)	0.61 (0.27, 1.35)	0.2207	
Female	0.68 (0.34, 1.38)	0.47 (0.23, 0.94)	1.46 (0.55, 3.92)	0.4506	
Baseline FVC percent predicted					0.2006
<=70%	0.45 (0.25, 0.82)	0.69 (0.44, 1.09)	0.65 (0.31, 1.39)	0.2694	
>70%	0.93 (0.40, 2.20)	0.60 (0.31, 1.18)	1.56 (0.52, 4.63)	0.4279	
Baseline HRCT pattern					0.9072
UIP-like	0.53 (0.30, 0.94)	0.62 (0.39, 0.97)	0.87 (0.42, 1.80)	0.6998	
Other fibrotic patterns	0.66 (0.27, 1.61)	0.83 (0.42, 1.65)	0.80 (0.26, 2.45)	0.6961	
Underlying ILD diagnosis					0.6095
iNSIP	0.84 (0.32, 2.26)	0.64 (0.23, 1.81)	1.32 (0.32, 5.52)	0.7051	
Unclassifiable IIP	0.92 (0.28, 3.02)	0.56 (0.25, 1.26)	1.64 (0.39, 6.95)	0.5039	
HP	0.32 (0.09, 1.15)	0.84 (0.41, 1.70)	0.38 (0.09, 1.65)	0.1961	
Autoimmune ILD	0.34 (0.12, 0.94)	0.58 (0.27, 1.27)	0.58 (0.16, 2.09)	0.4032	
Other ILD	0.90 (0.31, 2.64)	0.89 (0.30, 2.68)	1.00 (0.22, 4.69)	0.9958	
Region					0.0659
Europe	1.20 (0.45, 3.16)	0.95 (0.56, 1.61)	1.26 (0.42, 3.80)	0.6806	
Asia	0.70 (0.35, 1.42)	0.20 (0.07, 0.58)	3.57 (0.99, 12.94)	0.0527	
Canada and USA	0.00 (NC, NC)	0.57 (0.24, 1.37)	NC (NC, NC)	NC	
Rest of the World	0.22 (0.06, 0.79)	0.88 (0.24, 3.30)	0.25 (0.04, 1.57)	0.1402	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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M.1.1.1.2 Analyses of single endpoints

M.1.1.1.2.1 Time to death

Table M.1.1.1.2.1: 1 Indirect treatment comparison for the time to death over the whole trial

Subgroup Category	Nera 18mg vs Placebo Hazard ratio (95% CI)	Nin 150bid vs Placebo Hazard ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Hazard ratio (95% CI)	p-value	Interaction p-value
Overall	0.45 (0.24, 0.82)	0.78 (0.50, 1.21)	0.57 (0.27, 1.21)	0.1459	
Age					0.3369
<65 years	0.77 (0.24, 2.45)	0.75 (0.29, 1.96)	1.02 (0.23, 4.57)	0.9746	
>=65 years	0.36 (0.18, 0.75)	0.83 (0.50, 1.36)	0.44 (0.18, 1.05)	0.0655	
Sex					0.4442
Male	0.45 (0.20, 0.98)	0.93 (0.55, 1.56)	0.48 (0.19, 1.23)	0.1263	
Female	0.45 (0.17, 1.17)	0.50 (0.21, 1.19)	0.89 (0.25, 3.24)	0.8643	
Baseline FVC percent predicted					0.1021
<=70%	0.32 (0.15, 0.71)	0.87 (0.51, 1.47)	0.37 (0.15, 0.97)	0.0425	
>70%	0.84 (0.29, 2.41)	0.58 (0.26, 1.29)	1.45 (0.39, 5.44)	0.5787	
Baseline HRCT pattern					0.4289
UIP-like	0.45 (0.22, 0.91)	0.66 (0.40, 1.10)	0.68 (0.28, 1.63)	0.3895	
Other fibrotic patterns	0.44 (0.14, 1.40)	1.27 (0.53, 3.07)	0.34 (0.08, 1.47)	0.1502	
Underlying ILD diagnosis					0.6051
iNSIP	1.15 (0.31, 4.33)	0.63 (0.21, 1.95)	1.82 (0.32, 10.28)	0.4983	
Unclassifiable IIP	0.61 (0.15, 2.59)	0.78 (0.29, 2.09)	0.78 (0.14, 4.48)	0.7848	
HP	0.31 (0.07, 1.45)	0.93 (0.39, 2.18)	0.34 (0.06, 1.96)	0.2253	
Autoimmune ILD	0.35 (0.11, 1.12)	0.80 (0.32, 1.98)	0.44 (0.10, 1.93)	0.2743	
Other ILD	0.20 (0.03, 1.64)	0.78 (0.25, 2.46)	0.26 (0.02, 2.83)	0.2700	
Region					0.0965
Europe	0.84 (0.27, 2.60)	1.06 (0.58, 1.92)	0.79 (0.22, 2.85)	0.7176	
Asia	0.78 (0.31, 1.95)	0.24 (0.07, 0.87)	3.19 (0.67, 15.23)	0.1458	
Canada and USA	0.00 (NC, NC)	0.64 (0.23, 1.75)	NC (NC, NC)	NC	
Rest of the World	0.10 (0.01, 0.75)	0.85 (0.14, 5.13)	0.11 (0.01, 1.75)	0.1186	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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M.1.1.1.2.2 Time to first confirmed acute ILD exacerbation

Table M.1.1.1.2.2: 1 Indirect treatment comparison for the time to first confirmed acute ILD exacerbation over the whole trial

Subgroup Category	Nera 18mg vs Placebo Hazard ratio (95% CI)	Nin 150bid vs Placebo Hazard ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Hazard ratio (95% CI)	p-value	Interaction p-value
Overall	0.69 (0.34, 1.38)	0.63 (0.37, 1.07)	1.09 (0.45, 2.61)	0.8490	
Age					
<65 years	0.98 (0.29, 3.25)				
>=65 years	0.57 (0.24, 1.35)				
Sex					
Male	0.45 (0.16, 1.27)				
Female	1.05 (0.40, 2.81)				
Baseline FVC percent predicted					
<=70%	0.65 (0.29, 1.46)				
>70%	0.84 (0.21, 3.38)				
Baseline HRCT pattern					
UIP-like	0.48 (0.20, 1.17)				
Other fibrotic patterns	1.47 (0.41, 5.25)				
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	2.10 (0.41, 10.90)				
Asia	0.59 (0.22, 1.58)				
Canada and USA	0.00 (NC, NC)				
Rest of the World	0.49 (0.09, 2.68)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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M.1.1.2 Analyses of continuous variables

M.1.1.2.1 MMRM Analysis

Table M.1.1.2.1: 1 Indirect treatment comparison for the absolute change from baseline in EQ-5D VAS at week 52

Subgroup Category	Nera 18mg vs Placebo adj mean diff (95% CI)	Nin 150bid vs Placebo adj mean diff (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid adj mean diff (95% CI)	p-value	Interaction p-value
Overall	2.1 (-1.0, 5.2)	2.6 (-0.0, 5.3)	-0.5 (-4.6, 3.5)	0.8031	
Age					0.0467
<65 years	3.6 (-1.3, 8.5)	-1.0 (-5.2, 3.1)	4.7 (-1.7, 11.1)	0.1535	
>=65 years	1.0 (-3.0, 4.9)	4.7 (1.3, 8.1)	-3.7 (-9.0, 1.5)	0.1622	
Sex					0.5001
Male	3.4 (-0.9, 7.8)	5.2 (1.6, 8.9)	-1.8 (-7.5, 3.9)	0.5343	
Female	0.7 (-3.7, 5.0)	-0.3 (-4.2, 3.5)	1.0 (-4.8, 6.8)	0.7369	
Baseline FVC percent predicted					0.0641
<=70%	-0.8 (-5.2, 3.6)	4.0 (0.5, 7.5)	-4.8 (-10.4, 0.8)	0.0929	
>70%	3.7 (-0.5, 7.9)	0.8 (-3.2, 4.9)	2.9 (-3.0, 8.7)	0.3396	
Baseline HRCT pattern					0.0220
UIP-like	0.2 (-3.4, 3.9)	4.2 (0.8, 7.6)	-3.9 (-8.9, 1.1)	0.1246	
Other fibrotic patterns	6.4 (0.8, 12.0)	0.2 (-4.0, 4.5)	6.1 (-0.9, 13.2)	0.0858	
Underlying ILD diagnosis					0.1218
iNSIP	-2.9 (-9.6, 3.7)	6.4 (0.3, 12.6)	-9.3 (-18.4, -0.3)	0.0431	
Unclassifiable IIP	-1.2 (-8.6, 6.1)	3.7 (-2.6, 10.1)	-5.0 (-14.7, 4.7)	0.3161	
HP	6.2 (-1.8, 14.1)	1.5 (-3.7, 6.8)	4.6 (-4.9, 14.2)	0.3409	
Autoimmune ILD	0.6 (-4.7, 6.0)	-0.8 (-6.1, 4.5)	1.4 (-6.1, 8.9)	0.7180	
Other ILD	10.9 (2.5, 19.4)	4.4 (-3.3, 12.1)	6.5 (-4.9, 18.0)	0.2623	
Region					0.8646
Europe	1.6 (-5.3, 8.6)	3.1 (-0.8, 7.0)	-1.5 (-9.4, 6.5)	0.7169	
Asia	2.0 (-2.4, 6.4)	0.5 (-4.8, 5.9)	1.4 (-5.5, 8.4)	0.6837	
Canada and USA	4.6 (-5.3, 14.4)	2.7 (-3.2, 8.7)	1.8 (-9.7, 13.4)	0.7562	
Rest of the World	3.0 (-3.8, 9.8)	6.2 (-1.9, 14.3)	-3.2 (-13.7, 7.4)	0.5558	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Hedges´g will be presented in case of a significant treatment comparison.

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Table M.1.1.2.1: 1 Indirect treatment comparison for the absolute change from baseline in EQ-5D VAS at week 52

Subgroup Category	Nera 18mg vs Placebo Hedges'g (95% CI)	Nin 150bid vs Placebo Hedges'g (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Hedges'g (95% CI)
Overall			
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP	-0.19 (-0.64, 0.25)	0.37 (0.01, 0.72)	-0.56 (-1.12, 0.01)
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Hedges´g will be presented in case of a significant treatment comparison.

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M.1.2 Safety analysis

M.1.2.1 Safety analysis over the whole trial

M.1.2.1.1 Adverse events overall over the whole trial

Table M.1.2.1.1: 1 Indirect treatment comparison for the proportion of patients with any adverse events over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.98 (0.94, 1.02)	1.06 (1.02, 1.09)	0.93 (0.88, 0.98)	0.0077	
Age					0.1828
<65 years	0.94 (0.87, 1.03)	1.07 (1.00, 1.14)	0.88 (0.79, 0.98)	0.0217	
>=65 years	1.01 (0.96, 1.05)	1.05 (1.01, 1.09)	0.96 (0.91, 1.01)	0.1439	
Sex					0.9298
Male	0.99 (0.94, 1.04)	1.06 (1.01, 1.11)	0.93 (0.87, 1.00)	0.0488	
Female	0.97 (0.91, 1.04)	1.05 (1.00, 1.10)	0.93 (0.85, 1.01)	0.0741	
Baseline FVC percent predicted					0.8159
<=70%	0.94 (0.88, 1.01)	1.03 (0.99, 1.06)	0.92 (0.85, 0.99)	0.0215	
>70%	1.02 (0.96, 1.08)	1.10 (1.03, 1.17)	0.93 (0.85, 1.01)	0.0938	
Baseline HRCT pattern					0.4446
UIP-like	0.98 (0.92, 1.04)	1.07 (1.02, 1.12)	0.92 (0.85, 0.98)	0.0150	
Other fibrotic patterns	0.99 (0.93, 1.04)	1.03 (0.98, 1.09)	0.95 (0.89, 1.02)	0.1927	
Underlying ILD diagnosis					0.6873
iNSIP	0.93 (0.85, 1.03)	1.10 (0.97, 1.24)	0.85 (0.73, 0.99)	0.0381	
Unclassifiable IIP	1.01 (0.90, 1.12)	1.04 (0.98, 1.10)	0.97 (0.86, 1.09)	0.5698	
HP	0.96 (0.86, 1.07)	1.03 (1.00, 1.08)	0.93 (0.82, 1.04)	0.1880	
Autoimmune ILD	1.01 (0.93, 1.11)	1.05 (0.98, 1.12)	0.97 (0.87, 1.08)	0.5667	
Other ILD	0.99 (0.93, 1.06)	1.08 (0.99, 1.17)	0.92 (0.83, 1.03)	0.1446	
Region					0.1601
Europe	0.96 (0.91, 1.01)	1.03 (0.99, 1.07)	0.94 (0.88, 1.00)	0.0446	
Asia	0.98 (0.93, 1.03)	1.03 (0.99, 1.07)	0.96 (0.90, 1.02)	0.1650	
Canada and USA	0.97 (0.85, 1.12)	NC (NC, NC)	NC (NC, NC)	NC	
Rest of the World	0.99 (0.85, 1.15)	1.42 (1.07, 1.88)	0.70 (0.51, 0.96)	0.0259	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.1.1: 1 Indirect treatment comparison for the proportion of patients with any adverse events over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-1.86 (-6.23, 2.38)	5.14 (2.05, 8.23)	-7.00 (-12.30, -1.70)
Age			
<65 years	-5.41 (-14.00, 2.99)	6.21 (0.39, 12.04)	-11.62 (-21.93, -1.32)
>=65 years	0.57 (-4.38, 5.47)	4.68 (1.23, 8.13)	-4.11 (-10.13, 1.90)
Sex			
Male	-1.06 (-7.05, 4.64)	5.67 (1.39, 9.95)	-6.72 (-13.97, 0.52)
Female	-2.62 (-9.64, 4.24)	4.53 (0.06, 9.00)	-7.16 (-15.41, 1.10)
Baseline FVC percent predicted			
<=70%	-5.79 (-13.24, 0.39)	2.61 (-0.68, 5.91)	-8.41 (-15.97, -0.84)
>70%	1.74 (-4.20, 8.40)	8.66 (2.91, 14.41)	-6.93 (-15.45, 1.60)
Baseline HRCT pattern			
UIP-like	-2.08 (-7.83, 3.48)	6.31 (2.31, 10.32)	-8.39 (-15.32, -1.46)
Other fibrotic patterns	-1.47 (-8.94, 5.65)	3.22 (-1.61, 8.05)	-4.69 (-13.44, 4.06)
Underlying ILD diagnosis			
iNSIP	-6.59 (-17.28, 5.00)	8.50 (-2.19, 19.20)	-15.10 (-30.54, 0.35)
Unclassifiable IIP	0.56 (-11.63, 13.65)	4.00 (-1.43, 9.43)	-3.44 (-17.20, 10.32)
HP	-4.10 (-18.91, 7.56)	3.37 (-0.38, 7.12)	-7.47 (-21.23, 6.28)
Autoimmune ILD	1.33 (-7.68, 10.42)	4.38 (-1.86, 10.61)	-3.05 (-14.04, 7.94)
Other ILD	0.00 (NC, NC)	6.98 (-0.64, 14.59)	-6.98 (NC, NC)
Region			
Europe	-3.77 (-12.75, 5.40)	2.78 (-0.88, 6.45)	-6.56 (-16.35, 3.23)
Asia	-1.84 (-7.94, 3.96)	2.63 (-0.97, 6.23)	-4.47 (-11.43, 2.48)
Canada and USA	-2.55 (-23.83, 11.64)	0.00 (0.00, 0.00)	-2.55 (-20.28, 15.18)
Rest of the World	-0.76 (-15.00, 13.06)	25.96 (6.87, 45.05)	-26.72 (-50.41, -3.03)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.1.1: 1 Indirect treatment comparison for the proportion of patients with any adverse events over the whole trial

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.67 (0.28, 1.61)	4.06 (1.63, 10.10)	0.17 (0.05, 0.59)
Age			
<65 years	0.44 (0.13, 1.50)	3.38 (1.05, 10.89)	0.13 (0.02, 0.71)
>=65 years	1.19 (0.31, 4.55)	5.79 (1.28, 26.20)	0.21 (0.03, 1.55)
Sex			
Male	0.76 (0.20, 2.90)	4.65 (1.30, 16.61)	0.16 (0.03, 1.03)
Female	0.63 (0.20, 1.98)	3.47 (0.94, 12.87)	0.18 (0.03, 1.03)
Baseline FVC percent predicted			
<=70%	0.29 (0.07, 1.11)	2.78 (0.73, 10.65)	0.10 (0.02, 0.69)
>70%	1.46 (0.43, 4.92)	5.41 (1.53, 19.13)	0.27 (0.05, 1.56)
Baseline HRCT pattern			
UIP-like	0.69 (0.27, 1.77)	5.70 (1.63, 19.87)	0.12 (0.03, 0.58)
Other fibrotic patterns	0.51 (0.04, 5.74)	2.43 (0.61, 9.63)	0.21 (0.01, 3.40)
Underlying ILD diagnosis			
iNSIP	0.26 (0.03, 2.29)	2.60 (0.76, 8.93)	0.10 (0.01, 1.22)
Unclassifiable IIP	1.12 (0.15, 8.37)	NC (NC, NC)	NC (NC, NC)
HP	0.37 (0.03, 4.27)	NC (NC, NC)	NC (NC, NC)
Autoimmune ILD	1.25 (0.32, 4.86)	2.93 (0.57, 14.93)	0.43 (0.05, 3.56)
Other ILD	NC (NC, NC)	NC (NC, NC)	NC (NC, NC)
Region			
Europe	0.00 (NC, NC)	3.23 (0.64, 16.29)	NC (NC, NC)
Asia	0.59 (0.14, 2.55)	NC (NC, NC)	NC (NC, NC)
Canada and USA	0.55 (0.03, 9.43)	NC (NC, NC)	NC (NC, NC)
Rest of the World	0.93 (0.25, 3.46)	4.38 (1.28, 14.97)	0.21 (0.03, 1.28)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.1.1: 2 Indirect treatment comparison for the proportion of patients with any adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.99 (0.95, 1.04)	1.06 (1.02, 1.09)	0.94 (0.89, 0.99)	0.0241	
Age					
<65 years	0.97 (0.88, 1.06)				
>=65 years	1.01 (0.96, 1.05)				
Sex					
Male	0.99 (0.94, 1.04)				
Female	0.99 (0.92, 1.07)				
Baseline FVC percent predicted					
<=70%	0.95 (0.89, 1.02)				
>70%	1.03 (0.97, 1.10)				
Baseline HRCT pattern					
UIP-like	0.98 (0.92, 1.04)				
Other fibrotic patterns	1.02 (0.95, 1.09)				
Underlying ILD diagnosis					
iNSIP	0.93 (0.85, 1.03)				
Unclassifiable IIP	1.01 (0.90, 1.12)				
HP	0.96 (0.86, 1.07)				
Autoimmune ILD	1.05 (0.95, 1.15)				
Other ILD	0.99 (0.93, 1.06)				
Region					
Europe	0.96 (0.91, 1.01)				
Asia	0.99 (0.94, 1.05)				
Canada and USA	0.97 (0.85, 1.12)				
Rest of the World	1.02 (0.87, 1.19)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.1.1: 2 Indirect treatment comparison for the proportion of patients with any adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.95 (-5.45, 3.47)	5.14 (2.05, 8.23)	-6.10 (-11.52, -0.67)
Age			
<65 years	-3.00 (-11.96, 6.01)		
>=65 years	0.57 (-4.38, 5.47)		
Sex			
Male	-1.06 (-7.05, 4.64)		
Female	-0.74 (-8.04, 6.60)		
Baseline FVC percent predicted			
<=70%	-4.94 (-12.49, 1.49)		
>70%	2.70 (-3.42, 9.61)		
Baseline HRCT pattern			
UIP-like	-2.08 (-7.83, 3.48)		
Other fibrotic patterns	1.66 (-6.32, 10.16)		
Underlying ILD diagnosis			
iNSIP	-6.59 (-17.28, 5.00)		
Unclassifiable IIP	0.56 (-11.63, 13.65)		
HP	-4.10 (-18.91, 7.56)		
Autoimmune ILD	4.14 (-5.36, 13.90)		
Other ILD	0.00 (NC, NC)		
Region			
Europe	-3.77 (-12.75, 5.40)		
Asia	-0.90 (-7.14, 5.24)		
Canada and USA	-2.55 (-23.83, 11.64)		
Rest of the World	1.42 (-13.18, 15.64)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.1.1: 2 Indirect treatment comparison for the proportion of patients with any adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.83 (0.36, 1.90)	4.06 (1.63, 10.10)	0.20 (0.06, 0.70)
Age			
<65 years	0.68 (0.23, 2.01)		
>=65 years	1.19 (0.31, 4.55)		
Sex			
Male	0.76 (0.20, 2.90)		
Female	0.89 (0.31, 2.55)		
Baseline FVC percent predicted			
<=70%	0.39 (0.11, 1.32)		
>70%	1.72 (0.53, 5.58)		
Baseline HRCT pattern			
UIP-like	0.69 (0.27, 1.77)		
Other fibrotic patterns	1.57 (0.25, 9.74)		
Underlying ILD diagnosis			
iNSIP	0.26 (0.03, 2.29)		
Unclassifiable IIP	1.12 (0.15, 8.37)		
HP	0.37 (0.03, 4.27)		
Autoimmune ILD	1.80 (0.50, 6.46)		
Other ILD	NC (NC, NC)		
Region			
Europe	0.00 (NC, NC)		
Asia	0.80 (0.21, 3.06)		
Canada and USA	0.55 (0.03, 9.43)		
Rest of the World	1.14 (0.32, 4.05)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.1.1: 3 Indirect treatment comparison for the proportion of patients with serious adverse events over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.84 (0.69, 1.03)	0.89 (0.76, 1.05)	0.94 (0.73, 1.22)	0.6342	
Age					0.6347
<65 years	0.73 (0.50, 1.05)	0.85 (0.63, 1.16)	0.85 (0.53, 1.37)	0.5064	
>=65 years	0.91 (0.72, 1.15)	0.93 (0.77, 1.13)	0.98 (0.72, 1.32)	0.8694	
Sex					0.7673
Male	0.82 (0.63, 1.06)	0.90 (0.73, 1.10)	0.91 (0.65, 1.27)	0.5764	
Female	0.87 (0.64, 1.19)	0.89 (0.68, 1.16)	0.99 (0.66, 1.48)	0.9430	
Baseline FVC percent predicted					0.6624
<=70%	0.78 (0.60, 1.01)	0.86 (0.71, 1.04)	0.91 (0.66, 1.25)	0.5409	
>70%	0.98 (0.71, 1.35)	0.96 (0.71, 1.30)	1.02 (0.66, 1.59)	0.9225	
Baseline HRCT pattern					0.0360
UIP-like	0.97 (0.77, 1.23)	0.86 (0.71, 1.05)	1.13 (0.83, 1.54)	0.4456	
Other fibrotic patterns	0.59 (0.40, 0.86)	0.96 (0.72, 1.27)	0.61 (0.38, 0.99)	0.0451	
Underlying ILD diagnosis					0.7710
iNSIP	0.76 (0.49, 1.18)	0.75 (0.46, 1.23)	1.01 (0.52, 1.95)	0.9769	
Unclassifiable IIP	0.99 (0.65, 1.52)	0.81 (0.58, 1.13)	1.23 (0.71, 2.13)	0.4531	
HP	0.68 (0.38, 1.25)	0.97 (0.71, 1.30)	0.71 (0.36, 1.39)	0.3145	
Autoimmune ILD	1.01 (0.68, 1.51)	1.00 (0.73, 1.36)	1.02 (0.62, 1.68)	0.9504	
Other ILD	0.69 (0.44, 1.10)	0.82 (0.51, 1.32)	0.84 (0.43, 1.63)	0.6052	
Region					0.2383
Europe	1.02 (0.68, 1.53)	0.82 (0.65, 1.04)	1.24 (0.78, 1.97)	0.3714	
Asia	0.87 (0.67, 1.13)	0.87 (0.65, 1.18)	1.00 (0.67, 1.48)	0.9973	
Canada and USA	0.50 (0.20, 1.29)	1.00 (0.68, 1.46)	0.51 (0.18, 1.40)	0.1885	
Rest of the World	0.59 (0.32, 1.08)	1.11 (0.54, 2.27)	0.53 (0.21, 1.36)	0.1869	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.1.1: 3 Indirect treatment comparison for the proportion of patients with serious adverse events over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-8.17 (-17.27, 1.12)	-5.27 (-12.86, 2.32)	-2.90 (-14.82, 9.02)
Age			
<65 years	-12.90 (-26.86, 1.77)	-6.18 (-18.05, 5.70)	-6.72 (-25.32, 11.88)
>=65 years	-4.75 (-16.39, 7.07)	-3.55 (-13.31, 6.21)	-1.20 (-16.46, 14.06)
Sex			
Male	-10.13 (-22.63, 2.84)	-5.64 (-16.00, 4.72)	-4.49 (-20.90, 11.93)
Female	-5.86 (-18.73, 7.28)	-4.94 (-15.94, 6.05)	-0.92 (-17.94, 16.11)
Baseline FVC percent predicted			
<=70%	-13.29 (-26.09, 0.10)	-8.02 (-17.90, 1.86)	-5.27 (-21.68, 11.13)
>70%	-0.87 (-13.48, 11.66)	-1.64 (-13.11, 9.83)	0.77 (-16.24, 17.79)
Baseline HRCT pattern			
UIP-like	-1.36 (-12.28, 9.60)	-7.28 (-16.91, 2.35)	5.92 (-8.66, 20.49)
Other fibrotic patterns	-24.53 (-39.77, -7.37)	-1.94 (-14.22, 10.33)	-22.58 (-42.91, -2.26)
Underlying ILD diagnosis			
iNSIP	-12.50 (-31.30, 7.47)	-9.66 (-26.26, 6.94)	-2.84 (-28.37, 22.68)
Unclassifiable IIP	-0.28 (-21.66, 21.19)	-11.56 (-29.85, 6.72)	11.28 (-16.88, 39.45)
HP	-15.38 (-36.03, 7.86)	-1.75 (-16.66, 13.15)	-13.63 (-40.16, 12.90)
Autoimmune ILD	0.58 (-15.28, 16.42)	-0.08 (-15.12, 14.95)	0.67 (-21.18, 22.51)
Other ILD	-21.44 (-43.36, 3.21)	-9.06 (-30.73, 12.61)	-12.39 (-44.20, 19.42)
Region			
Europe	0.94 (-18.80, 20.60)	-9.62 (-20.86, 1.63)	10.56 (-12.12, 33.24)
Asia	-7.06 (-20.04, 6.26)	-7.21 (-22.89, 8.46)	0.15 (-20.31, 20.61)
Canada and USA	-23.14 (-45.29, 5.73)	-0.19 (-16.86, 16.47)	-22.94 (-53.41, 7.53)
Rest of the World	-17.90 (-35.71, 1.87)	3.04 (-18.34, 24.43)	-20.94 (-49.41, 7.53)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.1.1: 3 Indirect treatment comparison for the proportion of patients with serious adverse events over the whole trial

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.72 (0.49, 1.05)	0.81 (0.60, 1.10)	0.89 (0.55, 1.44)
Age			
<65 years	0.58 (0.32, 1.08)	0.77 (0.47, 1.27)	0.76 (0.34, 1.67)
>=65 years	0.83 (0.51, 1.33)	0.87 (0.59, 1.28)	0.95 (0.51, 1.77)
Sex			
Male	0.67 (0.39, 1.12)	0.80 (0.53, 1.21)	0.84 (0.43, 1.63)
Female	0.79 (0.46, 1.35)	0.82 (0.52, 1.29)	0.97 (0.48, 1.96)
Baseline FVC percent predicted			
<=70%	0.58 (0.34, 1.01)	0.72 (0.49, 1.08)	0.81 (0.41, 1.59)
>70%	0.96 (0.57, 1.64)	0.93 (0.57, 1.52)	1.03 (0.50, 2.13)
Baseline HRCT pattern			
UIP-like	0.95 (0.61, 1.48)	0.75 (0.51, 1.10)	1.27 (0.70, 2.29)
Other fibrotic patterns	0.37 (0.18, 0.74)	0.92 (0.56, 1.52)	0.40 (0.17, 0.94)
Underlying ILD diagnosis			
iNSIP	0.60 (0.27, 1.37)	0.65 (0.31, 1.37)	0.93 (0.31, 2.81)
Unclassifiable IIP	0.99 (0.40, 2.44)	0.63 (0.30, 1.32)	1.58 (0.49, 5.10)
HP	0.53 (0.20, 1.41)	0.93 (0.51, 1.69)	0.56 (0.18, 1.79)
Autoimmune ILD	1.02 (0.52, 2.00)	1.00 (0.55, 1.82)	1.03 (0.42, 2.53)
Other ILD	0.41 (0.14, 1.17)	0.69 (0.29, 1.67)	0.59 (0.15, 2.31)
Region			
Europe	1.04 (0.46, 2.36)	0.68 (0.43, 1.07)	1.53 (0.60, 3.90)
Asia	0.75 (0.44, 1.29)	0.75 (0.40, 1.41)	1.01 (0.44, 2.31)
Canada and USA	0.35 (0.09, 1.33)	0.99 (0.50, 1.95)	0.35 (0.08, 1.58)
Rest of the World	0.45 (0.18, 1.10)	1.16 (0.42, 3.22)	0.39 (0.10, 1.51)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.1.1: 4 Indirect treatment comparison for the proportion of patients with serious adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.85 (0.69, 1.05)	0.92 (0.78, 1.10)	0.92 (0.70, 1.20)	0.5436	
Age					
<65 years	0.74 (0.50, 1.08)				
>=65 years	0.92 (0.72, 1.17)				
Sex					
Male	0.84 (0.64, 1.10)				
Female	0.87 (0.63, 1.20)				
Baseline FVC percent predicted					
<=70%	0.77 (0.58, 1.02)				
>70%	1.00 (0.73, 1.38)				
Baseline HRCT pattern					
UIP-like	0.98 (0.77, 1.26)				
Other fibrotic patterns	0.59 (0.40, 0.89)				
Underlying ILD diagnosis					
iNSIP	0.80 (0.50, 1.28)				
Unclassifiable IIP	1.00 (0.64, 1.57)				
HP	0.62 (0.33, 1.16)				
Autoimmune ILD	1.05 (0.70, 1.57)				
Other ILD	0.72 (0.45, 1.15)				
Region					
Europe	0.99 (0.64, 1.53)				
Asia	0.90 (0.69, 1.18)				
Canada and USA	0.50 (0.20, 1.29)				
Rest of the World	0.62 (0.33, 1.15)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.1.1: 4 Indirect treatment comparison for the proportion of patients with serious adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-7.29 (-16.37, 1.98)	-3.45 (-11.00, 4.10)	-3.83 (-15.72, 8.05)
Age			
<65 years	-11.62 (-25.56, 2.92)		
>=65 years	-4.11 (-15.76, 7.70)		
Sex			
Male	-8.44 (-20.99, 4.50)		
Female	-5.81 (-18.61, 7.26)		
Baseline FVC percent predicted			
<=70%	-13.03 (-25.83, 0.41)		
>70%	0.09 (-12.52, 12.57)		
Baseline HRCT pattern			
UIP-like	-0.76 (-11.66, 10.17)		
Other fibrotic patterns	-22.92 (-38.24, -5.82)		
Underlying ILD diagnosis			
iNSIP	-9.32 (-28.32, 10.34)		
Unclassifiable IIP	0.00 (-21.45, 21.45)		
HP	-18.72 (-38.85, 4.52)		
Autoimmune ILD	1.99 (-13.88, 17.73)		
Other ILD	-18.67 (-40.91, 6.01)		
Region			
Europe	-0.33 (-20.04, 19.31)		
Asia	-5.17 (-18.22, 8.14)		
Canada and USA	-23.14 (-45.29, 5.73)		
Rest of the World	-15.72 (-33.60, 3.88)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.1.1: 4 Indirect treatment comparison for the proportion of patients with serious adverse events (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.74 (0.51, 1.08)	0.87 (0.64, 1.18)	0.86 (0.53, 1.39)
Age			
<65 years	0.61 (0.33, 1.14)		
>=65 years	0.85 (0.53, 1.37)		
Sex			
Male	0.71 (0.42, 1.20)		
Female	0.79 (0.46, 1.36)		
Baseline FVC percent predicted			
<=70%	0.59 (0.34, 1.02)		
>70%	1.00 (0.59, 1.71)		
Baseline HRCT pattern			
UIP-like	0.97 (0.62, 1.51)		
Other fibrotic patterns	0.39 (0.19, 0.79)		
Underlying ILD diagnosis			
iNSIP	0.68 (0.30, 1.56)		
Unclassifiable IIP	1.00 (0.41, 2.46)		
HP	0.45 (0.17, 1.23)		
Autoimmune ILD	1.09 (0.55, 2.13)		
Other ILD	0.46 (0.16, 1.31)		
Region			
Europe	0.99 (0.43, 2.25)		
Asia	0.81 (0.47, 1.39)		
Canada and USA	0.35 (0.09, 1.33)		
Rest of the World	0.49 (0.20, 1.20)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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M.1.2.2 Adverse events leading to treatment discontinuation over the whole trial

Table M.1.2.2: 1 Indirect treatment comparison for the proportion of patients with any adverse events leading to treatment discontinuation over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.79 (0.47, 1.34)	1.52 (1.09, 2.11)	0.52 (0.28, 0.97)	0.0410	
Age					0.7488
<65 years	0.57 (0.22, 1.49)	1.27 (0.66, 2.47)	0.44 (0.14, 1.44)	0.1754	
>=65 years	0.94 (0.50, 1.76)	1.68 (1.15, 2.45)	0.56 (0.27, 1.16)	0.1190	
Sex					0.4705
Male	0.65 (0.31, 1.38)	1.56 (1.00, 2.43)	0.42 (0.18, 1.00)	0.0496	
Female	0.97 (0.46, 2.07)	1.46 (0.89, 2.40)	0.66 (0.27, 1.64)	0.3739	
Baseline FVC percent predicted					0.3696
<=70%	0.48 (0.21, 1.10)	1.32 (0.88, 2.00)	0.36 (0.14, 0.91)	0.0314	
>70%	1.26 (0.59, 2.68)	1.90 (1.09, 3.33)	0.66 (0.26, 1.69)	0.3886	
Baseline HRCT pattern					0.8996
UIP-like	0.83 (0.46, 1.51)	1.67 (1.11, 2.51)	0.50 (0.24, 1.03)	0.0601	
Other fibrotic patterns	0.69 (0.23, 2.07)	1.27 (0.72, 2.23)	0.55 (0.16, 1.87)	0.3363	
Underlying ILD diagnosis					0.8258
iNSIP	1.70 (0.47, 6.16)	1.91 (0.83, 4.40)	0.89 (0.19, 4.14)	0.8821	
Unclassifiable IIP	0.90 (0.13, 6.06)	1.07 (0.54, 2.11)	0.84 (0.11, 6.41)	0.8704	
HP	0.43 (0.09, 2.00)	1.59 (0.82, 3.10)	0.27 (0.05, 1.44)	0.1265	
Autoimmune ILD	0.61 (0.23, 1.58)	1.52 (0.77, 2.99)	0.40 (0.12, 1.29)	0.1254	
Other ILD	1.03 (0.37, 2.88)	1.70 (0.67, 4.33)	0.61 (0.15, 2.43)	0.4801	
Region					0.8262
Europe	1.06 (0.36, 3.09)	1.45 (0.88, 2.40)	0.73 (0.22, 2.37)	0.5965	
Asia	0.87 (0.33, 2.31)	1.31 (0.71, 2.41)	0.66 (0.21, 2.11)	0.4871	
Canada and USA	0.59 (0.13, 2.60)	2.06 (1.00, 4.26)	0.29 (0.05, 1.49)	0.1374	
Rest of the World	0.71 (0.28, 1.84)	1.22 (0.33, 4.49)	0.59 (0.12, 2.93)	0.5145	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.2: 1 Indirect treatment comparison for the proportion of patients with any adverse events leading to treatment discontinuation over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-2.61 (-8.62, 3.38)	7.49 (1.64, 13.34)	-10.10 (-18.48, -1.72)
Age			
<65 years	-5.23 (-14.69, 3.81)	2.93 (-5.02, 10.87)	-8.16 (-20.35, 4.04)
>=65 years	-0.83 (-8.82, 7.27)	11.31 (3.22, 19.41)	-12.14 (-23.55, -0.73)
Sex			
Male	-4.78 (-13.25, 3.72)	8.22 (0.15, 16.28)	-13.00 (-24.71, -1.29)
Female	-0.31 (-9.05, 8.34)	6.63 (-1.86, 15.12)	-6.94 (-19.09, 5.21)
Baseline FVC percent predicted			
<=70%	-7.96 (-16.40, 0.87)	5.36 (-2.46, 13.17)	-13.32 (-24.97, -1.68)
>70%	2.48 (-6.07, 10.62)	10.46 (1.68, 19.25)	-7.98 (-20.10, 4.13)
Baseline HRCT pattern			
UIP-like	-2.25 (-9.63, 5.15)	9.71 (2.13, 17.29)	-11.96 (-22.55, -1.38)
Other fibrotic patterns	-3.36 (-14.21, 7.17)	3.85 (-5.28, 12.98)	-7.22 (-21.28, 6.84)
Underlying ILD diagnosis			
iNSIP	5.23 (-8.71, 17.54)	10.40 (-2.51, 23.31)	-5.17 (-23.58, 13.23)
Unclassifiable IIP	-0.56 (-13.65, 11.63)	1.44 (-14.04, 16.91)	-1.99 (-21.98, 17.99)
HP	-8.72 (-23.85, 8.05)	7.95 (-3.34, 19.23)	-16.66 (-36.20, 2.87)
Autoimmune ILD	-5.51 (-16.46, 5.36)	7.10 (-4.24, 18.43)	-12.61 (-28.34, 3.12)
Other ILD	0.56 (-18.60, 22.00)	9.73 (-7.30, 26.76)	-9.18 (-35.67, 17.32)
Region			
Europe	0.71 (-14.45, 14.30)	6.49 (-2.05, 15.04)	-5.79 (-22.51, 10.94)
Asia	-1.01 (-8.44, 6.33)	5.63 (-7.21, 18.47)	-6.63 (-21.44, 8.17)
Canada and USA	-8.24 (-27.51, 16.66)	13.82 (0.56, 27.08)	-22.06 (-47.81, 3.70)
Rest of the World	-5.61 (-21.10, 10.41)	2.24 (-12.65, 17.14)	-7.86 (-29.54, 13.83)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.2: 1 Indirect treatment comparison for the proportion of patients with any adverse events leading to treatment discontinuation over the whole trial

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.77 (0.43, 1.39)	1.66 (1.11, 2.48)	0.46 (0.23, 0.95)
Age			
<65 years	0.53 (0.19, 1.54)	1.32 (0.62, 2.79)	0.41 (0.11, 1.49)
>=65 years	0.93 (0.45, 1.90)	1.94 (1.20, 3.14)	0.48 (0.20, 1.13)
Sex			
Male	0.62 (0.27, 1.43)	1.73 (1.00, 2.97)	0.36 (0.13, 0.97)
Female	0.97 (0.41, 2.26)	1.59 (0.87, 2.88)	0.61 (0.22, 1.72)
Baseline FVC percent predicted			
<=70%	0.44 (0.17, 1.09)	1.41 (0.85, 2.35)	0.31 (0.11, 0.88)
>70%	1.29 (0.55, 3.02)	2.16 (1.12, 4.18)	0.60 (0.20, 1.75)
Baseline HRCT pattern			
UIP-like	0.81 (0.41, 1.60)	1.88 (1.14, 3.10)	0.43 (0.18, 1.00)
Other fibrotic patterns	0.67 (0.20, 2.22)	1.33 (0.68, 2.60)	0.50 (0.13, 2.00)
Underlying ILD diagnosis			
iNSIP	1.80 (0.44, 7.43)	2.16 (0.81, 5.79)	0.83 (0.15, 4.69)
Unclassifiable IIP	0.89 (0.12, 6.70)	1.09 (0.45, 2.63)	0.82 (0.09, 7.44)
HP	0.39 (0.07, 2.10)	1.75 (0.79, 3.90)	0.22 (0.03, 1.44)
Autoimmune ILD	0.57 (0.20, 1.67)	1.66 (0.74, 3.72)	0.35 (0.09, 1.32)
Other ILD	1.04 (0.29, 3.73)	1.91 (0.61, 5.99)	0.54 (0.10, 3.01)
Region			
Europe	1.07 (0.31, 3.64)	1.57 (0.86, 2.88)	0.68 (0.17, 2.66)
Asia	0.86 (0.30, 2.46)	1.40 (0.65, 3.05)	0.61 (0.17, 2.26)
Canada and USA	0.53 (0.09, 2.99)	2.45 (1.01, 5.93)	0.22 (0.03, 1.51)
Rest of the World	0.67 (0.22, 2.06)	1.25 (0.29, 5.45)	0.53 (0.08, 3.41)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.2: 2 Indirect treatment comparison for the proportion of patients with any adverse events leading to treatment discontinuation (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.93 (0.53, 1.60)	1.73 (1.21, 2.46)	0.54 (0.28, 1.03)	0.0605	
Age					0.8173
<65 years	0.71 (0.26, 1.95)	1.50 (0.75, 3.03)	0.47 (0.14, 1.62)	0.2310	
>=65 years	1.05 (0.55, 2.02)	1.89 (1.26, 2.83)	0.56 (0.26, 1.20)	0.1361	
Sex					0.6869
Male	0.80 (0.37, 1.76)	1.72 (1.08, 2.75)	0.47 (0.19, 1.16)	0.1022	
Female	1.06 (0.49, 2.30)	1.73 (1.01, 2.96)	0.61 (0.24, 1.57)	0.3063	
Baseline FVC percent predicted					0.5105
<=70%	0.57 (0.24, 1.35)	1.48 (0.96, 2.28)	0.39 (0.15, 1.01)	0.0535	
>70%	1.40 (0.64, 3.06)	2.26 (1.23, 4.17)	0.62 (0.23, 1.67)	0.3416	
Baseline HRCT pattern					0.8580
UIP-like	1.03 (0.54, 1.94)	1.88 (1.22, 2.91)	0.54 (0.25, 1.17)	0.1212	
Other fibrotic patterns	0.69 (0.23, 2.07)	1.46 (0.79, 2.67)	0.48 (0.14, 1.67)	0.2454	
Underlying ILD diagnosis					0.6582
iNSIP	5.09 (0.65, 39.76)	2.67 (1.02, 6.96)	1.91 (0.20, 18.43)	0.5768	
Unclassifiable IIP	0.90 (0.13, 6.06)	1.17 (0.58, 2.38)	0.77 (0.10, 5.88)	0.7993	
HP	0.43 (0.09, 2.00)	1.64 (0.82, 3.29)	0.26 (0.05, 1.42)	0.1208	
Autoimmune ILD	0.68 (0.25, 1.80)	1.82 (0.89, 3.75)	0.37 (0.11, 1.25)	0.1095	
Other ILD	1.20 (0.41, 3.50)	1.81 (0.65, 5.06)	0.66 (0.15, 2.93)	0.5873	
Region					0.9516
Europe	1.32 (0.41, 4.20)	1.74 (1.01, 3.01)	0.76 (0.21, 2.73)	0.6726	
Asia	0.87 (0.33, 2.31)	1.52 (0.79, 2.92)	0.57 (0.18, 1.84)	0.3469	
Canada and USA	0.88 (0.18, 4.33)	2.19 (1.01, 4.73)	0.40 (0.07, 2.36)	0.3135	
Rest of the World	0.80 (0.30, 2.12)	1.22 (0.33, 4.49)	0.66 (0.13, 3.35)	0.6147	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.2: 2 Indirect treatment comparison for the proportion of patients with any adverse events leading to treatment discontinuation (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.81 (-6.61, 4.99)	9.00 (3.34, 14.66)	-9.81 (-17.92, -1.70)
Age			
<65 years	-2.82 (-11.84, 5.82)	4.58 (-3.09, 12.25)	-7.40 (-19.10, 4.30)
>=65 years	0.61 (-7.20, 8.54)	12.66 (4.81, 20.50)	-12.05 (-23.16, -0.93)
Sex			
Male	-2.20 (-10.30, 5.96)	9.35 (1.49, 17.21)	-11.55 (-22.86, -0.24)
Female	0.63 (-7.96, 9.16)	8.57 (0.43, 16.72)	-7.94 (-19.75, 3.87)
Baseline FVC percent predicted			
<=70%	-5.42 (-13.53, 3.10)	6.92 (-0.67, 14.52)	-12.34 (-23.60, -1.08)
>70%	3.44 (-4.93, 11.44)	11.90 (3.47, 20.34)	-8.46 (-20.21, 3.29)
Baseline HRCT pattern			
UIP-like	0.28 (-6.78, 7.39)	11.17 (3.79, 18.54)	-10.89 (-21.11, -0.66)
Other fibrotic patterns	-3.36 (-14.21, 7.17)	5.46 (-3.28, 14.20)	-8.82 (-22.63, 4.99)
Underlying ILD diagnosis			
iNSIP	10.23 (-1.98, 21.70)	13.68 (1.43, 25.92)	-3.45 (-20.49, 13.58)
Unclassifiable IIP	-0.56 (-13.65, 11.63)	3.44 (-11.75, 18.62)	-3.99 (-23.75, 15.77)
HP	-8.72 (-23.85, 8.05)	7.88 (-3.10, 18.86)	-16.60 (-35.96, 2.77)
Autoimmune ILD	-4.10 (-14.83, 6.55)	9.37 (-1.63, 20.37)	-13.47 (-28.81, 1.86)
Other ILD	3.33 (-15.53, 24.39)	9.42 (-6.69, 25.54)	-6.09 (-31.75, 19.56)
Region			
Europe	3.21 (-11.45, 16.32)	8.57 (0.39, 16.74)	-5.36 (-21.47, 10.75)
Asia	-1.01 (-8.44, 6.33)	8.26 (-4.23, 20.75)	-9.27 (-23.78, 5.24)
Canada and USA	-1.57 (-19.98, 22.39)	13.78 (0.91, 26.65)	-15.35 (-40.14, 9.44)
Rest of the World	-3.44 (-18.68, 12.25)	2.24 (-12.65, 17.14)	-5.68 (-27.16, 15.79)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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Table M.1.2.2: 2 Indirect treatment comparison for the proportion of patients with any adverse events leading to treatment discontinuation (excluding disease-related events) over the whole trial

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.92 (0.50, 1.69)	1.92 (1.27, 2.93)	0.48 (0.23, 1.00)
Age			
<65 years	0.69 (0.23, 2.07)	1.58 (0.72, 3.48)	0.43 (0.11, 1.68)
>=65 years	1.06 (0.51, 2.22)	2.21 (1.34, 3.65)	0.48 (0.20, 1.17)
Sex			
Male	0.78 (0.33, 1.87)	1.93 (1.10, 3.38)	0.41 (0.14, 1.15)
Female	1.07 (0.45, 2.54)	1.92 (1.02, 3.61)	0.56 (0.19, 1.62)
Baseline FVC percent predicted			
<=70%	0.54 (0.21, 1.38)	1.61 (0.95, 2.72)	0.34 (0.11, 0.99)
>70%	1.45 (0.61, 3.47)	2.61 (1.29, 5.27)	0.56 (0.18, 1.71)
Baseline HRCT pattern			
UIP-like	1.03 (0.50, 2.10)	2.16 (1.28, 3.64)	0.48 (0.20, 1.15)
Other fibrotic patterns	0.67 (0.20, 2.22)	1.55 (0.76, 3.15)	0.43 (0.11, 1.74)
Underlying ILD diagnosis			
iNSIP	5.69 (0.67, 48.22)	3.14 (1.05, 9.33)	1.81 (0.16, 19.98)
Unclassifiable IIP	0.89 (0.12, 6.70)	1.22 (0.50, 3.02)	0.73 (0.08, 6.64)
HP	0.39 (0.07, 2.10)	1.80 (0.79, 4.11)	0.22 (0.03, 1.42)
Autoimmune ILD	0.65 (0.22, 1.92)	2.04 (0.87, 4.76)	0.32 (0.08, 1.26)
Other ILD	1.25 (0.34, 4.65)	2.03 (0.60, 6.83)	0.62 (0.10, 3.70)
Region			
Europe	1.37 (0.37, 5.04)	1.93 (1.02, 3.66)	0.71 (0.17, 3.04)
Asia	0.86 (0.30, 2.46)	1.69 (0.76, 3.77)	0.51 (0.14, 1.91)
Canada and USA	0.87 (0.14, 5.31)	2.59 (1.03, 6.50)	0.33 (0.04, 2.55)
Rest of the World	0.77 (0.24, 2.44)	1.25 (0.29, 5.45)	0.62 (0.10, 3.99)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).

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M.1.2.3 Adverse events on SOC level over the whole trial

Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Cardiac disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.77 (1.05, 2.96)	0.96 (0.66, 1.38)	1.85 (0.98, 3.49)	0.0586	
Age					
<65 years	1.26 (0.46, 3.47)	1.19 (0.57, 2.49)			
>=65 years	2.03 (1.11, 3.70)	0.92 (0.60, 1.41)			
Sex					
Male	2.09 (1.06, 4.11)	0.93 (0.61, 1.43)			
Female	1.40 (0.63, 3.15)	1.01 (0.50, 2.04)			
Baseline FVC percent predicted					
<=70%	2.46 (1.16, 5.22)	0.95 (0.59, 1.54)			
>70%	1.30 (0.64, 2.64)	0.96 (0.54, 1.72)			
Baseline HRCT pattern					
UIP-like	2.13 (1.14, 3.97)	0.80 (0.51, 1.26)			
Other fibrotic patterns	1.11 (0.43, 2.88)	1.35 (0.71, 2.56)			
Underlying ILD diagnosis					
iNSIP	1.21 (0.31, 4.78)	0.82 (0.29, 2.29)			
Unclassifiable IIP	1.26 (0.44, 3.62)	1.23 (0.51, 2.94)			
HP	1.63 (0.48, 5.54)	0.75 (0.38, 1.47)			
Autoimmune ILD	2.37 (0.96, 5.81)	1.43 (0.64, 3.22)			
Other ILD	2.88 (0.57, 14.54)	0.75 (0.30, 1.92)			
Region					
Europe	1.04 (0.46, 2.34)	0.77 (0.45, 1.31)			
Asia	2.23 (1.01, 4.90)	1.65 (0.69, 3.97)			
Canada and USA	1.76 (0.40, 7.80)	0.96 (0.49, 1.88)			
Rest of the World	3.21 (0.35, 29.69)	0.61 (0.06, 6.42)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Cardiac disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	6.90 (0.72, 13.14)	-0.65 (-6.00, 4.71)	7.55 (-0.65, 15.75)
Age			
<65 years	1.86 (-6.98, 10.60)	1.70 (-5.57, 8.97)	
>=65 years	10.38 (1.81, 19.02)	-1.51 (-8.91, 5.88)	
Sex			
Male	10.34 (1.10, 19.66)	-1.34 (-9.51, 6.83)	
Female	3.44 (-4.95, 11.84)	0.06 (-6.38, 6.50)	
Baseline FVC percent predicted			
<=70%	11.12 (2.08, 20.76)	-0.74 (-7.77, 6.29)	
>70%	3.13 (-5.76, 11.62)	-0.52 (-8.80, 7.75)	
Baseline HRCT pattern			
UIP-like	9.30 (1.86, 16.87)	-3.40 (-10.34, 3.54)	
Other fibrotic patterns	1.18 (-10.37, 12.63)	3.88 (-4.46, 12.22)	
Underlying ILD diagnosis			
iNSIP	1.59 (-11.80, 13.17)	-2.10 (-12.82, 8.62)	
Unclassifiable IIP	3.61 (-13.56, 20.04)	3.19 (-10.15, 16.53)	
HP	6.41 (-9.85, 24.41)	-4.82 (-15.89, 6.26)	
Autoimmune ILD	11.55 (-0.13, 23.27)	4.41 (-5.52, 14.34)	
Other ILD	10.44 (-5.39, 29.53)	-5.14 (-21.94, 11.66)	
Region			
Europe	0.75 (-16.40, 16.62)	-4.05 (-12.26, 4.16)	
Asia	9.28 (0.39, 18.27)	5.98 (-4.26, 16.22)	
Canada and USA	7.65 (-11.72, 31.93)	-0.89 (-14.29, 12.52)	
Rest of the World	4.80 (-5.44, 16.57)	-2.00 (-11.18, 7.18)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Cardiac disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.91 (1.07, 3.43)	0.95 (0.62, 1.46)	2.01 (0.97, 4.17)
Age			
<65 years	1.28 (0.43, 3.87)	1.21 (0.53, 2.74)	
>=65 years	2.30 (1.15, 4.60)	0.90 (0.54, 1.51)	
Sex			
Male	2.36 (1.08, 5.13)	0.92 (0.54, 1.56)	
Female	1.46 (0.60, 3.57)	1.01 (0.46, 2.19)	
Baseline FVC percent predicted			
<=70%	2.79 (1.19, 6.55)	0.94 (0.54, 1.65)	
>70%	1.34 (0.60, 3.01)	0.96 (0.49, 1.89)	
Baseline HRCT pattern			
UIP-like	2.37 (1.17, 4.79)	0.77 (0.45, 1.32)	
Other fibrotic patterns	1.12 (0.38, 3.30)	1.41 (0.67, 2.95)	
Underlying ILD diagnosis			
iNSIP	1.23 (0.28, 5.49)	0.80 (0.25, 2.52)	
Unclassifiable IIP	1.32 (0.38, 4.58)	1.27 (0.46, 3.57)	
HP	1.75 (0.43, 7.18)	0.71 (0.31, 1.58)	
Autoimmune ILD	2.71 (0.98, 7.52)	1.50 (0.60, 3.78)	
Other ILD	3.24 (0.54, 19.25)	0.71 (0.23, 2.22)	
Region			
Europe	1.05 (0.38, 2.91)	0.73 (0.39, 1.37)	
Asia	2.48 (1.03, 5.98)	1.77 (0.66, 4.76)	
Canada and USA	1.93 (0.34, 10.83)	0.95 (0.41, 2.20)	
Rest of the World	3.38 (0.34, 33.76)	0.60 (0.05, 6.90)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Ear and labyrinth disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	5.05 (1.12, 22.76)	0.75 (0.32, 1.75)	6.75 (1.20, 38.07)	0.0306	
Age					
<65 years					
>=65 years					
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like					
Other fibrotic patterns					
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Ear and labyrinth disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	3.64 (0.54, 7.32)	-0.91 (-3.58, 1.75)	4.56 (0.25, 8.87)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Ear and labyrinth disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	5.24 (1.13, 24.19)	0.74 (0.31, 1.78)	7.07 (1.21, 41.27)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Eye disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.09 (0.51, 2.34)	0.82 (0.48, 1.39)	1.33 (0.53, 3.38)	0.5420	
Age					
<65 years	1.18 (0.33, 4.24)	1.74 (0.44, 6.81)			
>=65 years	1.05 (0.41, 2.72)	0.74 (0.41, 1.33)			
Sex					
Male	0.75 (0.24, 2.28)	0.64 (0.33, 1.25)			
Female	1.56 (0.53, 4.60)	1.26 (0.51, 3.10)			
Baseline FVC percent predicted					
<=70%	1.23 (0.37, 4.12)	1.07 (0.50, 2.28)			
>70%	0.96 (0.36, 2.55)	0.63 (0.30, 1.35)			
Baseline HRCT pattern					
UIP-like	0.82 (0.33, 2.02)	0.90 (0.49, 1.65)			
Other fibrotic patterns	2.42 (0.49, 12.05)	0.62 (0.21, 1.84)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	0.94 (0.27, 3.29)	0.95 (0.41, 2.23)			
Asia	0.99 (0.33, 2.97)	0.61 (0.25, 1.50)			
Canada and USA	1.76 (0.12, 26.45)	0.74 (0.25, 2.20)			
Rest of the World	1.07 (0.07, 16.57)	NC (NC, NC)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Eye disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.50 (-4.01, 5.06)	-1.53 (-5.59, 2.52)	2.04 (-4.05, 8.12)
Age			
<65 years	0.86 (-6.78, 8.39)	1.84 (-2.53, 6.21)	
>=65 years	0.31 (-5.67, 6.43)	-3.10 (-9.03, 2.83)	
Sex			
Male	-1.53 (-7.96, 4.87)	-4.04 (-10.05, 1.98)	
Female	2.62 (-4.24, 9.64)	1.34 (-3.91, 6.60)	
Baseline FVC percent predicted			
<=70%	0.97 (-5.10, 7.82)	0.42 (-4.46, 5.29)	
>70%	-0.28 (-7.51, 6.43)	-4.24 (-11.15, 2.67)	
Baseline HRCT pattern			
UIP-like	-1.13 (-6.68, 4.38)	-0.97 (-6.56, 4.62)	
Other fibrotic patterns	4.45 (-4.26, 13.70)	-2.43 (-7.91, 3.05)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	-0.57 (-14.67, 11.83)	-0.31 (-5.94, 5.32)	
Asia	-0.05 (-6.89, 6.75)	-5.61 (-15.70, 4.48)	
Canada and USA	2.55 (-11.64, 23.83)	-2.68 (-12.19, 6.82)	
Rest of the World	0.15 (-9.21, 10.05)	3.13 (-2.90, 9.15)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Eye disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.10 (0.49, 2.46)	0.81 (0.45, 1.43)	1.36 (0.51, 3.68)
Age			
<65 years	1.19 (0.31, 4.59)	1.77 (0.43, 7.25)	
>=65 years	1.06 (0.38, 2.90)	0.71 (0.37, 1.37)	
Sex			
Male	0.73 (0.23, 2.39)	0.61 (0.30, 1.28)	
Female	1.60 (0.51, 5.06)	1.28 (0.49, 3.33)	
Baseline FVC percent predicted			
<=70%	1.24 (0.35, 4.42)	1.07 (0.48, 2.41)	
>70%	0.96 (0.33, 2.73)	0.61 (0.26, 1.39)	
Baseline HRCT pattern			
UIP-like	0.81 (0.31, 2.11)	0.89 (0.46, 1.74)	
Other fibrotic patterns	2.54 (0.47, 13.60)	0.60 (0.19, 1.90)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	0.94 (0.23, 3.74)	0.95 (0.38, 2.36)	
Asia	0.99 (0.31, 3.17)	0.57 (0.21, 1.57)	
Canada and USA	1.81 (0.11, 30.97)	0.71 (0.22, 2.37)	
Rest of the World	1.07 (0.06, 17.68)	NC (NC, NC)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.18 (0.95, 1.46)	1.70 (1.51, 1.91)	0.70 (0.54, 0.89)	0.0038	
Age					0.0131
<65 years	0.86 (0.59, 1.25)	1.91 (1.53, 2.38)	0.45 (0.29, 0.70)	0.0003	
>=65 years	1.41 (1.08, 1.84)	1.60 (1.39, 1.84)	0.88 (0.65, 1.19)	0.4017	
Sex					0.8815
Male	1.19 (0.87, 1.62)	1.68 (1.43, 1.97)	0.71 (0.50, 1.00)	0.0524	
Female	1.17 (0.87, 1.58)	1.72 (1.44, 2.05)	0.68 (0.48, 0.96)	0.0299	
Baseline FVC percent predicted					0.7220
<=70%	1.13 (0.83, 1.53)	1.58 (1.36, 1.82)	0.71 (0.51, 1.00)	0.0527	
>70%	1.24 (0.91, 1.68)	1.90 (1.55, 2.32)	0.65 (0.45, 0.94)	0.0221	
Baseline HRCT pattern					0.1724
UIP-like	1.28 (0.99, 1.65)	1.64 (1.42, 1.89)	0.78 (0.58, 1.05)	0.0972	
Other fibrotic patterns	0.97 (0.64, 1.46)	1.81 (1.47, 2.23)	0.54 (0.34, 0.85)	0.0075	
Underlying ILD diagnosis					0.4025
iNSIP	1.12 (0.63, 1.97)	2.54 (1.68, 3.84)	0.44 (0.22, 0.89)	0.0219	
Unclassifiable IIP	1.18 (0.74, 1.89)	2.19 (1.57, 3.06)	0.54 (0.30, 0.96)	0.0349	
HP	0.99 (0.58, 1.71)	1.39 (1.15, 1.69)	0.71 (0.40, 1.27)	0.2506	
Autoimmune ILD	1.23 (0.85, 1.79)	1.54 (1.25, 1.91)	0.80 (0.52, 1.23)	0.3067	
Other ILD	1.54 (0.92, 2.59)	1.57 (1.15, 2.15)	0.98 (0.53, 1.80)	0.9478	
Region					0.6121
Europe	1.39 (0.82, 2.38)	1.91 (1.56, 2.34)	0.73 (0.41, 1.30)	0.2818	
Asia	1.10 (0.82, 1.47)	1.64 (1.34, 2.00)	0.67 (0.47, 0.96)	0.0269	
Canada and USA	0.99 (0.57, 1.74)	1.17 (0.99, 1.39)	0.85 (0.47, 1.52)	0.5790	
Rest of the World	1.56 (0.88, 2.76)	3.83 (1.88, 7.80)	0.41 (0.16, 1.01)	0.0539	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	7.18 (-2.04, 16.23)	34.49 (27.82, 41.16)	-27.31 (-38.63, -16.00)
Age			
<65 years	-5.81 (-20.00, 8.67)	39.04 (28.15, 49.93)	-44.84 (-62.85, -26.84)
>=65 years	15.66 (3.79, 26.93)	32.16 (23.78, 40.54)	-16.50 (-30.79, -2.21)
Sex			
Male	7.11 (-5.63, 19.56)	34.08 (24.99, 43.16)	-26.96 (-42.49, -11.43)
Female	7.11 (-6.10, 19.98)	34.96 (25.13, 44.79)	-27.84 (-44.18, -11.51)
Baseline FVC percent predicted			
<=70%	5.16 (-8.03, 18.19)	30.82 (22.12, 39.51)	-25.66 (-41.39, -9.93)
>70%	9.12 (-3.76, 21.50)	39.62 (29.28, 49.96)	-30.50 (-46.83, -14.18)
Baseline HRCT pattern			
UIP-like	10.74 (-0.26, 21.39)	33.01 (24.62, 41.40)	-22.27 (-35.96, -8.57)
Other fibrotic patterns	-1.28 (-17.73, 15.25)	36.94 (25.98, 47.90)	-38.22 (-58.02, -18.42)
Underlying ILD diagnosis			
iNSIP	3.86 (-15.38, 21.99)	45.49 (29.89, 61.10)	-41.63 (-65.98, -17.28)
Unclassifiable IIP	8.06 (-13.86, 28.89)	50.19 (35.01, 65.37)	-42.13 (-68.35, -15.91)
HP	-0.26 (-22.46, 22.31)	23.85 (11.09, 36.61)	-24.11 (-49.87, 1.66)
Autoimmune ILD	9.13 (-7.10, 24.72)	29.60 (16.53, 42.67)	-20.47 (-41.05, 0.12)
Other ILD	21.11 (-4.09, 42.89)	30.72 (11.84, 49.61)	-9.61 (-39.75, 20.53)
Region			
Europe	12.78 (-7.19, 30.95)	38.34 (28.20, 48.48)	-25.56 (-47.16, -3.96)
Asia	4.27 (-8.97, 17.29)	37.04 (24.93, 49.15)	-32.77 (-50.64, -14.91)
Canada and USA	-0.39 (-27.84, 26.66)	12.65 (-0.54, 25.85)	-13.05 (-43.32, 17.23)
Rest of the World	15.93 (-3.91, 34.25)	50.80 (30.73, 70.88)	-34.88 (-62.57, -7.18)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.34 (0.92, 1.96)	5.36 (3.72, 7.72)	0.25 (0.15, 0.42)
Age			
<65 years	0.78 (0.42, 1.45)	6.05 (3.45, 10.62)	0.13 (0.06, 0.30)
>=65 years	1.89 (1.16, 3.06)	5.16 (3.18, 8.36)	0.37 (0.18, 0.73)
Sex			
Male	1.34 (0.79, 2.28)	5.33 (3.24, 8.79)	0.25 (0.12, 0.52)
Female	1.33 (0.78, 2.29)	5.39 (3.17, 9.19)	0.25 (0.12, 0.53)
Baseline FVC percent predicted			
<=70%	1.23 (0.72, 2.13)	4.65 (2.89, 7.49)	0.27 (0.13, 0.55)
>70%	1.45 (0.86, 2.47)	6.54 (3.71, 11.53)	0.22 (0.10, 0.48)
Baseline HRCT pattern			
UIP-like	1.55 (0.99, 2.43)	5.22 (3.27, 8.35)	0.30 (0.15, 0.57)
Other fibrotic patterns	0.95 (0.47, 1.91)	5.64 (3.16, 10.06)	0.17 (0.07, 0.42)
Underlying ILD diagnosis			
iNSIP	1.19 (0.50, 2.80)	7.17 (3.26, 15.78)	0.17 (0.05, 0.53)
Unclassifiable IIP	1.38 (0.56, 3.41)	16.30 (5.58, 47.59)	0.08 (0.02, 0.34)
HP	0.99 (0.38, 2.59)	3.54 (1.71, 7.33)	0.28 (0.08, 0.93)
Autoimmune ILD	1.45 (0.74, 2.83)	4.42 (2.14, 9.14)	0.33 (0.12, 0.88)
Other ILD	2.36 (0.83, 6.69)	4.64 (1.61, 13.36)	0.51 (0.11, 2.25)
Region			
Europe	1.72 (0.73, 4.04)	5.67 (3.38, 9.49)	0.30 (0.11, 0.82)
Asia	1.19 (0.69, 2.04)	13.64 (4.52, 41.13)	0.09 (0.03, 0.30)
Canada and USA	0.98 (0.30, 3.24)	2.27 (0.94, 5.51)	0.43 (0.10, 1.91)
Rest of the World	2.01 (0.83, 4.84)	10.06 (3.32, 30.45)	0.20 (0.05, 0.82)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: General disorders and administration site conditions

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.72 (0.56, 0.93)	0.85 (0.68, 1.07)	0.85 (0.60, 1.19)	0.3404	
Age					
<65 years	0.70 (0.47, 1.06)	1.02 (0.70, 1.51)			
>=65 years	0.74 (0.53, 1.02)	0.78 (0.59, 1.04)			
Sex					
Male	0.67 (0.47, 0.96)	0.82 (0.61, 1.10)			
Female	0.79 (0.55, 1.13)	0.90 (0.63, 1.28)			
Baseline FVC percent predicted					
<=70%	0.87 (0.63, 1.21)	0.76 (0.58, 1.01)			
>70%	0.61 (0.41, 0.91)	1.04 (0.70, 1.54)			
Baseline HRCT pattern					
UIP-like	0.68 (0.49, 0.94)	0.94 (0.71, 1.24)			
Other fibrotic patterns	0.81 (0.54, 1.21)	0.72 (0.48, 1.06)			
Underlying ILD diagnosis					
iNSIP	1.03 (0.56, 1.91)	0.89 (0.45, 1.73)			
Unclassifiable IIP	0.58 (0.32, 1.07)	1.13 (0.73, 1.75)			
HP	0.47 (0.25, 0.91)	0.82 (0.55, 1.22)			
Autoimmune ILD	0.72 (0.45, 1.16)	0.58 (0.32, 1.06)			
Other ILD	1.11 (0.58, 2.12)	0.83 (0.49, 1.42)			
Region					
Europe	0.91 (0.52, 1.57)	0.73 (0.53, 1.02)			
Asia	0.65 (0.45, 0.94)	1.02 (0.58, 1.78)			
Canada and USA	0.76 (0.36, 1.60)	1.00 (0.70, 1.42)			
Rest of the World	0.74 (0.39, 1.40)	0.49 (0.10, 2.35)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: General disorders and administration site conditions

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-11.44 (-20.12, -2.51)	-4.92 (-11.98, 2.13)	-6.52 (-17.80, 4.76)
Age			
<65 years	-12.62 (-26.33, 1.71)	0.68 (-10.31, 11.67)	
>=65 years	-10.70 (-21.69, 0.71)	-8.13 (-17.28, 1.02)	
Sex			
Male	-14.27 (-26.13, -1.78)	-6.56 (-16.34, 3.22)	
Female	-8.43 (-20.82, 4.30)	-3.07 (-13.21, 7.08)	
Baseline FVC percent predicted			
<=70%	-5.53 (-18.34, 7.68)	-9.28 (-18.70, 0.14)	
>70%	-15.07 (-26.72, -3.07)	1.12 (-9.35, 11.59)	
Baseline HRCT pattern			
UIP-like	-12.62 (-22.66, -2.18)	-1.94 (-10.99, 7.10)	
Other fibrotic patterns	-9.00 (-25.13, 7.81)	-9.80 (-21.02, 1.42)	
Underlying ILD diagnosis			
iNSIP	0.91 (-17.83, 18.64)	-2.64 (-17.08, 11.80)	
Unclassifiable IIP	-19.72 (-39.18, 1.89)	5.31 (-12.94, 23.56)	
HP	-29.74 (-48.71, -6.20)	-7.18 (-21.42, 7.06)	
Autoimmune ILD	-10.87 (-25.72, 4.72)	-11.42 (-23.63, 0.79)	
Other ILD	3.89 (-19.38, 27.49)	-7.34 (-28.69, 14.00)	
Region			
Europe	-3.54 (-22.68, 15.36)	-10.17 (-20.75, 0.40)	
Asia	-15.37 (-27.62, -2.43)	0.37 (-13.06, 13.79)	
Canada and USA	-11.37 (-36.25, 17.23)	-0.06 (-16.86, 16.73)	
Rest of the World	-9.20 (-27.15, 9.81)	-6.57 (-20.00, 6.86)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: General disorders and administration site conditions

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.61 (0.41, 0.90)	0.80 (0.57, 1.11)	0.76 (0.46, 1.27)
Age			
<65 years	0.58 (0.31, 1.08)	1.03 (0.60, 1.77)	
>=65 years	0.63 (0.38, 1.03)	0.69 (0.46, 1.05)	
Sex			
Male	0.53 (0.31, 0.93)	0.74 (0.48, 1.16)	
Female	0.69 (0.39, 1.21)	0.86 (0.53, 1.41)	
Baseline FVC percent predicted			
<=70%	0.80 (0.46, 1.38)	0.66 (0.44, 1.01)	
>70%	0.49 (0.28, 0.87)	1.06 (0.62, 1.81)	
Baseline HRCT pattern			
UIP-like	0.56 (0.35, 0.91)	0.92 (0.61, 1.38)	
Other fibrotic patterns	0.69 (0.34, 1.39)	0.62 (0.36, 1.08)	
Underlying ILD diagnosis			
iNSIP	1.04 (0.43, 2.53)	0.86 (0.36, 2.01)	
Unclassifiable IIP	0.42 (0.16, 1.10)	1.24 (0.59, 2.63)	
HP	0.28 (0.10, 0.78)	0.73 (0.39, 1.37)	
Autoimmune ILD	0.61 (0.30, 1.24)	0.50 (0.24, 1.07)	
Other ILD	1.18 (0.41, 3.37)	0.74 (0.30, 1.80)	
Region			
Europe	0.86 (0.36, 2.02)	0.63 (0.39, 1.02)	
Asia	0.51 (0.29, 0.90)	1.02 (0.49, 2.14)	
Canada and USA	0.62 (0.18, 2.12)	1.00 (0.51, 1.95)	
Rest of the World	0.64 (0.26, 1.61)	0.45 (0.08, 2.51)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Infections and infestations

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.91 (0.81, 1.03)	0.94 (0.84, 1.06)	0.97 (0.82, 1.14)	0.6892	
Age					
<65 years	0.85 (0.70, 1.04)	1.02 (0.85, 1.22)			
>=65 years	0.95 (0.82, 1.10)	0.90 (0.77, 1.04)			
Sex					
Male	0.86 (0.72, 1.01)	0.94 (0.80, 1.10)			
Female	0.97 (0.82, 1.16)	0.95 (0.80, 1.12)			
Baseline FVC percent predicted					
<=70%	0.81 (0.67, 0.97)	0.92 (0.81, 1.05)			
>70%	1.01 (0.86, 1.19)	0.98 (0.79, 1.20)			
Baseline HRCT pattern					
UIP-like	0.91 (0.79, 1.05)	0.96 (0.84, 1.11)			
Other fibrotic patterns	0.91 (0.74, 1.12)	0.91 (0.75, 1.10)			
Underlying ILD diagnosis					
iNSIP	0.83 (0.62, 1.10)	0.85 (0.62, 1.16)			
Unclassifiable IIP	0.87 (0.63, 1.18)	0.90 (0.67, 1.21)			
HP	0.93 (0.67, 1.28)	0.90 (0.75, 1.09)			
Autoimmune ILD	1.08 (0.86, 1.35)	1.09 (0.87, 1.37)			
Other ILD	0.85 (0.69, 1.05)	0.96 (0.68, 1.36)			
Region					
Europe	0.96 (0.75, 1.22)	1.03 (0.88, 1.20)			
Asia	0.87 (0.74, 1.03)	0.89 (0.69, 1.13)			
Canada and USA	0.92 (0.67, 1.25)	0.83 (0.66, 1.05)			
Rest of the World	0.99 (0.70, 1.41)	0.79 (0.43, 1.43)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Infections and infestations

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-6.60 (-14.97, 1.89)	-3.81 (-11.12, 3.49)	-2.79 (-13.94, 8.37)
Age			
<65 years	-11.06 (-24.27, 2.81)	1.11 (-10.57, 12.80)	
>=65 years	-3.68 (-14.32, 7.00)	-7.04 (-16.42, 2.35)	
Sex			
Male	-11.00 (-22.52, 0.87)	-4.08 (-14.10, 5.95)	
Female	-1.97 (-13.95, 10.12)	-3.48 (-14.14, 7.17)	
Baseline FVC percent predicted			
<=70%	-14.81 (-26.89, -2.40)	-5.69 (-14.85, 3.46)	
>70%	0.62 (-10.92, 12.40)	-1.36 (-13.10, 10.37)	
Baseline HRCT pattern			
UIP-like	-6.55 (-16.59, 3.64)	-2.43 (-11.65, 6.79)	
Other fibrotic patterns	-6.87 (-21.61, 8.36)	-6.08 (-18.03, 5.87)	
Underlying ILD diagnosis			
iNSIP	-12.50 (-29.93, 6.90)	-9.09 (-26.42, 8.23)	
Unclassifiable IIP	-9.72 (-29.26, 11.23)	-6.19 (-24.17, 11.80)	
HP	-5.13 (-26.48, 15.88)	-7.36 (-20.61, 5.89)	
Autoimmune ILD	5.23 (-9.94, 20.05)	5.71 (-8.68, 20.10)	
Other ILD	-14.44 (-33.99, 2.37)	-2.26 (-23.48, 18.95)	
Region			
Europe	-3.30 (-20.42, 15.07)	2.13 (-8.37, 12.64)	
Asia	-10.07 (-21.71, 1.96)	-7.56 (-22.79, 7.67)	
Canada and USA	-6.86 (-32.36, 15.06)	-12.68 (-28.09, 2.73)	
Rest of the World	-0.56 (-20.27, 19.13)	-9.21 (-31.86, 13.43)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Infections and infestations

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.73 (0.48, 1.10)	0.85 (0.62, 1.16)	0.86 (0.51, 1.44)
Age			
<65 years	0.59 (0.31, 1.15)	1.05 (0.63, 1.74)	
>=65 years	0.83 (0.49, 1.42)	0.74 (0.49, 1.11)	
Sex			
Male	0.59 (0.33, 1.05)	0.84 (0.55, 1.29)	
Female	0.91 (0.51, 1.64)	0.86 (0.54, 1.37)	
Baseline FVC percent predicted			
<=70%	0.50 (0.27, 0.90)	0.77 (0.50, 1.18)	
>70%	1.03 (0.58, 1.84)	0.95 (0.59, 1.53)	
Baseline HRCT pattern			
UIP-like	0.73 (0.45, 1.19)	0.90 (0.60, 1.35)	
Other fibrotic patterns	0.70 (0.32, 1.54)	0.77 (0.46, 1.29)	
Underlying ILD diagnosis			
iNSIP	0.57 (0.24, 1.37)	0.69 (0.34, 1.40)	
Unclassifiable IIP	0.64 (0.24, 1.69)	0.77 (0.36, 1.65)	
HP	0.79 (0.28, 2.20)	0.69 (0.35, 1.35)	
Autoimmune ILD	1.28 (0.62, 2.61)	1.28 (0.68, 2.41)	
Other ILD	0.24 (0.04, 1.33)	0.91 (0.37, 2.23)	
Region			
Europe	0.84 (0.33, 2.15)	1.10 (0.68, 1.80)	
Asia	0.60 (0.33, 1.11)	0.72 (0.38, 1.39)	
Canada and USA	0.65 (0.15, 2.84)	0.55 (0.26, 1.15)	
Rest of the World	0.98 (0.42, 2.27)	0.68 (0.26, 1.78)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Injury, poisoning and procedural complications

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.91 (0.56, 1.48)	0.93 (0.66, 1.31)	0.98 (0.54, 1.78)	0.9497	
Age					
<65 years	1.21 (0.47, 3.11)	1.27 (0.66, 2.47)			
>=65 years	0.82 (0.47, 1.46)	0.84 (0.55, 1.26)			
Sex					
Male	0.60 (0.26, 1.37)	0.70 (0.42, 1.16)			
Female	1.15 (0.63, 2.12)	1.21 (0.75, 1.95)			
Baseline FVC percent predicted					
<=70%	1.84 (0.79, 4.33)	0.74 (0.47, 1.17)			
>70%	0.57 (0.31, 1.04)	1.27 (0.74, 2.17)			
Baseline HRCT pattern					
UIP-like	0.77 (0.44, 1.36)	0.86 (0.55, 1.34)			
Other fibrotic patterns	1.45 (0.55, 3.85)	1.04 (0.60, 1.79)			
Underlying ILD diagnosis					
iNSIP	1.45 (0.28, 7.56)	1.43 (0.42, 4.82)			
Unclassifiable IIP	0.60 (0.24, 1.52)	0.78 (0.35, 1.73)			
HP	0.43 (0.09, 2.00)	0.66 (0.35, 1.22)			
Autoimmune ILD	1.39 (0.60, 3.26)	1.30 (0.69, 2.47)			
Other ILD	1.15 (0.34, 3.87)	0.97 (0.36, 2.63)			
Region					
Europe	0.75 (0.31, 1.84)	0.68 (0.38, 1.21)			
Asia	1.24 (0.61, 2.52)	1.14 (0.54, 2.38)			
Canada and USA	0.11 (0.01, 1.89)	1.14 (0.68, 1.92)			
Rest of the World	1.43 (0.34, 6.01)	0.61 (0.06, 6.42)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Injury, poisoning and procedural complications

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-1.24 (-7.56, 5.08)	-1.26 (-6.88, 4.37)	0.01 (-8.44, 8.47)
Age			
<65 years	1.79 (-7.48, 10.94)	2.93 (-5.02, 10.87)	
>=65 years	-2.91 (-11.47, 5.76)	-3.38 (-10.99, 4.24)	
Sex			
Male	-4.86 (-12.85, 3.08)	-5.22 (-12.61, 2.16)	
Female	2.34 (-7.67, 12.25)	3.37 (-5.20, 11.95)	
Baseline FVC percent predicted			
<=70%	5.72 (-2.24, 14.46)	-4.88 (-12.19, 2.44)	
>70%	-9.06 (-19.00, 0.60)	3.89 (-4.88, 12.66)	
Baseline HRCT pattern			
UIP-like	-3.50 (-11.15, 4.18)	-2.43 (-9.46, 4.61)	
Other fibrotic patterns	4.26 (-7.22, 15.71)	0.66 (-8.66, 9.98)	
Underlying ILD diagnosis			
iNSIP	2.27 (-10.05, 12.90)	2.82 (-6.65, 12.28)	
Unclassifiable IIP	-10.00 (-27.92, 8.02)	-4.38 (-18.59, 9.84)	
HP	-8.72 (-23.85, 8.05)	-8.12 (-19.85, 3.61)	
Autoimmune ILD	4.45 (-7.12, 16.07)	4.82 (-6.81, 16.46)	
Other ILD	2.11 (-15.50, 22.33)	-0.49 (-16.49, 15.52)	
Region			
Europe	-4.91 (-21.34, 10.37)	-5.29 (-13.05, 2.47)	
Asia	2.70 (-6.45, 11.84)	1.98 (-9.39, 13.36)	
Canada and USA	-23.33 (-40.93, -1.59)	3.81 (-11.51, 19.12)	
Rest of the World	2.78 (-9.56, 15.80)	-2.00 (-11.18, 7.18)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Injury, poisoning and procedural complications

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.90 (0.51, 1.56)	0.91 (0.60, 1.38)	0.98 (0.49, 1.96)
Age			
<65 years	1.24 (0.44, 3.49)	1.32 (0.62, 2.79)	
>=65 years	0.80 (0.41, 1.55)	0.80 (0.48, 1.32)	
Sex			
Male	0.57 (0.23, 1.41)	0.66 (0.37, 1.19)	
Female	1.19 (0.57, 2.46)	1.26 (0.70, 2.26)	
Baseline FVC percent predicted			
<=70%	1.96 (0.77, 5.02)	0.70 (0.40, 1.20)	
>70%	0.51 (0.25, 1.05)	1.33 (0.70, 2.53)	
Baseline HRCT pattern			
UIP-like	0.74 (0.38, 1.42)	0.83 (0.49, 1.42)	
Other fibrotic patterns	1.53 (0.51, 4.57)	1.05 (0.54, 2.02)	
Underlying ILD diagnosis			
iNSIP	1.49 (0.26, 8.56)	1.47 (0.40, 5.50)	
Unclassifiable IIP	0.53 (0.17, 1.67)	0.74 (0.28, 1.95)	
HP	0.39 (0.07, 2.10)	0.59 (0.28, 1.28)	
Autoimmune ILD	1.47 (0.55, 3.90)	1.38 (0.63, 3.02)	
Other ILD	1.18 (0.28, 4.92)	0.96 (0.29, 3.17)	
Region			
Europe	0.71 (0.24, 2.09)	0.64 (0.33, 1.24)	
Asia	1.28 (0.57, 2.88)	1.16 (0.49, 2.79)	
Canada and USA	0.00 (NC, NC)	1.20 (0.57, 2.51)	
Rest of the World	1.47 (0.31, 6.98)	0.60 (0.05, 6.90)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Investigations

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.18 (0.86, 1.61)	1.85 (1.45, 2.37)	0.64 (0.43, 0.95)	0.0258	
Age					0.0984
<65 years	0.89 (0.50, 1.58)	2.28 (1.47, 3.54)	0.39 (0.19, 0.81)	0.0108	
>=65 years	1.35 (0.93, 1.96)	1.67 (1.23, 2.25)	0.81 (0.50, 1.31)	0.3971	
Sex					0.5013
Male	1.31 (0.86, 1.99)	1.80 (1.25, 2.59)	0.72 (0.41, 1.27)	0.2573	
Female	1.05 (0.66, 1.66)	1.90 (1.36, 2.66)	0.55 (0.31, 0.98)	0.0409	
Baseline FVC percent predicted					0.9181
<=70%	0.97 (0.63, 1.50)	1.55 (1.14, 2.11)	0.62 (0.37, 1.07)	0.0845	
>70%	1.48 (0.93, 2.36)	2.47 (1.62, 3.77)	0.60 (0.32, 1.12)	0.1105	
Baseline HRCT pattern					0.6932
UIP-like	1.39 (0.96, 1.99)	2.59 (1.83, 3.66)	0.54 (0.32, 0.88)	0.0146	
Other fibrotic patterns	0.74 (0.39, 1.40)	1.16 (0.80, 1.68)	0.64 (0.31, 1.34)	0.2351	
Underlying ILD diagnosis					0.0678
iNSIP	1.45 (0.69, 3.06)	3.13 (1.45, 6.76)	0.46 (0.16, 1.36)	0.1605	
Unclassifiable IIP	2.06 (0.96, 4.42)	1.20 (0.70, 2.05)	1.72 (0.67, 4.37)	0.2565	
HP	0.54 (0.21, 1.37)	1.39 (0.92, 2.10)	0.39 (0.14, 1.08)	0.0702	
Autoimmune ILD	0.91 (0.53, 1.57)	2.84 (1.66, 4.85)	0.32 (0.15, 0.69)	0.0036	
Other ILD	1.65 (0.68, 3.95)	1.84 (0.86, 3.95)	0.89 (0.28, 2.87)	0.8517	
Region					0.2395
Europe	0.97 (0.40, 2.38)	1.83 (1.18, 2.84)	0.53 (0.20, 1.44)	0.2138	
Asia	1.28 (0.87, 1.88)	2.76 (1.68, 4.53)	0.46 (0.25, 0.87)	0.0164	
Canada and USA	1.24 (0.58, 2.64)	1.10 (0.77, 1.57)	1.13 (0.49, 2.61)	0.7807	
Rest of the World	1.25 (0.46, 3.42)	NC (NC, NC)	NC (NC, NC)	NC	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Investigations

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	4.31 (-3.91, 12.47)	18.01 (11.16, 24.86)	-13.70 (-24.37, -3.02)
Age			
<65 years	-2.44 (-14.80, 9.86)	22.21 (11.65, 32.78)	-24.65 (-40.89, -8.41)
>=65 years	8.91 (-1.95, 19.55)	15.53 (6.58, 24.47)	-6.62 (-20.60, 7.37)
Sex			
Male	7.39 (-4.24, 18.83)	15.43 (6.36, 24.50)	-8.03 (-22.71, 6.64)
Female	1.16 (-10.40, 12.63)	21.07 (10.74, 31.40)	-19.91 (-35.38, -4.44)
Baseline FVC percent predicted			
<=70%	-0.88 (-12.62, 11.21)	13.40 (4.31, 22.50)	-14.29 (-29.28, 0.70)
>70%	9.65 (-1.75, 20.45)	24.51 (14.16, 34.86)	-14.86 (-30.04, 0.31)
Baseline HRCT pattern			
UIP-like	9.05 (-0.91, 18.80)	26.21 (17.77, 34.66)	-17.16 (-30.14, -4.19)
Other fibrotic patterns	-6.87 (-21.12, 7.63)	4.53 (-6.90, 15.97)	-11.40 (-29.76, 6.97)
Underlying ILD diagnosis			
iNSIP	9.09 (-8.92, 25.23)	24.46 (10.24, 38.68)	-15.37 (-37.59, 6.85)
Unclassifiable IIP	20.56 (-0.16, 38.75)	5.94 (-11.37, 23.24)	14.62 (-11.42, 40.66)
HP	-14.10 (-32.32, 6.74)	11.26 (-2.86, 25.38)	-25.37 (-49.47, -1.26)
Autoimmune ILD	-2.45 (-16.83, 12.08)	29.21 (16.01, 42.42)	-31.67 (-51.25, -12.09)
Other ILD	12.56 (-8.93, 34.41)	15.61 (-3.44, 34.65)	-3.05 (-31.90, 25.80)
Region			
Europe	-0.52 (-16.93, 14.53)	13.54 (4.17, 22.92)	-14.06 (-32.38, 4.25)
Asia	8.14 (-4.49, 20.40)	34.69 (20.53, 48.86)	-26.56 (-45.41, -7.70)
Canada and USA	7.84 (-18.67, 34.67)	4.33 (-12.44, 21.09)	3.52 (-27.98, 35.02)
Rest of the World	3.24 (-11.80, 18.58)	25.00 (10.00, 40.00)	-21.76 (-43.11, -0.42)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Investigations

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.25 (0.82, 1.91)	2.40 (1.70, 3.38)	0.52 (0.30, 0.90)
Age			
<65 years	0.87 (0.42, 1.79)	3.12 (1.74, 5.57)	0.28 (0.11, 0.71)
>=65 years	1.54 (0.91, 2.60)	2.09 (1.36, 3.21)	0.74 (0.37, 1.45)
Sex			
Male	1.45 (0.81, 2.60)	2.23 (1.37, 3.62)	0.65 (0.30, 1.39)
Female	1.06 (0.57, 1.97)	2.62 (1.61, 4.28)	0.41 (0.18, 0.89)
Baseline FVC percent predicted			
<=70%	0.96 (0.52, 1.75)	1.88 (1.22, 2.92)	0.51 (0.24, 1.07)
>70%	1.68 (0.91, 3.11)	3.50 (1.99, 6.15)	0.48 (0.21, 1.10)
Baseline HRCT pattern			
UIP-like	1.57 (0.95, 2.59)	3.77 (2.38, 5.98)	0.42 (0.21, 0.82)
Other fibrotic patterns	0.68 (0.30, 1.54)	1.24 (0.72, 2.11)	0.55 (0.21, 1.46)
Underlying ILD diagnosis			
iNSIP	1.64 (0.62, 4.32)	4.33 (1.69, 11.06)	0.38 (0.10, 1.46)
Unclassifiable IIP	2.76 (0.98, 7.81)	1.31 (0.59, 2.89)	2.11 (0.57, 7.80)
HP	0.45 (0.14, 1.46)	1.65 (0.88, 3.10)	0.27 (0.07, 1.04)
Autoimmune ILD	0.88 (0.42, 1.86)	4.35 (2.12, 8.91)	0.20 (0.07, 0.57)
Other ILD	1.95 (0.60, 6.33)	2.28 (0.82, 6.30)	0.86 (0.18, 4.07)
Region			
Europe	0.96 (0.33, 2.86)	2.18 (1.25, 3.81)	0.44 (0.13, 1.50)
Asia	1.44 (0.81, 2.56)	4.86 (2.37, 9.96)	0.30 (0.12, 0.75)
Canada and USA	1.40 (0.41, 4.78)	1.19 (0.61, 2.33)	1.18 (0.29, 4.78)
Rest of the World	1.30 (0.40, 4.22)	NC (NC, NC)	NC (NC, NC)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Metabolism and nutrition disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.77 (0.52, 1.14)	1.39 (1.03, 1.88)	0.55 (0.33, 0.91)	0.0194	
Age					0.2794
<65 years	0.61 (0.28, 1.33)	1.74 (0.96, 3.15)	0.35 (0.13, 0.93)	0.0352	
>=65 years	0.86 (0.54, 1.35)	1.31 (0.92, 1.86)	0.65 (0.37, 1.16)	0.1472	
Sex					0.4744
Male	0.86 (0.50, 1.49)	1.32 (0.88, 1.97)	0.65 (0.33, 1.29)	0.2221	
Female	0.68 (0.38, 1.21)	1.49 (0.94, 2.35)	0.45 (0.22, 0.95)	0.0358	
Baseline FVC percent predicted					0.6997
<=70%	0.61 (0.34, 1.10)	1.10 (0.76, 1.59)	0.56 (0.28, 1.11)	0.0960	
>70%	0.98 (0.55, 1.74)	2.16 (1.25, 3.72)	0.45 (0.21, 1.00)	0.0502	
Baseline HRCT pattern					0.7341
UIP-like	0.85 (0.55, 1.32)	1.53 (1.05, 2.22)	0.56 (0.31, 0.99)	0.0462	
Other fibrotic patterns	0.53 (0.21, 1.35)	1.17 (0.70, 1.95)	0.45 (0.16, 1.31)	0.1426	
Underlying ILD diagnosis					0.2336
iNSIP	0.40 (0.15, 1.11)	2.48 (0.94, 6.54)	0.16 (0.04, 0.66)	0.0113	
Unclassifiable IIP	0.77 (0.29, 2.08)	1.37 (0.75, 2.50)	0.56 (0.18, 1.81)	0.3348	
HP	0.65 (0.18, 2.39)	0.62 (0.34, 1.11)	1.05 (0.25, 4.39)	0.9449	
Autoimmune ILD	0.79 (0.43, 1.46)	2.50 (1.22, 5.15)	0.32 (0.12, 0.81)	0.0169	
Other ILD	1.68 (0.64, 4.40)	1.70 (0.78, 3.71)	0.99 (0.29, 3.42)	0.9870	
Region					0.7354
Europe	0.57 (0.21, 1.50)	1.85 (1.03, 3.30)	0.31 (0.10, 0.95)	0.0414	
Asia	0.72 (0.44, 1.17)	1.33 (0.83, 2.11)	0.54 (0.27, 1.06)	0.0748	
Canada and USA	0.71 (0.15, 3.25)	1.08 (0.66, 1.77)	0.65 (0.13, 3.26)	0.6047	
Rest of the World	1.60 (0.49, 5.30)	1.22 (0.08, 18.73)	1.32 (0.07, 25.97)	0.8565	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Metabolism and nutrition disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-4.81 (-12.00, 2.43)	6.87 (0.70, 13.05)	-11.69 (-21.18, -2.19)
Age			
<65 years	-6.64 (-17.24, 3.76)	8.57 (-0.20, 17.35)	-15.21 (-28.90, -1.53)
>=65 years	-3.32 (-12.99, 6.49)	6.51 (-1.85, 14.87)	-9.83 (-22.67, 3.01)
Sex			
Male	-2.71 (-12.77, 7.49)	5.94 (-2.59, 14.46)	-8.65 (-21.89, 4.60)
Female	-7.02 (-17.33, 3.35)	7.95 (-0.99, 16.89)	-14.97 (-28.64, -1.30)
Baseline FVC percent predicted			
<=70%	-9.15 (-19.32, 1.66)	2.22 (-6.13, 10.56)	-11.36 (-24.76, 2.04)
>70%	-0.37 (-10.46, 9.33)	13.41 (4.38, 22.43)	-13.78 (-27.17, -0.38)
Baseline HRCT pattern			
UIP-like	-3.32 (-12.23, 5.68)	9.22 (1.26, 17.18)	-12.54 (-24.52, -0.56)
Other fibrotic patterns	-8.10 (-20.14, 3.78)	3.03 (-6.69, 12.76)	-11.13 (-26.54, 4.28)
Underlying ILD diagnosis			
iNSIP	-13.41 (-29.27, 1.21)	12.12 (0.09, 24.14)	-25.52 (-44.94, -6.11)
Unclassifiable IIP	-4.44 (-21.93, 12.64)	8.81 (-7.69, 25.32)	-13.26 (-37.16, 10.65)
HP	-5.38 (-21.15, 12.23)	-10.30 (-22.49, 1.89)	4.92 (-15.75, 25.58)
Autoimmune ILD	-5.35 (-18.94, 8.51)	15.38 (4.01, 26.75)	-20.73 (-38.56, -2.91)
Other ILD	11.33 (-9.16, 32.80)	12.97 (-5.83, 31.78)	-1.64 (-29.81, 26.53)
Region			
Europe	-8.68 (-24.62, 6.05)	8.63 (0.75, 16.51)	-17.31 (-34.55, -0.07)
Asia	-7.73 (-18.92, 3.67)	9.08 (-5.55, 23.71)	-16.81 (-35.29, 1.67)
Canada and USA	-4.90 (-23.81, 19.52)	2.40 (-13.23, 18.03)	-7.30 (-34.02, 19.41)
Rest of the World	5.26 (-8.52, 19.57)	0.56 (-7.25, 8.37)	4.70 (-11.37, 20.77)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Metabolism and nutrition disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.72 (0.45, 1.18)	1.52 (1.04, 2.22)	0.48 (0.26, 0.88)
Age			
<65 years	0.56 (0.23, 1.38)	1.93 (0.96, 3.86)	0.29 (0.09, 0.91)
>=65 years	0.82 (0.46, 1.47)	1.43 (0.90, 2.26)	0.57 (0.27, 1.21)
Sex			
Male	0.84 (0.43, 1.64)	1.42 (0.86, 2.37)	0.59 (0.25, 1.36)
Female	0.62 (0.31, 1.25)	1.65 (0.93, 2.90)	0.38 (0.15, 0.93)
Baseline FVC percent predicted			
<=70%	0.55 (0.27, 1.11)	1.13 (0.71, 1.82)	0.48 (0.21, 1.13)
>70%	0.97 (0.49, 1.95)	2.54 (1.33, 4.87)	0.38 (0.15, 0.99)
Baseline HRCT pattern			
UIP-like	0.82 (0.47, 1.42)	1.72 (1.07, 2.76)	0.47 (0.23, 0.98)
Other fibrotic patterns	0.48 (0.17, 1.39)	1.22 (0.65, 2.29)	0.40 (0.12, 1.36)
Underlying ILD diagnosis			
iNSIP	0.34 (0.11, 1.12)	2.85 (0.95, 8.57)	0.12 (0.02, 0.61)
Unclassifiable IIP	0.73 (0.22, 2.42)	1.55 (0.67, 3.56)	0.47 (0.11, 2.03)
HP	0.61 (0.14, 2.67)	0.54 (0.26, 1.14)	1.13 (0.22, 5.88)
Autoimmune ILD	0.74 (0.33, 1.63)	3.02 (1.29, 7.07)	0.24 (0.08, 0.78)
Other ILD	1.94 (0.56, 6.70)	2.02 (0.72, 5.65)	0.96 (0.19, 4.81)
Region			
Europe	0.51 (0.16, 1.61)	2.04 (1.05, 3.99)	0.25 (0.07, 0.95)
Asia	0.65 (0.34, 1.23)	1.52 (0.77, 3.00)	0.43 (0.17, 1.09)
Canada and USA	0.67 (0.11, 3.88)	1.12 (0.54, 2.30)	0.60 (0.09, 4.00)
Rest of the World	1.70 (0.45, 6.50)	1.23 (0.07, 20.40)	1.39 (0.06, 31.30)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Musculoskeletal and connective tissue disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.75, 1.36)	0.90 (0.72, 1.14)	1.12 (0.76, 1.63)	0.5710	
Age					
<65 years	0.98 (0.60, 1.60)	0.81 (0.57, 1.15)			
>=65 years	1.03 (0.70, 1.51)	0.97 (0.72, 1.31)			
Sex					
Male	0.90 (0.56, 1.44)	0.87 (0.64, 1.19)			
Female	1.09 (0.74, 1.62)	0.94 (0.68, 1.32)			
Baseline FVC percent predicted					
<=70%	1.40 (0.92, 2.13)	0.90 (0.67, 1.19)			
>70%	0.73 (0.47, 1.13)	0.92 (0.63, 1.33)			
Baseline HRCT pattern					
UIP-like	0.92 (0.64, 1.30)	1.11 (0.82, 1.49)			
Other fibrotic patterns	1.32 (0.72, 2.39)	0.68 (0.48, 0.97)			
Underlying ILD diagnosis					
iNSIP	0.65 (0.29, 1.46)	0.87 (0.42, 1.83)			
Unclassifiable IIP	0.99 (0.48, 2.05)	1.14 (0.63, 2.08)			
HP	1.04 (0.47, 2.31)	0.97 (0.66, 1.42)			
Autoimmune ILD	1.17 (0.71, 1.92)	0.77 (0.51, 1.16)			
Other ILD	1.31 (0.66, 2.60)	0.97 (0.51, 1.83)			
Region					
Europe	1.38 (0.78, 2.45)	0.68 (0.48, 0.97)			
Asia	0.74 (0.48, 1.13)	0.92 (0.57, 1.49)			
Canada and USA	1.76 (0.67, 4.62)	1.37 (0.95, 1.99)			
Rest of the World	0.94 (0.37, 2.36)	0.49 (0.10, 2.35)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Musculoskeletal and connective tissue disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.25 (-8.05, 8.55)	-3.11 (-10.15, 3.93)	3.36 (-7.52, 14.24)
Age			
<65 years	-0.44 (-13.73, 12.76)	-6.87 (-18.31, 4.58)	
>=65 years	0.69 (-9.87, 11.30)	-0.94 (-9.90, 8.01)	
Sex			
Male	-2.48 (-13.42, 8.62)	-4.28 (-13.90, 5.33)	
Female	2.84 (-9.51, 15.04)	-1.75 (-12.09, 8.59)	
Baseline FVC percent predicted			
<=70%	9.80 (-2.38, 21.89)	-3.58 (-12.88, 5.71)	
>70%	-8.19 (-19.62, 3.25)	-2.49 (-13.25, 8.27)	
Baseline HRCT pattern			
UIP-like	-2.47 (-12.37, 7.52)	2.91 (-5.86, 11.68)	
Other fibrotic patterns	6.91 (-8.06, 21.42)	-13.02 (-24.66, -1.39)	
Underlying ILD diagnosis			
iNSIP	-8.64 (-25.58, 7.44)	-2.48 (-16.08, 11.11)	
Unclassifiable IIP	-0.28 (-20.09, 19.15)	3.69 (-12.84, 20.21)	
HP	1.03 (-18.83, 21.97)	-1.30 (-15.73, 13.14)	
Autoimmune ILD	4.69 (-10.36, 19.48)	-9.28 (-23.56, 4.99)	
Other ILD	9.44 (-13.82, 32.43)	-0.98 (-21.34, 19.38)	
Region			
Europe	11.51 (-8.19, 29.44)	-11.35 (-21.61, -1.09)	
Asia	-8.72 (-20.53, 3.41)	-2.47 (-16.94, 12.01)	
Canada and USA	15.29 (-9.66, 40.94)	14.60 (-1.99, 31.19)	
Rest of the World	-1.11 (-16.74, 14.90)	-6.57 (-20.00, 6.86)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Musculoskeletal and connective tissue disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.67, 1.54)	0.86 (0.62, 1.20)	1.17 (0.69, 1.99)
Age			
<65 years	0.98 (0.50, 1.91)	0.73 (0.44, 1.23)	
>=65 years	1.04 (0.61, 1.76)	0.96 (0.62, 1.46)	
Sex			
Male	0.87 (0.47, 1.61)	0.82 (0.52, 1.28)	
Female	1.14 (0.64, 2.03)	0.92 (0.57, 1.49)	
Baseline FVC percent predicted			
<=70%	1.61 (0.89, 2.91)	0.85 (0.55, 1.30)	
>70%	0.66 (0.36, 1.19)	0.89 (0.53, 1.49)	
Baseline HRCT pattern			
UIP-like	0.89 (0.54, 1.45)	1.15 (0.75, 1.76)	
Other fibrotic patterns	1.44 (0.65, 3.20)	0.56 (0.33, 0.95)	
Underlying ILD diagnosis			
iNSIP	0.59 (0.21, 1.61)	0.85 (0.34, 2.10)	
Unclassifiable IIP	0.99 (0.36, 2.70)	1.20 (0.52, 2.75)	
HP	1.05 (0.36, 3.11)	0.95 (0.51, 1.75)	
Autoimmune ILD	1.25 (0.61, 2.56)	0.66 (0.35, 1.25)	
Other ILD	1.52 (0.52, 4.41)	0.96 (0.38, 2.44)	
Region			
Europe	1.66 (0.69, 3.95)	0.58 (0.35, 0.95)	
Asia	0.65 (0.36, 1.19)	0.89 (0.45, 1.77)	
Canada and USA	2.18 (0.57, 8.31)	1.81 (0.91, 3.57)	
Rest of the World	0.92 (0.30, 2.81)	0.45 (0.08, 2.51)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.21 (0.53, 2.74)	1.00 (0.52, 1.92)	1.21 (0.43, 3.46)	0.7162	
Age					
<65 years	0.94 (0.24, 3.65)	1.31 (0.38, 4.52)			
>=65 years	1.40 (0.50, 3.94)	0.92 (0.42, 2.01)			
Sex					
Male	0.65 (0.22, 1.94)	1.07 (0.50, 2.28)			
Female	3.40 (0.72, 16.01)	0.81 (0.22, 2.94)			
Baseline FVC percent predicted					
<=70%	1.64 (0.38, 7.15)	0.88 (0.34, 2.22)			
>70%	0.96 (0.36, 2.55)	1.14 (0.45, 2.87)			
Baseline HRCT pattern					
UIP-like	1.71 (0.64, 4.59)	1.18 (0.54, 2.58)			
Other fibrotic patterns	0.48 (0.09, 2.56)	0.66 (0.19, 2.29)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.95 (-3.32, 5.29)	-0.02 (-3.37, 3.34)	0.97 (-4.49, 6.43)
Age			
<65 years	-0.27 (-7.73, 6.92)	1.01 (-3.63, 5.65)	
>=65 years	1.74 (-3.88, 7.66)	-0.49 (-5.11, 4.13)	
Sex			
Male	-2.39 (-9.03, 4.15)	0.48 (-4.82, 5.79)	
Female	4.54 (-1.22, 10.93)	-0.63 (-4.40, 3.14)	
Baseline FVC percent predicted			
<=70%	1.62 (-3.69, 7.91)	-0.58 (-4.65, 3.48)	
>70%	-0.28 (-7.51, 6.43)	0.82 (-4.89, 6.54)	
Baseline HRCT pattern			
UIP-like	2.70 (-2.46, 8.14)	0.97 (-3.55, 5.49)	
Other fibrotic patterns	-3.22 (-12.24, 5.06)	-1.63 (-6.46, 3.21)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.22 (0.52, 2.89)	1.00 (0.50, 1.99)	1.23 (0.41, 3.70)
Age			
<65 years	0.94 (0.23, 3.89)	1.32 (0.36, 4.79)	
>=65 years	1.43 (0.48, 4.24)	0.92 (0.40, 2.10)	
Sex			
Male	0.64 (0.20, 2.01)	1.08 (0.48, 2.43)	
Female	3.57 (0.72, 17.59)	0.80 (0.21, 3.04)	
Baseline FVC percent predicted			
<=70%	1.67 (0.36, 7.63)	0.87 (0.33, 2.30)	
>70%	0.96 (0.33, 2.73)	1.15 (0.43, 3.08)	
Baseline HRCT pattern			
UIP-like	1.76 (0.62, 4.96)	1.19 (0.52, 2.73)	
Other fibrotic patterns	0.47 (0.08, 2.65)	0.65 (0.18, 2.36)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Nervous system disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.22 (0.85, 1.75)	1.11 (0.84, 1.47)	1.10 (0.70, 1.74)	0.6820	
Age					
<65 years	0.82 (0.41, 1.61)	1.02 (0.62, 1.68)			
>=65 years	1.47 (0.96, 2.24)	1.18 (0.84, 1.66)			
Sex					
Male	1.23 (0.75, 2.01)	0.96 (0.63, 1.46)			
Female	1.22 (0.72, 2.05)	1.27 (0.86, 1.86)			
Baseline FVC percent predicted					
<=70%	1.29 (0.76, 2.20)	1.05 (0.73, 1.52)			
>70%	1.14 (0.70, 1.86)	1.20 (0.77, 1.87)			
Baseline HRCT pattern					
UIP-like	1.38 (0.90, 2.11)	0.96 (0.66, 1.38)			
Other fibrotic patterns	0.90 (0.46, 1.76)	1.37 (0.89, 2.13)			
Underlying ILD diagnosis					
iNSIP	1.94 (0.55, 6.86)	1.06 (0.46, 2.43)			
Unclassifiable IIP	0.68 (0.26, 1.76)	1.20 (0.66, 2.17)			
HP	1.11 (0.61, 2.04)	0.85 (0.51, 1.41)			
Autoimmune ILD	1.66 (0.85, 3.26)	1.36 (0.74, 2.49)			
Other ILD	1.65 (0.68, 3.95)	1.26 (0.57, 2.76)			
Region					
Europe	1.23 (0.66, 2.31)	1.18 (0.77, 1.80)			
Asia	1.24 (0.68, 2.26)	0.74 (0.35, 1.59)			
Canada and USA	1.47 (0.53, 4.11)	1.24 (0.82, 1.86)			
Rest of the World	0.96 (0.43, 2.14)	0.81 (0.14, 4.57)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Nervous system disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	4.27 (-3.40, 11.89)	2.35 (-4.02, 8.71)	1.92 (-8.03, 11.87)
Age			
<65 years	-3.30 (-14.61, 7.89)	0.42 (-9.18, 10.01)	
>=65 years	9.40 (-0.89, 19.52)	4.09 (-4.37, 12.54)	
Sex			
Male	4.50 (-6.29, 15.24)	-0.79 (-9.09, 7.52)	
Female	4.07 (-6.86, 14.84)	6.03 (-3.73, 15.79)	
Baseline FVC percent predicted			
<=70%	5.12 (-5.60, 16.15)	1.19 (-7.16, 9.54)	
>70%	3.04 (-8.02, 13.69)	3.97 (-5.87, 13.82)	
Baseline HRCT pattern			
UIP-like	6.97 (-2.21, 16.06)	-0.97 (-8.89, 6.94)	
Other fibrotic patterns	-2.18 (-16.13, 11.76)	7.77 (-2.85, 18.39)	
Underlying ILD diagnosis			
iNSIP	7.05 (-7.16, 19.66)	0.87 (-11.71, 13.45)	
Unclassifiable IIP	-7.22 (-24.96, 10.34)	5.25 (-11.39, 21.89)	
HP	4.10 (-17.88, 26.14)	-4.28 (-17.32, 8.76)	
Autoimmune ILD	10.22 (-3.21, 23.33)	6.13 (-5.92, 18.17)	
Other ILD	12.56 (-8.93, 34.41)	5.39 (-13.16, 23.93)	
Region			
Europe	6.46 (-12.57, 24.08)	3.62 (-5.76, 13.00)	
Asia	3.60 (-6.58, 13.70)	-4.45 (-15.65, 6.75)	
Canada and USA	9.41 (-14.25, 35.35)	8.54 (-7.90, 24.99)	
Rest of the World	-0.81 (-17.60, 16.33)	-1.44 (-13.29, 10.40)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Nervous system disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.29 (0.82, 2.03)	1.14 (0.79, 1.65)	1.13 (0.63, 2.02)
Age			
<65 years	0.79 (0.35, 1.77)	1.03 (0.55, 1.91)	
>=65 years	1.66 (0.95, 2.91)	1.24 (0.79, 1.96)	
Sex			
Male	1.30 (0.69, 2.44)	0.95 (0.57, 1.60)	
Female	1.28 (0.66, 2.48)	1.37 (0.82, 2.30)	
Baseline FVC percent predicted			
<=70%	1.37 (0.70, 2.68)	1.07 (0.67, 1.72)	
>70%	1.19 (0.64, 2.22)	1.26 (0.71, 2.23)	
Baseline HRCT pattern			
UIP-like	1.51 (0.88, 2.59)	0.94 (0.59, 1.51)	
Other fibrotic patterns	0.88 (0.38, 2.05)	1.52 (0.85, 2.72)	
Underlying ILD diagnosis			
iNSIP	2.10 (0.52, 8.47)	1.07 (0.40, 2.84)	
Unclassifiable IIP	0.62 (0.19, 1.99)	1.29 (0.57, 2.95)	
HP	1.19 (0.45, 3.17)	0.80 (0.40, 1.58)	
Autoimmune ILD	1.89 (0.82, 4.36)	1.47 (0.69, 3.13)	
Other ILD	1.95 (0.60, 6.33)	1.35 (0.48, 3.78)	
Region			
Europe	1.36 (0.55, 3.33)	1.23 (0.71, 2.13)	
Asia	1.29 (0.63, 2.66)	0.70 (0.29, 1.71)	
Canada and USA	1.67 (0.42, 6.59)	1.43 (0.72, 2.84)	
Rest of the World	0.95 (0.35, 2.63)	0.80 (0.13, 5.11)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Psychiatric disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.07 (0.76, 1.49)	0.95 (0.63, 1.42)	1.13 (0.67, 1.90)	0.6597	
Age					
<65 years	1.00 (0.55, 1.80)	1.10 (0.59, 2.07)			
>=65 years	1.11 (0.74, 1.67)	0.85 (0.50, 1.45)			
Sex					
Male	0.87 (0.55, 1.38)	1.10 (0.60, 2.01)			
Female	1.34 (0.82, 2.20)	0.84 (0.48, 1.45)			
Baseline FVC percent predicted					
<=70%	0.92 (0.58, 1.45)	0.92 (0.57, 1.48)			
>70%	1.32 (0.79, 2.21)	1.01 (0.47, 2.18)			
Baseline HRCT pattern					
UIP-like	1.03 (0.68, 1.54)	1.15 (0.71, 1.88)			
Other fibrotic patterns	1.16 (0.64, 2.10)	0.62 (0.29, 1.31)			
Underlying ILD diagnosis					
iNSIP	0.66 (0.31, 1.40)	1.33 (0.45, 3.98)			
Unclassifiable IIP	1.41 (0.61, 3.26)	1.56 (0.57, 4.28)			
HP	0.65 (0.28, 1.53)	0.64 (0.29, 1.37)			
Autoimmune ILD	1.22 (0.67, 2.22)	0.80 (0.36, 1.81)			
Other ILD	2.16 (0.88, 5.30)	1.13 (0.35, 3.61)			
Region					
Europe	0.81 (0.43, 1.53)	0.89 (0.46, 1.74)			
Asia	0.99 (0.60, 1.63)	1.06 (0.48, 2.35)			
Canada and USA	1.76 (0.75, 4.18)	0.96 (0.49, 1.88)			
Rest of the World	1.38 (0.56, 3.37)	0.61 (0.06, 6.42)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Psychiatric disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	1.57 (-6.35, 9.48)	-0.64 (-5.65, 4.37)	2.21 (-7.16, 11.58)
Age			
<65 years	-0.03 (-12.21, 12.00)	1.27 (-6.92, 9.46)	
>=65 years	2.81 (-7.56, 13.18)	-1.98 (-8.28, 4.33)	
Sex			
Male	-3.34 (-14.33, 7.83)	1.00 (-5.41, 7.42)	
Female	6.79 (-4.54, 17.87)	-2.51 (-10.34, 5.32)	
Baseline FVC percent predicted			
<=70%	-2.12 (-13.62, 9.81)	-1.26 (-8.34, 5.82)	
>70%	5.92 (-4.90, 16.27)	0.13 (-6.57, 6.82)	
Baseline HRCT pattern			
UIP-like	0.59 (-8.73, 9.93)	1.94 (-4.67, 8.56)	
Other fibrotic patterns	3.84 (-11.09, 18.46)	-4.86 (-12.39, 2.66)	
Underlying ILD diagnosis			
iNSIP	-9.32 (-26.61, 7.34)	2.74 (-7.55, 13.03)	
Unclassifiable IIP	8.06 (-11.25, 26.20)	5.62 (-6.55, 17.80)	
HP	-10.77 (-29.61, 10.41)	-6.14 (-16.35, 4.07)	
Autoimmune ILD	4.59 (-9.37, 18.38)	-2.66 (-12.52, 7.20)	
Other ILD	19.33 (-2.57, 40.71)	1.53 (-12.87, 15.93)	
Region			
Europe	-6.08 (-24.50, 12.01)	-1.14 (-8.02, 5.73)	
Asia	-0.21 (-11.41, 10.97)	0.77 (-10.01, 11.54)	
Canada and USA	17.84 (-8.47, 43.41)	-0.89 (-14.29, 12.52)	
Rest of the World	5.71 (-10.40, 21.91)	-2.00 (-11.18, 7.18)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Psychiatric disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.09 (0.70, 1.69)	0.94 (0.59, 1.50)	1.16 (0.61, 2.19)
Age			
<65 years	1.00 (0.47, 2.10)	1.12 (0.54, 2.31)	
>=65 years	1.16 (0.67, 2.00)	0.83 (0.45, 1.52)	
Sex			
Male	0.83 (0.45, 1.53)	1.11 (0.57, 2.18)	
Female	1.47 (0.77, 2.78)	0.81 (0.43, 1.55)	
Baseline FVC percent predicted			
<=70%	0.90 (0.48, 1.66)	0.91 (0.52, 1.58)	
>70%	1.43 (0.75, 2.72)	1.02 (0.44, 2.35)	
Baseline HRCT pattern			
UIP-like	1.03 (0.61, 1.75)	1.18 (0.67, 2.08)	
Other fibrotic patterns	1.23 (0.55, 2.71)	0.59 (0.26, 1.35)	
Underlying ILD diagnosis			
iNSIP	0.59 (0.22, 1.55)	1.38 (0.41, 4.59)	
Unclassifiable IIP	1.57 (0.53, 4.62)	1.67 (0.53, 5.23)	
HP	0.56 (0.18, 1.73)	0.59 (0.24, 1.44)	
Autoimmune ILD	1.29 (0.59, 2.83)	0.78 (0.31, 1.96)	
Other ILD	2.81 (0.85, 9.32)	1.15 (0.31, 4.33)	
Region			
Europe	0.75 (0.30, 1.83)	0.88 (0.42, 1.86)	
Asia	0.99 (0.52, 1.88)	1.07 (0.43, 2.68)	
Canada and USA	2.30 (0.64, 8.31)	0.95 (0.41, 2.20)	
Rest of the World	1.47 (0.50, 4.38)	0.60 (0.05, 6.90)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Renal and urinary disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.62 (0.30, 1.28)	1.66 (0.95, 2.92)	0.37 (0.15, 0.93)	0.0347	
Age					0.8705
<65 years	0.63 (0.11, 3.67)	1.92 (0.68, 5.36)	0.33 (0.04, 2.53)	0.2851	
>=65 years	0.63 (0.29, 1.39)	1.59 (0.81, 3.13)	0.40 (0.14, 1.13)	0.0825	
Sex					0.0778
Male	0.44 (0.16, 1.20)	2.47 (1.12, 5.46)	0.18 (0.05, 0.64)	0.0081	
Female	0.97 (0.32, 2.92)	1.01 (0.43, 2.35)	0.97 (0.24, 3.87)	0.9612	
Baseline FVC percent predicted					0.8876
<=70%	0.41 (0.14, 1.23)	1.20 (0.61, 2.36)	0.34 (0.09, 1.25)	0.1042	
>70%	0.98 (0.34, 2.82)	3.30 (1.10, 9.86)	0.30 (0.06, 1.36)	0.1180	
Baseline HRCT pattern					0.0374
UIP-like	0.41 (0.16, 1.03)	2.38 (1.06, 5.30)	0.17 (0.05, 0.59)	0.0048	
Other fibrotic patterns	1.62 (0.40, 6.49)	1.09 (0.48, 2.48)	1.48 (0.30, 7.43)	0.6333	
Underlying ILD diagnosis					0.3897
iNSIP	0.18 (0.04, 0.81)	NC (NC, NC)	NC (NC, NC)	NC	
Unclassifiable IIP	2.71 (0.11, 64.43)	NC (NC, NC)	NC (NC, NC)	NC	
HP	1.30 (0.19, 8.70)	0.74 (0.30, 1.86)	1.75 (0.21, 14.48)	0.6024	
Autoimmune ILD	0.51 (0.13, 1.95)	1.61 (0.47, 5.50)	0.32 (0.05, 1.95)	0.2142	
Other ILD	2.16 (0.39, 12.00)	1.41 (0.41, 4.89)	1.53 (0.18, 12.68)	0.6950	
Region					0.1086
Europe	0.25 (0.05, 1.18)	1.59 (0.59, 4.27)	0.16 (0.03, 0.99)	0.0488	
Asia	0.50 (0.19, 1.27)	2.16 (0.70, 6.73)	0.23 (0.05, 1.00)	0.0501	
Canada and USA	8.61 (0.44, 169.58)	1.29 (0.54, 3.06)	6.69 (0.30, 149.05)	0.2301	
Rest of the World	3.20 (0.13, 76.60)	NC (NC, NC)	NC (NC, NC)	NC	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Renal and urinary disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-3.11 (-7.97, 1.63)	3.60 (-0.34, 7.53)	-6.71 (-12.91, -0.50)
Age			
<65 years	-1.34 (-8.03, 4.78)	3.78 (-1.94, 9.50)	-5.12 (-13.71, 3.46)
>=65 years	-3.97 (-10.99, 3.02)	3.65 (-1.66, 8.97)	-7.63 (-16.42, 1.17)
Sex			
Male	-5.84 (-13.17, 1.24)	6.65 (1.12, 12.19)	-12.49 (-21.58, -3.40)
Female	-0.16 (-6.97, 6.56)	0.04 (-5.48, 5.56)	-0.20 (-8.93, 8.53)
Baseline FVC percent predicted			
<=70%	-6.00 (-13.23, 1.40)	1.42 (-3.96, 6.80)	-7.42 (-16.50, 1.66)
>70%	-0.12 (-7.01, 6.23)	6.66 (0.98, 12.34)	-6.78 (-15.51, 1.94)
Baseline HRCT pattern			
UIP-like	-5.60 (-11.56, 0.08)	5.34 (0.59, 10.09)	-10.94 (-18.45, -3.43)
Other fibrotic patterns	2.89 (-6.38, 12.37)	0.73 (-6.12, 7.58)	2.16 (-9.45, 13.77)
Underlying ILD diagnosis			
iNSIP	-16.36 (-31.35, -3.49)	9.38 (2.23, 16.52)	-25.74 (-41.39, -10.08)
Unclassifiable IIP	2.50 (-7.36, 12.88)	9.38 (2.23, 16.52)	-6.88 (-19.26, 5.51)
HP	1.54 (-11.17, 16.66)	-2.90 (-11.73, 5.93)	4.44 (-12.04, 20.92)
Autoimmune ILD	-4.16 (-13.39, 4.66)	2.77 (-4.35, 9.89)	-6.94 (-18.43, 4.56)
Other ILD	6.44 (-8.38, 24.84)	3.86 (-9.96, 17.67)	2.59 (-19.02, 24.20)
Region			
Europe	-11.23 (-25.56, 0.76)	2.41 (-2.63, 7.45)	-13.64 (-27.73, 0.45)
Asia	-5.71 (-13.73, 1.99)	6.13 (-2.49, 14.75)	-11.84 (-23.51, -0.18)
Canada and USA	11.76 (-2.40, 34.34)	3.33 (-8.06, 14.73)	8.43 (-13.18, 30.05)
Rest of the World	2.33 (-5.62, 12.06)	3.13 (-2.90, 9.15)	-0.80 (-11.50, 9.90)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Renal and urinary disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.60 (0.27, 1.29)	1.73 (0.94, 3.16)	0.35 (0.13, 0.92)
Age			
<65 years	0.62 (0.10, 3.81)	1.99 (0.67, 5.91)	0.31 (0.04, 2.58)
>=65 years	0.60 (0.26, 1.43)	1.65 (0.79, 3.45)	0.37 (0.12, 1.14)
Sex			
Male	0.41 (0.14, 1.20)	2.66 (1.14, 6.20)	0.15 (0.04, 0.61)
Female	0.97 (0.30, 3.11)	1.01 (0.41, 2.49)	0.96 (0.22, 4.22)
Baseline FVC percent predicted			
<=70%	0.38 (0.12, 1.23)	1.21 (0.58, 2.54)	0.32 (0.08, 1.26)
>70%	0.98 (0.32, 3.00)	3.54 (1.12, 11.15)	0.28 (0.06, 1.37)
Baseline HRCT pattern			
UIP-like	0.39 (0.15, 1.02)	2.51 (1.07, 5.88)	0.15 (0.04, 0.56)
Other fibrotic patterns	1.67 (0.38, 7.28)	1.10 (0.45, 2.69)	1.52 (0.27, 8.50)
Underlying ILD diagnosis			
iNSIP	0.15 (0.03, 0.76)	NC (NC, NC)	NC (NC, NC)
Unclassifiable IIP	NC (NC, NC)	NC (NC, NC)	NC (NC, NC)
HP	1.32 (0.18, 9.97)	0.72 (0.26, 1.98)	1.84 (0.19, 17.66)
Autoimmune ILD	0.49 (0.12, 2.02)	1.66 (0.45, 6.10)	0.29 (0.04, 2.02)
Other ILD	2.32 (0.36, 15.01)	1.48 (0.37, 5.96)	1.57 (0.15, 16.14)
Region			
Europe	0.22 (0.04, 1.17)	1.63 (0.58, 4.61)	0.14 (0.02, 0.96)
Asia	0.47 (0.17, 1.29)	2.31 (0.68, 7.86)	0.20 (0.04, 0.99)
Canada and USA	NC (NC, NC)	1.34 (0.49, 3.63)	NC (NC, NC)
Rest of the World	NC (NC, NC)	NC (NC, NC)	NC (NC, NC)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Reproductive system and breast disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	2.52 (0.80, 7.92)	0.23 (0.07, 0.80)	10.96 (2.02, 59.54)	0.0055	
Age					0.9656
<65 years	4.24 (0.94, 19.07)	0.87 (0.12, 6.09)	4.88 (0.42, 56.93)	0.2064	
>=65 years	0.53 (0.05, 5.74)	0.10 (0.01, 0.76)	5.32 (0.23, 122.95)	0.2966	
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like					
Other fibrotic patterns					
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Reproductive system and breast disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	2.74 (-0.68, 6.52)	-3.02 (-5.35, -0.70)	5.77 (1.48, 10.06)
Age			
<65 years	7.82 (0.20, 16.08)	-0.21 (-3.23, 2.80)	8.03 (-0.46, 16.53)
>=65 years	-0.68 (-4.39, 2.88)	-4.72 (-7.90, -1.54)	4.04 (-0.79, 8.87)
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Reproductive system and breast disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	2.60 (0.80, 8.40)	0.22 (0.06, 0.79)	11.64 (2.07, 65.39)
Age			
<65 years	4.61 (0.97, 22.03)	0.87 (0.12, 6.26)	5.31 (0.43, 65.95)
>=65 years	0.52 (0.05, 5.84)	0.09 (0.01, 0.74)	5.55 (0.23, 132.13)
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.81, 1.26)	0.85 (0.73, 0.99)	1.19 (0.91, 1.56)	0.2068	
Age					
<65 years	0.85 (0.57, 1.28)	0.82 (0.63, 1.06)			
>=65 years	1.11 (0.85, 1.44)	0.88 (0.73, 1.06)			
Sex					
Male	1.11 (0.82, 1.51)	0.97 (0.80, 1.17)			
Female	0.91 (0.66, 1.26)	0.70 (0.54, 0.90)			
Baseline FVC percent predicted					
<=70%	1.07 (0.81, 1.42)	0.75 (0.63, 0.90)			
>70%	1.00 (0.70, 1.42)	1.05 (0.80, 1.38)			
Baseline HRCT pattern					
UIP-like	1.08 (0.82, 1.42)	0.87 (0.72, 1.05)			
Other fibrotic patterns	0.88 (0.60, 1.28)	0.82 (0.64, 1.05)			
Underlying ILD diagnosis					
iNSIP	1.21 (0.67, 2.18)	0.74 (0.47, 1.16)			
Unclassifiable IIP	1.13 (0.61, 2.07)	0.85 (0.64, 1.13)			
HP	0.75 (0.49, 1.14)	0.89 (0.70, 1.14)			
Autoimmune ILD	1.05 (0.68, 1.64)	0.63 (0.42, 0.94)			
Other ILD	1.35 (0.83, 2.19)	1.23 (0.84, 1.80)			
Region					
Europe	1.11 (0.74, 1.68)	0.99 (0.79, 1.25)			
Asia	0.95 (0.68, 1.31)	0.73 (0.54, 0.99)			
Canada and USA	1.93 (1.10, 3.38)	0.76 (0.59, 0.99)			
Rest of the World	0.57 (0.28, 1.13)	0.61 (0.26, 1.44)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.37 (-8.73, 9.47)	-8.30 (-15.88, -0.71)	8.67 (-3.18, 20.52)
Age			
<65 years	-5.60 (-19.58, 8.62)	-9.62 (-21.73, 2.49)	
>=65 years	4.52 (-7.23, 16.12)	-6.97 (-16.70, 2.77)	
Sex			
Male	4.49 (-8.23, 17.03)	-1.75 (-12.07, 8.57)	
Female	-3.92 (-16.74, 9.07)	-16.00 (-26.97, -5.02)	
Baseline FVC percent predicted			
<=70%	3.20 (-10.07, 16.34)	-15.77 (-25.51, -6.03)	
>70%	-0.09 (-12.48, 12.13)	2.09 (-9.64, 13.81)	
Baseline HRCT pattern			
UIP-like	2.93 (-7.83, 13.62)	-7.28 (-16.91, 2.35)	
Other fibrotic patterns	-6.01 (-22.40, 10.83)	-9.96 (-22.27, 2.35)	
Underlying ILD diagnosis			
iNSIP	6.36 (-12.84, 24.16)	-11.45 (-28.41, 5.51)	
Unclassifiable IIP	4.17 (-16.88, 24.45)	-10.19 (-27.90, 7.52)	
HP	-16.67 (-37.76, 6.35)	-6.90 (-21.44, 7.64)	
Autoimmune ILD	1.93 (-13.63, 17.39)	-17.32 (-31.66, -2.98)	
Other ILD	15.56 (-9.47, 37.86)	12.00 (-9.42, 33.41)	
Region			
Europe	5.33 (-14.63, 24.71)	-0.31 (-11.61, 10.99)	
Asia	-2.26 (-15.17, 10.75)	-16.22 (-31.74, -0.71)	
Canada and USA	33.92 (4.25, 55.81)	-17.24 (-33.14, -1.34)	
Rest of the World	-16.03 (-33.32, 2.90)	-12.02 (-31.84, 7.80)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.02 (0.70, 1.48)	0.72 (0.53, 0.97)	1.42 (0.87, 2.30)
Age			
<65 years	0.78 (0.42, 1.47)	0.68 (0.42, 1.11)	
>=65 years	1.20 (0.74, 1.94)	0.76 (0.51, 1.12)	
Sex			
Male	1.20 (0.71, 2.04)	0.93 (0.61, 1.42)	
Female	0.85 (0.49, 1.47)	0.52 (0.33, 0.82)	
Baseline FVC percent predicted			
<=70%	1.14 (0.66, 1.95)	0.52 (0.35, 0.79)	
>70%	1.00 (0.58, 1.72)	1.09 (0.67, 1.76)	
Baseline HRCT pattern			
UIP-like	1.13 (0.72, 1.78)	0.75 (0.51, 1.10)	
Other fibrotic patterns	0.78 (0.39, 1.57)	0.67 (0.41, 1.10)	
Underlying ILD diagnosis			
iNSIP	1.33 (0.56, 3.19)	0.61 (0.30, 1.27)	
Unclassifiable IIP	1.20 (0.47, 3.08)	0.64 (0.30, 1.40)	
HP	0.50 (0.19, 1.33)	0.75 (0.41, 1.38)	
Autoimmune ILD	1.09 (0.55, 2.16)	0.47 (0.25, 0.89)	
Other ILD	1.88 (0.67, 5.28)	1.64 (0.67, 3.98)	
Region			
Europe	1.24 (0.54, 2.82)	0.99 (0.63, 1.55)	
Asia	0.91 (0.53, 1.57)	0.52 (0.27, 0.98)	
Canada and USA	4.15 (1.15, 14.92)	0.47 (0.23, 0.96)	
Rest of the World	0.45 (0.18, 1.16)	0.52 (0.17, 1.59)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Skin and subcutaneous tissue disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.93 (0.56, 1.56)	1.35 (0.99, 1.84)	0.69 (0.38, 1.26)	0.2246	
Age					
<65 years	1.06 (0.43, 2.62)	1.84 (1.09, 3.11)			
>=65 years	0.89 (0.48, 1.65)	1.12 (0.75, 1.66)			
Sex					
Male	0.72 (0.32, 1.62)	1.31 (0.84, 2.04)			
Female	1.11 (0.57, 2.16)	1.40 (0.91, 2.16)			
Baseline FVC percent predicted					
<=70%	1.60 (0.73, 3.48)	1.71 (1.14, 2.55)			
>70%	0.59 (0.30, 1.18)	0.94 (0.57, 1.55)			
Baseline HRCT pattern					
UIP-like	1.03 (0.57, 1.86)	1.28 (0.86, 1.89)			
Other fibrotic patterns	0.73 (0.27, 1.98)	1.49 (0.89, 2.48)			
Underlying ILD diagnosis					
iNSIP	1.21 (0.31, 4.78)	2.04 (0.89, 4.66)			
Unclassifiable IIP	0.45 (0.12, 1.67)	1.48 (0.72, 3.03)			
HP	0.65 (0.18, 2.39)	0.81 (0.45, 1.44)			
Autoimmune ILD	1.69 (0.65, 4.40)	1.45 (0.84, 2.52)			
Other ILD	0.96 (0.30, 3.06)	2.83 (0.58, 13.74)			
Region					
Europe	0.65 (0.24, 1.78)	1.49 (0.83, 2.68)			
Asia	1.07 (0.51, 2.24)	1.20 (0.73, 1.98)			
Canada and USA	0.25 (0.03, 1.88)	1.45 (0.86, 2.45)			
Rest of the World	5.35 (0.65, 43.96)	0.81 (0.14, 4.57)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Skin and subcutaneous tissue disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.80 (-6.89, 5.30)	5.97 (-0.09, 12.03)	-6.77 (-15.37, 1.82)
Age			
<65 years	0.59 (-8.93, 9.92)	11.85 (2.29, 21.41)	
>=65 years	-1.55 (-9.63, 6.63)	2.15 (-5.62, 9.92)	
Sex			
Male	-3.10 (-11.08, 4.90)	4.85 (-3.15, 12.86)	
Female	1.47 (-7.99, 10.87)	7.31 (-1.90, 16.52)	
Baseline FVC percent predicted			
<=70%	5.07 (-3.36, 14.16)	10.99 (2.97, 19.01)	
>70%	-6.67 (-15.89, 2.08)	-1.19 (-10.34, 7.95)	
Baseline HRCT pattern			
UIP-like	0.31 (-7.06, 7.74)	4.85 (-2.84, 12.55)	
Other fibrotic patterns	-3.41 (-14.77, 7.72)	7.81 (-2.02, 17.64)	
Underlying ILD diagnosis			
iNSIP	1.59 (-11.80, 13.17)	11.96 (-1.14, 25.06)	
Unclassifiable IIP	-9.17 (-25.16, 6.01)	8.56 (-6.62, 23.74)	
HP	-5.38 (-21.15, 12.23)	-4.55 (-16.73, 7.63)	
Autoimmune ILD	5.84 (-5.00, 16.86)	8.73 (-4.02, 21.48)	
Other ILD	-0.67 (-18.66, 19.96)	8.51 (-3.95, 20.96)	
Region			
Europe	-6.18 (-21.84, 8.08)	5.35 (-2.35, 13.05)	
Asia	0.83 (-8.08, 9.72)	5.33 (-8.92, 19.58)	
Canada and USA	-17.45 (-35.70, 6.60)	11.18 (-4.15, 26.52)	
Rest of the World	9.45 (-1.81, 22.43)	-1.44 (-13.29, 10.40)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Skin and subcutaneous tissue disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.93 (0.52, 1.65)	1.46 (0.99, 2.14)	0.64 (0.32, 1.27)
Age			
<65 years	1.07 (0.39, 2.91)	2.14 (1.13, 4.05)	
>=65 years	0.87 (0.43, 1.78)	1.15 (0.70, 1.87)	
Sex			
Male	0.70 (0.29, 1.71)	1.39 (0.81, 2.38)	
Female	1.13 (0.52, 2.45)	1.54 (0.89, 2.66)	
Baseline FVC percent predicted			
<=70%	1.69 (0.71, 4.05)	1.96 (1.19, 3.24)	
>70%	0.55 (0.25, 1.21)	0.92 (0.50, 1.70)	
Baseline HRCT pattern			
UIP-like	1.03 (0.52, 2.03)	1.36 (0.83, 2.21)	
Other fibrotic patterns	0.70 (0.23, 2.14)	1.64 (0.87, 3.08)	
Underlying ILD diagnosis			
iNSIP	1.23 (0.28, 5.49)	2.36 (0.89, 6.27)	
Unclassifiable IIP	0.41 (0.09, 1.76)	1.65 (0.66, 4.09)	
HP	0.61 (0.14, 2.67)	0.76 (0.37, 1.58)	
Autoimmune ILD	1.81 (0.62, 5.27)	1.63 (0.80, 3.33)	
Other ILD	0.95 (0.24, 3.80)	3.11 (0.57, 17.05)	
Region			
Europe	0.60 (0.19, 1.95)	1.59 (0.81, 3.11)	
Asia	1.08 (0.47, 2.50)	1.30 (0.65, 2.60)	
Canada and USA	0.21 (0.02, 1.84)	1.71 (0.81, 3.58)	
Rest of the World	5.92 (0.66, 52.91)	0.80 (0.13, 5.11)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Vascular disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.88 (0.50, 1.55)	0.86 (0.57, 1.30)	1.02 (0.51, 2.07)	0.9498	
Age					
<65 years	0.63 (0.23, 1.69)	0.87 (0.44, 1.71)			
>=65 years	1.05 (0.52, 2.12)	0.85 (0.51, 1.44)			
Sex					
Male	0.52 (0.23, 1.17)	0.79 (0.42, 1.48)			
Female	1.67 (0.68, 4.07)	0.92 (0.53, 1.59)			
Baseline FVC percent predicted					
<=70%	0.43 (0.18, 1.06)	0.78 (0.47, 1.30)			
>70%	1.96 (0.78, 4.91)	1.01 (0.50, 2.05)			
Baseline HRCT pattern					
UIP-like	0.89 (0.44, 1.81)	1.00 (0.57, 1.75)			
Other fibrotic patterns	0.85 (0.33, 2.20)	0.71 (0.38, 1.31)			
Underlying ILD diagnosis					
iNSIP	0.36 (0.12, 1.12)	0.68 (0.23, 2.03)			
Unclassifiable IIP	3.60 (0.42, 30.74)	0.67 (0.24, 1.87)			
HP	0.52 (0.11, 2.50)	1.38 (0.64, 2.97)			
Autoimmune ILD	1.78 (0.54, 5.80)	0.78 (0.33, 1.84)			
Other ILD	0.86 (0.23, 3.29)	0.71 (0.25, 1.98)			
Region					
Europe	0.88 (0.32, 2.42)	0.57 (0.33, 0.98)			
Asia	0.69 (0.27, 1.75)	2.89 (0.81, 10.26)			
Canada and USA	0.88 (0.09, 9.03)	1.03 (0.41, 2.59)			
Rest of the World	1.07 (0.33, 3.44)	1.22 (0.18, 8.18)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Vascular disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-1.27 (-6.92, 4.37)	-1.85 (-6.80, 3.11)	0.58 (-6.94, 8.09)
Age			
<65 years	-4.03 (-13.28, 4.82)	-1.61 (-9.42, 6.21)	
>=65 years	0.53 (-6.88, 8.08)	-1.93 (-8.36, 4.49)	
Sex			
Male	-6.59 (-14.81, 1.59)	-2.36 (-8.62, 3.90)	
Female	4.41 (-3.48, 12.40)	-1.21 (-9.05, 6.63)	
Baseline FVC percent predicted			
<=70%	-8.16 (-16.33, 0.35)	-3.29 (-10.05, 3.47)	
>70%	5.52 (-2.15, 12.97)	0.15 (-7.02, 7.32)	
Baseline HRCT pattern			
UIP-like	-1.05 (-7.61, 5.52)	0.00 (-5.96, 5.96)	
Other fibrotic patterns	-1.89 (-13.49, 9.53)	-4.90 (-13.55, 3.76)	
Underlying ILD diagnosis			
iNSIP	-12.73 (-28.13, 1.06)	-3.66 (-14.02, 6.69)	
Unclassifiable IIP	7.22 (-5.67, 20.47)	-4.63 (-16.60, 7.35)	
HP	-6.15 (-20.85, 10.18)	4.24 (-5.90, 14.38)	
Autoimmune ILD	4.37 (-5.09, 14.21)	-2.74 (-12.18, 6.69)	
Other ILD	-1.89 (-18.61, 17.69)	-5.45 (-21.28, 10.39)	
Region			
Europe	-1.79 (-17.36, 12.29)	-8.72 (-16.98, -0.46)	
Asia	-2.89 (-10.71, 4.74)	7.45 (-0.82, 15.71)	
Canada and USA	-0.78 (-16.22, 20.86)	0.35 (-10.49, 11.18)	
Rest of the World	0.76 (-13.06, 15.00)	1.12 (-9.75, 12.00)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Vascular disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.87 (0.46, 1.63)	0.84 (0.53, 1.34)	1.03 (0.47, 2.26)
Age			
<65 years	0.60 (0.20, 1.77)	0.85 (0.40, 1.83)	
>=65 years	1.06 (0.48, 2.32)	0.84 (0.46, 1.52)	
Sex			
Male	0.49 (0.20, 1.18)	0.77 (0.39, 1.54)	
Female	1.75 (0.66, 4.63)	0.91 (0.48, 1.72)	
Baseline FVC percent predicted			
<=70%	0.40 (0.15, 1.05)	0.75 (0.42, 1.35)	
>70%	2.08 (0.77, 5.62)	1.02 (0.47, 2.22)	
Baseline HRCT pattern			
UIP-like	0.88 (0.40, 1.91)	1.00 (0.54, 1.87)	
Other fibrotic patterns	0.83 (0.28, 2.44)	0.67 (0.33, 1.37)	
Underlying ILD diagnosis			
iNSIP	0.31 (0.09, 1.13)	0.65 (0.20, 2.18)	
Unclassifiable IIP	3.89 (0.41, 36.54)	0.64 (0.20, 2.03)	
HP	0.49 (0.09, 2.70)	1.45 (0.60, 3.50)	
Autoimmune ILD	1.86 (0.52, 6.67)	0.76 (0.29, 1.99)	
Other ILD	0.85 (0.18, 3.91)	0.66 (0.20, 2.23)	
Region			
Europe	0.86 (0.27, 2.80)	0.52 (0.27, 0.97)	
Asia	0.67 (0.25, 1.84)	3.13 (0.81, 12.03)	
Canada and USA	0.88 (0.07, 10.43)	1.03 (0.36, 2.93)	
Rest of the World	1.08 (0.29, 4.02)	1.23 (0.16, 9.28)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Cardiac disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.51 (0.70, 3.30)	0.96 (0.55, 1.66)	1.58 (0.61, 4.11)	0.3443	
Age					
<65 years	1.26 (0.29, 5.45)	0.65 (0.15, 2.86)			
>=65 years	1.65 (0.66, 4.14)	1.09 (0.60, 1.96)			
Sex					
Male	2.35 (0.75, 7.42)	0.88 (0.48, 1.65)			
Female	0.97 (0.32, 2.92)	1.21 (0.38, 3.87)			
Baseline FVC percent predicted					
<=70%	1.23 (0.45, 3.38)	0.70 (0.34, 1.42)			
>70%	2.24 (0.61, 8.22)	1.59 (0.64, 3.99)			
Baseline HRCT pattern					
UIP-like	2.46 (0.89, 6.82)	1.06 (0.55, 2.05)			
Other fibrotic patterns	0.58 (0.14, 2.33)	0.74 (0.27, 2.08)			
Underlying ILD diagnosis					
iNSIP	3.66 (0.18, 74.23)	NC (NC, NC)			
Unclassifiable IIP	1.35 (0.24, 7.63)	0.98 (0.28, 3.45)			
HP	1.95 (0.35, 10.94)	0.48 (0.17, 1.33)			
Autoimmune ILD	1.52 (0.45, 5.16)	1.61 (0.47, 5.50)			
Other ILD	0.72 (0.07, 7.52)	0.45 (0.09, 2.20)			
Region					
Europe	0.75 (0.23, 2.43)	0.95 (0.44, 2.06)			
Asia	1.49 (0.43, 5.12)	1.15 (0.37, 3.63)			
Canada and USA	1.76 (0.12, 26.45)	0.69 (0.20, 2.32)			
Rest of the World	7.48 (0.40, 140.67)	1.22 (0.08, 18.73)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Cardiac disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	2.31 (-2.14, 6.92)	-0.32 (-4.23, 3.58)	2.64 (-3.34, 8.62)
Age			
<65 years	0.93 (-6.12, 7.91)	-1.15 (-5.15, 2.85)	
>=65 years	3.30 (-2.87, 9.80)	0.84 (-5.01, 6.69)	
Sex			
Male	4.66 (-1.68, 11.57)	-1.24 (-7.50, 5.03)	
Female	-0.16 (-6.97, 6.56)	0.67 (-3.48, 4.83)	
Baseline FVC percent predicted			
<=70%	1.36 (-5.53, 8.99)	-2.69 (-7.91, 2.53)	
>70%	3.57 (-2.56, 9.64)	3.02 (-2.85, 8.88)	
Baseline HRCT pattern			
UIP-like	4.63 (-0.57, 10.26)	0.49 (-4.76, 5.73)	
Other fibrotic patterns	-3.27 (-12.95, 5.87)	-1.64 (-7.32, 4.04)	
Underlying ILD diagnosis			
iNSIP	3.64 (-5.51, 12.32)	7.81 (1.24, 14.39)	
Unclassifiable IIP	1.94 (-11.57, 14.95)	-0.19 (-10.18, 9.80)	
HP	4.87 (-8.58, 20.93)	-6.41 (-14.91, 2.10)	
Autoimmune ILD	2.94 (-6.26, 12.47)	2.77 (-4.35, 9.89)	
Other ILD	-1.56 (-14.57, 14.50)	-6.36 (-18.29, 5.56)	
Region			
Europe	-3.07 (-17.69, 9.84)	-0.37 (-6.50, 5.75)	
Asia	1.83 (-4.46, 8.34)	1.02 (-7.06, 9.09)	
Canada and USA	2.55 (-11.64, 23.83)	-2.73 (-11.47, 6.01)	
Rest of the World	6.98 (-1.99, 18.61)	0.56 (-7.25, 8.37)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Cardiac disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.55 (0.68, 3.53)	0.95 (0.53, 1.72)	1.63 (0.59, 4.49)
Age			
<65 years	1.27 (0.28, 5.85)	0.65 (0.14, 2.94)	
>=65 years	1.71 (0.64, 4.56)	1.10 (0.57, 2.11)	
Sex			
Male	2.47 (0.74, 8.27)	0.87 (0.44, 1.74)	
Female	0.97 (0.30, 3.11)	1.22 (0.36, 4.07)	
Baseline FVC percent predicted			
<=70%	1.25 (0.42, 3.69)	0.68 (0.31, 1.45)	
>70%	2.32 (0.60, 8.99)	1.65 (0.62, 4.38)	
Baseline HRCT pattern			
UIP-like	2.59 (0.89, 7.52)	1.07 (0.52, 2.18)	
Other fibrotic patterns	0.56 (0.13, 2.46)	0.73 (0.25, 2.17)	
Underlying ILD diagnosis			
iNSIP	NC (NC, NC)	NC (NC, NC)	
Unclassifiable IIP	1.38 (0.22, 8.76)	0.97 (0.25, 3.84)	
HP	2.06 (0.32, 13.16)	0.45 (0.15, 1.35)	
Autoimmune ILD	1.57 (0.42, 5.82)	1.66 (0.45, 6.10)	
Other ILD	0.71 (0.06, 8.26)	0.42 (0.08, 2.32)	
Region			
Europe	0.73 (0.20, 2.71)	0.95 (0.41, 2.19)	
Asia	1.51 (0.42, 5.53)	1.17 (0.34, 4.00)	
Canada and USA	1.81 (0.11, 30.97)	0.67 (0.18, 2.48)	
Rest of the World	NC (NC, NC)	1.23 (0.07, 20.40)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: General disorders and administration site conditions

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.43 (0.24, 0.77)	0.40 (0.13, 1.26)	1.08 (0.30, 3.92)	0.9016	
Age					
<65 years	0.44 (0.17, 1.09)				
>=65 years	0.43 (0.21, 0.90)				
Sex					
Male	0.35 (0.15, 0.79)	0.42 (0.11, 1.61)			
Female	0.56 (0.24, 1.27)	0.34 (0.04, 3.19)			
Baseline FVC percent predicted					
<=70%	0.48 (0.25, 0.92)	0.49 (0.15, 1.61)			
>70%	0.48 (0.14, 1.59)	0.00 (NC, NC)			
Baseline HRCT pattern					
UIP-like	0.35 (0.18, 0.70)				
Other fibrotic patterns	0.81 (0.26, 2.52)				
Underlying ILD diagnosis					
iNSIP	0.91 (0.26, 3.17)				
Unclassifiable IIP	0.68 (0.16, 2.81)				
HP	0.14 (0.02, 1.08)				
Autoimmune ILD	0.10 (0.01, 0.77)				
Other ILD	0.90 (0.33, 2.43)				
Region					
Europe	0.75 (0.23, 2.43)				
Asia	0.45 (0.21, 0.93)				
Canada and USA	0.59 (0.07, 5.22)				
Rest of the World	0.07 (0.00, 1.21)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: General disorders and administration site conditions

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-8.95 (-14.93, -3.06)	-1.82 (-4.00, 0.37)	-7.13 (-13.46, -0.80)
Age			
<65 years	-8.84 (-18.85, 0.76)		
>=65 years	-9.01 (-16.68, -1.39)		
Sex			
Male	-11.80 (-20.41, -3.25)	-2.28 (-5.71, 1.15)	
Female	-5.87 (-14.40, 2.42)	-1.29 (-3.82, 1.23)	
Baseline FVC percent predicted			
<=70%	-12.27 (-22.04, -1.86)	-2.10 (-5.54, 1.33)	
>70%	-3.50 (-10.31, 2.38)	-1.45 (-3.44, 0.54)	
Baseline HRCT pattern			
UIP-like	-11.86 (-19.23, -4.57)		
Other fibrotic patterns	-1.80 (-12.32, 8.47)		
Underlying ILD diagnosis			
iNSIP	-0.91 (-14.94, 11.19)		
Unclassifiable IIP	-3.61 (-18.64, 10.45)		
HP	-19.74 (-35.25, -2.81)		
Autoimmune ILD	-12.66 (-22.66, -3.83)		
Other ILD	-2.22 (-21.61, 19.60)		
Region			
Europe	-3.07 (-17.69, 9.84)		
Asia	-10.46 (-19.81, -1.18)		
Canada and USA	-4.12 (-20.47, 17.97)		
Rest of the World	-15.22 (-28.22, -4.01)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: General disorders and administration site conditions

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.39 (0.21, 0.74)	0.39 (0.12, 1.26)	1.00 (0.26, 3.78)
Age			
<65 years	0.39 (0.14, 1.09)		
>=65 years	0.39 (0.17, 0.88)		
Sex			
Male	0.30 (0.12, 0.75)	0.41 (0.11, 1.63)	
Female	0.52 (0.21, 1.30)	0.33 (0.03, 3.22)	
Baseline FVC percent predicted			
<=70%	0.42 (0.19, 0.89)	0.48 (0.14, 1.63)	
>70%	0.46 (0.13, 1.62)	0.00 (NC, NC)	
Baseline HRCT pattern			
UIP-like	0.31 (0.14, 0.66)		
Other fibrotic patterns	0.79 (0.23, 2.74)		
Underlying ILD diagnosis			
iNSIP	0.90 (0.23, 3.59)		
Unclassifiable IIP	0.65 (0.13, 3.12)		
HP	0.11 (0.01, 0.97)		
Autoimmune ILD	0.09 (0.01, 0.71)		
Other ILD	0.88 (0.25, 3.07)		
Region			
Europe	0.73 (0.20, 2.71)		
Asia	0.39 (0.17, 0.91)		
Canada and USA	0.56 (0.05, 5.88)		
Rest of the World	0.00 (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Infections and infestations

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.79 (0.54, 1.17)	1.06 (0.73, 1.54)	0.75 (0.44, 1.28)	0.2902	
Age					
<65 years	0.50 (0.23, 1.12)	1.00 (0.50, 2.03)			
>=65 years	0.95 (0.61, 1.49)	1.12 (0.72, 1.74)			
Sex					
Male	0.84 (0.51, 1.41)	1.28 (0.78, 2.09)			
Female	0.74 (0.41, 1.34)	0.82 (0.46, 1.47)			
Baseline FVC percent predicted					
<=70%	0.81 (0.50, 1.30)	1.04 (0.69, 1.58)			
>70%	0.89 (0.46, 1.72)	1.11 (0.51, 2.42)			
Baseline HRCT pattern					
UIP-like	0.90 (0.57, 1.42)	1.10 (0.70, 1.73)			
Other fibrotic patterns	0.58 (0.27, 1.23)	0.99 (0.52, 1.90)			
Underlying ILD diagnosis					
iNSIP	1.21 (0.48, 3.06)	0.43 (0.16, 1.17)			
Unclassifiable IIP	0.68 (0.26, 1.76)	4.30 (1.00, 18.51)			
HP	0.65 (0.18, 2.39)	0.98 (0.49, 1.97)			
Autoimmune ILD	0.68 (0.33, 1.40)	1.22 (0.65, 2.27)			
Other ILD	0.96 (0.46, 2.00)	0.85 (0.20, 3.55)			
Region					
Europe	1.81 (0.69, 4.73)	1.03 (0.62, 1.72)			
Asia	0.63 (0.38, 1.04)	1.20 (0.60, 2.40)			
Canada and USA	0.71 (0.15, 3.25)	0.51 (0.13, 1.98)			
Rest of the World	0.61 (0.19, 1.94)	1.52 (0.45, 5.21)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Infections and infestations

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-4.35 (-11.64, 2.99)	0.86 (-4.47, 6.20)	-5.21 (-14.27, 3.84)
Age			
<65 years	-8.98 (-19.57, 1.39)	0.05 (-7.51, 7.60)	
>=65 years	-1.05 (-10.92, 8.92)	1.90 (-5.39, 9.19)	
Sex			
Male	-3.49 (-13.94, 7.11)	3.76 (-3.74, 11.25)	
Female	-5.13 (-15.29, 5.04)	-2.52 (-10.04, 5.00)	
Baseline FVC percent predicted			
<=70%	-5.24 (-16.43, 6.49)	0.74 (-6.97, 8.46)	
>70%	-1.52 (-10.87, 7.40)	0.85 (-5.72, 7.42)	
Baseline HRCT pattern			
UIP-like	-2.07 (-10.80, 6.72)	1.46 (-5.49, 8.41)	
Other fibrotic patterns	-9.80 (-23.08, 3.67)	-0.10 (-8.35, 8.15)	
Underlying ILD diagnosis			
iNSIP	3.18 (-13.00, 17.69)	-10.22 (-21.90, 1.45)	
Unclassifiable IIP	-7.22 (-24.96, 10.34)	13.19 (2.47, 23.91)	
HP	-5.38 (-21.15, 12.23)	-0.25 (-11.07, 10.56)	
Autoimmune ILD	-6.84 (-19.40, 5.93)	3.69 (-8.09, 15.46)	
Other ILD	-1.33 (-23.37, 22.24)	-1.41 (-13.61, 10.79)	
Region			
Europe	10.14 (-6.28, 24.82)	0.56 (-7.85, 8.97)	
Asia	-10.54 (-21.59, 0.79)	3.20 (-8.72, 15.11)	
Canada and USA	-4.90 (-23.81, 19.52)	-4.22 (-12.51, 4.07)	
Rest of the World	-5.92 (-20.09, 8.57)	5.37 (-10.41, 21.15)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Infections and infestations

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.75 (0.47, 1.21)	1.07 (0.69, 1.66)	0.70 (0.37, 1.34)
Age			
<65 years	0.45 (0.18, 1.13)	1.00 (0.46, 2.21)	
>=65 years	0.94 (0.53, 1.67)	1.15 (0.68, 1.94)	
Sex			
Male	0.81 (0.42, 1.54)	1.34 (0.75, 2.38)	
Female	0.70 (0.34, 1.42)	0.80 (0.41, 1.56)	
Baseline FVC percent predicted			
<=70%	0.75 (0.40, 1.42)	1.05 (0.63, 1.75)	
>70%	0.88 (0.41, 1.88)	1.12 (0.48, 2.63)	
Baseline HRCT pattern			
UIP-like	0.88 (0.50, 1.54)	1.12 (0.65, 1.91)	
Other fibrotic patterns	0.52 (0.21, 1.28)	0.99 (0.47, 2.08)	
Underlying ILD diagnosis			
iNSIP	1.26 (0.42, 3.80)	0.39 (0.13, 1.18)	
Unclassifiable IIP	0.62 (0.19, 1.99)	4.98 (1.05, 23.62)	
HP	0.61 (0.14, 2.67)	0.98 (0.43, 2.23)	
Autoimmune ILD	0.62 (0.26, 1.50)	1.27 (0.59, 2.75)	
Other ILD	0.94 (0.32, 2.80)	0.84 (0.17, 4.00)	
Region			
Europe	2.05 (0.66, 6.38)	1.04 (0.57, 1.91)	
Asia	0.55 (0.29, 1.05)	1.25 (0.54, 2.88)	
Canada and USA	0.67 (0.11, 3.88)	0.49 (0.12, 2.05)	
Rest of the World	0.57 (0.15, 2.11)	1.62 (0.40, 6.62)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.26 (0.51, 3.14)	1.00 (0.44, 2.27)	1.27 (0.37, 4.31)	0.7071	
Age					
<65 years	0.94 (0.20, 4.54)	1.31 (0.22, 7.69)			
>=65 years	1.47 (0.48, 4.53)	0.97 (0.38, 2.46)			
Sex					
Male	0.75 (0.24, 2.28)	1.11 (0.44, 2.82)			
Female	4.86 (0.58, 40.93)	0.67 (0.11, 3.96)			
Baseline FVC percent predicted					
<=70%	0.82 (0.14, 4.81)	0.79 (0.21, 2.89)			
>70%	1.34 (0.45, 3.98)	1.18 (0.41, 3.43)			
Baseline HRCT pattern					
UIP-like	1.64 (0.55, 4.91)	1.25 (0.50, 3.10)			
Other fibrotic patterns	0.65 (0.11, 3.74)	0.33 (0.03, 3.14)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.94 (-2.99, 4.97)	-0.01 (-2.74, 2.72)	0.95 (-3.87, 5.77)
Age			
<65 years	-0.21 (-7.06, 6.38)	0.51 (-2.81, 3.82)	
>=65 years	1.71 (-3.59, 7.33)	-0.14 (-4.07, 3.79)	
Sex			
Male	-1.53 (-7.96, 4.87)	0.51 (-3.92, 4.94)	
Female	3.64 (-1.31, 9.40)	-0.64 (-3.47, 2.19)	
Baseline FVC percent predicted			
<=70%	-0.46 (-5.36, 5.00)	-0.55 (-3.54, 2.44)	
>70%	1.64 (-5.09, 8.02)	0.80 (-4.24, 5.84)	
Baseline HRCT pattern			
UIP-like	2.03 (-2.73, 7.08)	0.97 (-2.98, 4.92)	
Other fibrotic patterns	-1.66 (-10.16, 6.32)	-1.61 (-4.70, 1.49)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.27 (0.49, 3.29)	1.00 (0.43, 2.33)	1.28 (0.36, 4.57)
Age			
<65 years	0.94 (0.18, 4.80)	1.31 (0.22, 7.99)	
>=65 years	1.50 (0.46, 4.85)	0.97 (0.36, 2.56)	
Sex			
Male	0.73 (0.23, 2.39)	1.12 (0.42, 2.97)	
Female	5.05 (0.58, 43.95)	0.67 (0.11, 4.05)	
Baseline FVC percent predicted			
<=70%	0.82 (0.13, 4.98)	0.78 (0.21, 2.96)	
>70%	1.37 (0.43, 4.31)	1.19 (0.39, 3.65)	
Baseline HRCT pattern			
UIP-like	1.68 (0.54, 5.24)	1.26 (0.49, 3.27)	
Other fibrotic patterns	0.64 (0.10, 3.93)	0.33 (0.03, 3.17)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Nervous system disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	2.22 (0.78, 6.28)				
Age					
<65 years	1.89 (0.17, 20.42)				
>=65 years	2.37 (0.75, 7.51)				
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%	11.04 (0.60, 202.56)				
>70%	1.17 (0.38, 3.59)				
Baseline HRCT pattern					
UIP-like	2.74 (0.74, 10.12)				
Other fibrotic patterns	1.45 (0.25, 8.42)				
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	3.80 (0.19, 76.95)				
Asia	3.96 (0.86, 18.23)				
Canada and USA	5.17 (0.22, 120.26)				
Rest of the World	0.15 (0.01, 2.87)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Nervous system disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	2.75 (-0.89, 6.69)		
Age			
<65 years	1.07 (-4.49, 6.79)		
>=65 years	3.94 (-1.40, 9.84)		
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%	4.17 (0.12, 10.23)		
>70%	0.84 (-5.78, 7.03)		
Baseline HRCT pattern			
UIP-like	3.30 (-1.06, 8.18)		
Other fibrotic patterns	1.42 (-6.72, 9.72)		
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	3.77 (-5.40, 12.75)		
Asia	5.59 (-0.38, 12.32)		
Canada and USA	5.88 (-6.46, 26.98)		
Rest of the World	-6.52 (-17.50, 2.73)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Nervous system disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	2.28 (0.78, 6.69)		
Age			
<65 years	1.91 (0.17, 21.43)		
>=65 years	2.47 (0.74, 8.22)		
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%	NC (NC, NC)		
>70%	1.18 (0.36, 3.85)		
Baseline HRCT pattern			
UIP-like	2.83 (0.74, 10.88)		
Other fibrotic patterns	1.48 (0.24, 9.14)		
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	NC (NC, NC)		
Asia	4.20 (0.87, 20.27)		
Canada and USA	NC (NC, NC)		
Rest of the World	0.00 (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.64 (0.40, 1.05)	0.70 (0.53, 0.92)	0.93 (0.53, 1.62)	0.7864	
Age					
<65 years	0.47 (0.19, 1.20)	0.61 (0.36, 1.04)			
>=65 years	0.75 (0.42, 1.32)	0.76 (0.55, 1.05)			
Sex					
Male	0.73 (0.39, 1.38)	0.82 (0.59, 1.15)			
Female	0.55 (0.25, 1.18)	0.52 (0.32, 0.84)			
Baseline FVC percent predicted					
<=70%	0.61 (0.34, 1.10)	0.64 (0.47, 0.88)			
>70%	0.94 (0.38, 2.36)	0.85 (0.49, 1.46)			
Baseline HRCT pattern					
UIP-like	0.82 (0.44, 1.52)	0.65 (0.47, 0.91)			
Other fibrotic patterns	0.42 (0.19, 0.96)	0.81 (0.49, 1.34)			
Underlying ILD diagnosis					
iNSIP	2.18 (0.46, 10.26)	0.57 (0.27, 1.21)			
Unclassifiable IIP	1.08 (0.36, 3.24)	0.71 (0.45, 1.13)			
HP	0.24 (0.06, 0.99)	0.75 (0.44, 1.29)			
Autoimmune ILD	0.56 (0.20, 1.60)	0.48 (0.23, 1.00)			
Other ILD	0.64 (0.22, 1.85)	0.93 (0.43, 1.99)			
Region					
Europe	0.38 (0.14, 1.02)	0.78 (0.51, 1.18)			
Asia	0.99 (0.52, 1.88)	0.54 (0.33, 0.88)			
Canada and USA	0.19 (0.01, 3.35)	0.69 (0.36, 1.31)			
Rest of the World	0.36 (0.08, 1.67)	0.98 (0.29, 3.33)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-5.76 (-12.15, 0.62)	-8.52 (-14.97, -2.06)	2.76 (-6.32, 11.84)
Age			
<65 years	-7.64 (-17.48, 1.78)	-8.64 (-18.01, 0.72)	
>=65 years	-4.39 (-12.93, 4.27)	-7.59 (-16.29, 1.10)	
Sex			
Male	-4.63 (-13.95, 4.81)	-5.37 (-14.66, 3.93)	
Female	-6.84 (-15.74, 1.88)	-12.25 (-20.95, -3.55)	
Baseline FVC percent predicted			
<=70%	-9.15 (-19.32, 1.66)	-12.79 (-21.76, -3.83)	
>70%	-0.43 (-8.00, 6.60)	-2.69 (-11.37, 6.00)	
Baseline HRCT pattern			
UIP-like	-2.27 (-9.49, 4.98)	-11.17 (-19.62, -2.71)	
Other fibrotic patterns	-14.39 (-27.37, -1.17)	-4.14 (-13.94, 5.66)	
Underlying ILD diagnosis			
iNSIP	5.91 (-6.98, 17.41)	-10.53 (-24.29, 3.23)	
Unclassifiable IIP	1.11 (-15.66, 17.20)	-13.19 (-31.16, 4.79)	
HP	-21.54 (-37.84, -2.81)	-6.73 (-19.33, 5.87)	
Autoimmune ILD	-5.53 (-16.04, 4.80)	-11.75 (-22.82, -0.69)	
Other ILD	-9.00 (-27.72, 12.78)	-1.90 (-20.68, 16.89)	
Region			
Europe	-15.57 (-31.67, -0.27)	-5.72 (-15.22, 3.78)	
Asia	-0.14 (-9.89, 9.59)	-19.32 (-33.77, -4.87)	
Canada and USA	-13.33 (-29.68, 6.77)	-8.18 (-22.02, 5.67)	
Rest of the World	-8.39 (-21.46, 4.44)	-0.32 (-15.86, 15.22)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.3: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.60 (0.34, 1.06)	0.62 (0.43, 0.89)	0.97 (0.50, 1.89)
Age			
<65 years	0.43 (0.15, 1.21)	0.55 (0.29, 1.05)	
>=65 years	0.71 (0.36, 1.39)	0.68 (0.44, 1.06)	
Sex			
Male	0.69 (0.33, 1.45)	0.76 (0.48, 1.22)	
Female	0.51 (0.21, 1.20)	0.44 (0.24, 0.80)	
Baseline FVC percent predicted			
<=70%	0.55 (0.27, 1.11)	0.54 (0.34, 0.84)	
>70%	0.94 (0.35, 2.53)	0.82 (0.43, 1.56)	
Baseline HRCT pattern			
UIP-like	0.80 (0.40, 1.61)	0.56 (0.36, 0.87)	
Other fibrotic patterns	0.36 (0.14, 0.94)	0.77 (0.41, 1.44)	
Underlying ILD diagnosis			
iNSIP	2.33 (0.44, 12.18)	0.50 (0.20, 1.25)	
Unclassifiable IIP	1.09 (0.30, 3.95)	0.57 (0.27, 1.23)	
HP	0.18 (0.04, 0.90)	0.69 (0.34, 1.40)	
Autoimmune ILD	0.53 (0.17, 1.67)	0.42 (0.18, 0.98)	
Other ILD	0.57 (0.15, 2.11)	0.90 (0.33, 2.49)	
Region			
Europe	0.31 (0.10, 1.00)	0.72 (0.42, 1.24)	
Asia	0.99 (0.47, 2.10)	0.41 (0.20, 0.81)	
Canada and USA	0.00 (NC, NC)	0.62 (0.27, 1.41)	
Rest of the World	0.33 (0.06, 1.71)	0.97 (0.24, 3.97)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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M.1.2.4 Adverse events on PT level over the whole trial

Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.55 (1.09, 2.22)	2.82 (2.32, 3.42)	0.55 (0.37, 0.83)	0.0042	
Age					0.0185
<65 years	0.94 (0.51, 1.76)	3.45 (2.39, 4.96)	0.27 (0.13, 0.56)	0.0004	
>=65 years	2.01 (1.29, 3.14)	2.56 (2.03, 3.22)	0.79 (0.48, 1.30)	0.3505	
Sex					0.5941
Male	1.38 (0.84, 2.25)	2.78 (2.14, 3.60)	0.50 (0.29, 0.86)	0.0131	
Female	1.77 (1.05, 3.01)	2.86 (2.13, 3.84)	0.62 (0.34, 1.13)	0.1208	
Baseline FVC percent predicted					0.4483
<=70%	1.37 (0.87, 2.16)	2.76 (2.14, 3.56)	0.50 (0.30, 0.84)	0.0087	
>70%	2.00 (1.11, 3.62)	2.90 (2.14, 3.93)	0.69 (0.35, 1.34)	0.2746	
Baseline HRCT pattern					0.4199
UIP-like	1.69 (1.11, 2.55)	2.75 (2.17, 3.49)	0.61 (0.38, 0.99)	0.0444	
Other fibrotic patterns	1.23 (0.61, 2.51)	2.94 (2.09, 4.14)	0.42 (0.19, 0.92)	0.0308	
Underlying ILD diagnosis					0.7779
iNSIP	1.58 (0.66, 3.79)	3.15 (1.89, 5.26)	0.50 (0.18, 1.38)	0.1808	
Unclassifiable IIP	1.98 (0.76, 5.15)	4.17 (2.27, 7.66)	0.48 (0.15, 1.48)	0.1983	
HP	1.63 (0.73, 3.61)	2.59 (1.85, 3.62)	0.63 (0.26, 1.49)	0.2913	
Autoimmune ILD	1.08 (0.58, 2.02)	2.40 (1.67, 3.46)	0.45 (0.22, 0.92)	0.0298	
Other ILD	2.88 (1.12, 7.41)	2.78 (1.60, 4.81)	1.04 (0.35, 3.09)	0.9482	
Region					0.3616
Europe	2.42 (0.97, 6.04)	3.47 (2.48, 4.85)	0.70 (0.26, 1.85)	0.4673	
Asia	1.09 (0.64, 1.84)	2.84 (1.94, 4.16)	0.38 (0.20, 0.73)	0.0038	
Canada and USA	1.76 (0.75, 4.18)	1.75 (1.30, 2.36)	1.01 (0.40, 2.51)	0.9864	
Rest of the World	2.50 (1.05, 5.91)	5.48 (2.06, 14.57)	0.46 (0.12, 1.67)	0.2363	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	9.71 (1.92, 17.36)	46.61 (39.88, 53.34)	-36.90 (-47.15, -26.66)
Age			
<65 years	-1.10 (-12.92, 10.60)	50.56 (40.14, 60.99)	-51.66 (-67.37, -35.94)
>=65 years	16.79 (6.51, 26.71)	44.49 (35.74, 53.23)	-27.70 (-41.06, -14.34)
Sex			
Male	7.16 (-3.72, 17.92)	47.19 (38.03, 56.35)	-40.03 (-54.20, -25.85)
Female	12.40 (1.24, 23.17)	45.91 (35.99, 55.84)	-33.51 (-48.30, -18.72)
Baseline FVC percent predicted			
<=70%	8.17 (-3.54, 19.95)	45.52 (36.68, 54.37)	-37.35 (-52.05, -22.64)
>70%	12.50 (2.22, 22.21)	48.17 (37.79, 58.54)	-35.67 (-50.08, -21.26)
Baseline HRCT pattern			
UIP-like	12.15 (2.70, 21.38)	47.57 (39.08, 56.06)	-35.42 (-48.05, -22.80)
Other fibrotic patterns	4.02 (-9.68, 17.48)	45.05 (34.06, 56.05)	-41.03 (-58.50, -23.56)
Underlying ILD diagnosis			
iNSIP	8.64 (-8.21, 23.62)	45.88 (30.45, 61.30)	-37.24 (-59.41, -15.07)
Unclassifiable IIP	13.61 (-5.04, 30.82)	57.00 (41.97, 72.03)	-43.39 (-66.79, -19.99)
HP	12.82 (-7.78, 33.18)	48.23 (35.26, 61.20)	-35.41 (-59.66, -11.17)
Autoimmune ILD	1.73 (-11.91, 15.34)	39.88 (26.09, 53.68)	-38.15 (-57.54, -18.77)
Other ILD	26.11 (3.89, 46.89)	45.47 (26.03, 64.91)	-19.36 (-48.35, 9.63)
Region			
Europe	17.69 (0.39, 32.78)	50.37 (40.67, 60.07)	-32.68 (-51.56, -13.81)
Asia	1.68 (-9.22, 12.53)	50.85 (37.31, 64.38)	-49.17 (-66.53, -31.80)
Canada and USA	17.84 (-8.47, 43.41)	32.64 (17.12, 48.17)	-14.80 (-45.03, 15.43)
Rest of the World	19.51 (2.05, 35.97)	45.99 (26.34, 65.64)	-26.48 (-52.43, -0.52)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.76 (1.12, 2.77)	7.55 (5.35, 10.65)	0.23 (0.13, 0.41)
Age			
<65 years	0.93 (0.43, 2.01)	9.50 (5.36, 16.86)	0.10 (0.04, 0.26)
>=65 years	2.52 (1.42, 4.48)	6.78 (4.38, 10.49)	0.37 (0.18, 0.77)
Sex			
Male	1.51 (0.81, 2.83)	7.77 (4.85, 12.45)	0.19 (0.09, 0.43)
Female	2.08 (1.07, 4.05)	7.33 (4.42, 12.14)	0.28 (0.12, 0.65)
Baseline FVC percent predicted			
<=70%	1.53 (0.83, 2.84)	7.15 (4.57, 11.18)	0.21 (0.10, 0.46)
>70%	2.33 (1.15, 4.74)	8.17 (4.76, 14.04)	0.29 (0.12, 0.70)
Baseline HRCT pattern			
UIP-like	1.98 (1.16, 3.38)	7.93 (5.11, 12.31)	0.25 (0.12, 0.50)
Other fibrotic patterns	1.30 (0.54, 3.12)	7.12 (4.07, 12.46)	0.18 (0.06, 0.52)
Underlying ILD diagnosis			
iNSIP	1.75 (0.60, 5.10)	7.56 (3.38, 16.91)	0.23 (0.06, 0.88)
Unclassifiable IIP	2.35 (0.73, 7.59)	13.67 (5.46, 34.19)	0.17 (0.04, 0.76)
HP	1.94 (0.65, 5.74)	8.42 (4.22, 16.78)	0.23 (0.06, 0.83)
Autoimmune ILD	1.11 (0.50, 2.46)	5.43 (2.82, 10.46)	0.20 (0.07, 0.57)
Other ILD	4.13 (1.20, 14.25)	7.14 (2.68, 19.03)	0.58 (0.12, 2.81)
Region			
Europe	3.03 (1.00, 9.14)	9.45 (5.56, 16.06)	0.32 (0.09, 1.09)
Asia	1.11 (0.57, 2.15)	9.55 (4.58, 19.93)	0.12 (0.04, 0.31)
Canada and USA	2.30 (0.64, 8.31)	4.14 (1.98, 8.65)	0.56 (0.13, 2.44)
Rest of the World	3.22 (1.10, 9.38)	11.25 (3.23, 39.19)	0.29 (0.06, 1.48)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Gastrooesophageal reflux disease

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.91 (0.38, 2.19)	1.88 (0.85, 4.16)	0.48 (0.15, 1.58)	0.2280	
Age					
<65 years	0.38 (0.08, 1.89)	3.19 (0.91, 11.18)			
>=65 years	1.47 (0.48, 4.53)	1.09 (0.36, 3.32)			
Sex					
Male	1.05 (0.35, 3.14)	1.98 (0.61, 6.45)			
Female	0.73 (0.17, 3.18)	1.81 (0.62, 5.28)			
Baseline FVC percent predicted					
<=70%	0.61 (0.12, 3.28)	0.98 (0.35, 2.75)			
>70%	0.98 (0.34, 2.82)	5.07 (1.13, 22.73)			
Baseline HRCT pattern					
UIP-like	0.88 (0.30, 2.56)	1.80 (0.61, 5.28)			
Other fibrotic patterns	0.97 (0.20, 4.63)	1.98 (0.61, 6.42)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	2.28 (0.10, 54.49)	1.59 (0.39, 6.54)			
Asia	0.62 (0.21, 1.83)	1.92 (0.36, 10.20)			
Canada and USA	1.76 (0.12, 26.45)	1.54 (0.46, 5.23)			
Rest of the World	2.14 (0.20, 22.75)	NC (NC, NC)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Gastrooesophageal reflux disease

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.41 (-4.48, 3.64)	2.40 (-0.55, 5.35)	-2.82 (-7.83, 2.20)
Age			
<65 years	-3.75 (-11.25, 2.85)	5.43 (0.16, 10.71)	
>=65 years	1.71 (-3.59, 7.33)	0.25 (-3.08, 3.58)	
Sex			
Male	0.23 (-6.12, 6.74)	2.21 (-1.53, 5.95)	
Female	-1.02 (-6.84, 4.51)	2.64 (-2.03, 7.30)	
Baseline FVC percent predicted			
<=70%	-1.31 (-6.53, 4.29)	-0.06 (-3.76, 3.65)	
>70%	-0.12 (-7.01, 6.23)	5.90 (1.09, 10.72)	
Baseline HRCT pattern			
UIP-like	-0.53 (-5.44, 4.36)	1.94 (-1.55, 5.44)	
Other fibrotic patterns	-0.14 (-8.88, 8.42)	3.15 (-2.11, 8.41)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	1.89 (-7.01, 9.94)	1.21 (-2.41, 4.82)	
Asia	-2.87 (-10.03, 3.99)	2.43 (-3.60, 8.46)	
Canada and USA	2.55 (-11.64, 23.83)	3.16 (-5.63, 11.94)	
Rest of the World	2.48 (-7.28, 13.43)	6.25 (-2.14, 14.64)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Gastrooesophageal reflux disease

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.90 (0.36, 2.27)	1.93 (0.85, 4.40)	0.47 (0.14, 1.61)
Age			
<65 years	0.36 (0.07, 1.92)	3.38 (0.92, 12.41)	
>=65 years	1.50 (0.46, 4.85)	1.09 (0.35, 3.44)	
Sex			
Male	1.05 (0.33, 3.35)	2.02 (0.60, 6.84)	
Female	0.72 (0.16, 3.30)	1.86 (0.61, 5.69)	
Baseline FVC percent predicted			
<=70%	0.61 (0.11, 3.38)	0.98 (0.34, 2.86)	
>70%	0.98 (0.32, 3.00)	5.40 (1.16, 25.11)	
Baseline HRCT pattern			
UIP-like	0.87 (0.29, 2.66)	1.84 (0.60, 5.58)	
Other fibrotic patterns	0.97 (0.19, 4.98)	2.05 (0.60, 6.99)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	NC (NC, NC)	1.61 (0.38, 6.86)	
Asia	0.60 (0.19, 1.90)	1.97 (0.35, 11.10)	
Canada and USA	1.81 (0.11, 30.97)	1.60 (0.43, 5.94)	
Rest of the World	2.20 (0.19, 25.12)	NC (NC, NC)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.91 (0.87, 4.18)	3.02 (2.10, 4.34)	0.63 (0.27, 1.50)	0.2971	
Age					
<65 years	1.26 (0.29, 5.45)	3.32 (1.79, 6.16)			
>=65 years	2.28 (0.89, 5.83)	2.87 (1.83, 4.50)			
Sex					
Male	4.18 (0.91, 19.26)	2.75 (1.55, 4.89)			
Female	1.25 (0.48, 3.24)	3.23 (2.03, 5.14)			
Baseline FVC percent predicted					
<=70%	2.05 (0.77, 5.43)	2.73 (1.75, 4.26)			
>70%	1.96 (0.52, 7.38)	3.60 (1.92, 6.73)			
Baseline HRCT pattern					
UIP-like	3.33 (1.11, 10.00)	3.47 (2.10, 5.74)			
Other fibrotic patterns	0.78 (0.22, 2.76)	2.54 (1.51, 4.28)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	3.67 (-0.82, 8.38)	20.15 (14.25, 26.05)	-16.48 (-23.95, -9.00)
Age			
<65 years	0.93 (-6.12, 7.91)	21.12 (11.93, 30.32)	
>=65 years	5.53 (-0.70, 12.22)	19.58 (11.89, 27.26)	
Sex			
Male	5.48 (-0.10, 11.98)	13.88 (6.64, 21.12)	
Female	1.65 (-5.82, 9.15)	27.53 (18.20, 36.87)	
Baseline FVC percent predicted			
<=70%	5.33 (-1.93, 13.51)	19.72 (11.84, 27.60)	
>70%	2.76 (-3.23, 8.63)	20.71 (11.86, 29.55)	
Baseline HRCT pattern			
UIP-like	5.91 (0.79, 11.59)	20.39 (13.16, 27.62)	
Other fibrotic patterns	-1.75 (-11.67, 7.84)	19.74 (9.68, 29.80)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.98 (0.86, 4.55)	3.89 (2.53, 5.98)	0.51 (0.20, 1.30)
Age			
<65 years	1.27 (0.28, 5.85)	4.33 (2.11, 8.88)	
>=65 years	2.42 (0.89, 6.57)	3.67 (2.14, 6.29)	
Sex			
Male	4.43 (0.92, 21.33)	3.24 (1.69, 6.22)	
Female	1.27 (0.46, 3.55)	4.71 (2.64, 8.41)	
Baseline FVC percent predicted			
<=70%	2.17 (0.76, 6.21)	3.51 (2.05, 6.01)	
>70%	2.01 (0.51, 7.99)	4.64 (2.26, 9.53)	
Baseline HRCT pattern			
UIP-like	3.55 (1.13, 11.14)	4.46 (2.50, 7.98)	
Other fibrotic patterns	0.76 (0.19, 2.97)	3.29 (1.73, 6.25)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.50 (0.31, 0.82)				
Age					
<65 years	0.55 (0.27, 1.14)				
>=65 years	0.46 (0.24, 0.90)				
Sex					
Male	0.44 (0.23, 0.85)				
Female	0.61 (0.29, 1.28)				
Baseline FVC percent predicted					
<=70%	0.61 (0.34, 1.10)				
>70%	0.42 (0.18, 1.00)				
Baseline HRCT pattern					
UIP-like	0.42 (0.23, 0.76)				
Other fibrotic patterns	0.78 (0.33, 1.84)				
Underlying ILD diagnosis					
iNSIP	0.45 (0.16, 1.29)				
Unclassifiable IIP	0.72 (0.21, 2.48)				
HP	0.26 (0.06, 1.10)				
Autoimmune ILD	0.34 (0.11, 1.00)				
Other ILD	1.23 (0.47, 3.24)				
Region					
Europe	0.66 (0.26, 1.67)				
Asia	0.45 (0.21, 0.93)				
Canada and USA	0.44 (0.05, 3.64)				
Rest of the World	0.43 (0.14, 1.26)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-9.37 (-15.89, -2.86)		
Age			
<65 years	-9.12 (-20.24, 1.93)		
>=65 years	-9.65 (-17.73, -1.54)		
Sex			
Male	-12.50 (-21.94, -2.88)		
Female	-5.92 (-14.94, 2.95)		
Baseline FVC percent predicted			
<=70%	-9.15 (-19.32, 1.66)		
>70%	-7.82 (-16.20, -0.16)		
Baseline HRCT pattern			
UIP-like	-11.81 (-19.56, -4.04)		
Other fibrotic patterns	-3.50 (-15.79, 8.66)		
Underlying ILD diagnosis			
iNSIP	-10.91 (-26.54, 3.24)		
Unclassifiable IIP	-3.89 (-19.85, 11.32)		
HP	-18.97 (-35.15, -0.61)		
Autoimmune ILD	-11.19 (-22.11, -0.52)		
Other ILD	4.56 (-15.42, 26.27)		
Region			
Europe	-6.79 (-22.98, 8.23)		
Asia	-10.46 (-19.81, -1.18)		
Canada and USA	-7.45 (-24.50, 15.12)		
Rest of the World	-12.44 (-27.37, 3.09)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.45 (0.26, 0.79)		
Age			
<65 years	0.50 (0.21, 1.16)		
>=65 years	0.41 (0.20, 0.88)		
Sex			
Male	0.38 (0.18, 0.81)		
Female	0.57 (0.25, 1.32)		
Baseline FVC percent predicted			
<=70%	0.55 (0.27, 1.11)		
>70%	0.38 (0.15, 0.99)		
Baseline HRCT pattern			
UIP-like	0.36 (0.18, 0.72)		
Other fibrotic patterns	0.74 (0.27, 2.03)		
Underlying ILD diagnosis			
iNSIP	0.40 (0.12, 1.33)		
Unclassifiable IIP	0.69 (0.17, 2.79)		
HP	0.21 (0.04, 1.03)		
Autoimmune ILD	0.30 (0.09, 0.97)		
Other ILD	1.31 (0.38, 4.50)		
Region			
Europe	0.61 (0.20, 1.85)		
Asia	0.39 (0.17, 0.91)		
Canada and USA	0.41 (0.04, 3.96)		
Rest of the World	0.37 (0.11, 1.28)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Fatigue

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.83 (0.35, 1.95)	1.61 (0.96, 2.72)	0.51 (0.19, 1.40)	0.1919	
Age					
<65 years	0.63 (0.11, 3.67)	2.79 (1.05, 7.38)			
>=65 years	0.92 (0.34, 2.47)	1.22 (0.64, 2.33)			
Sex					
Male	1.05 (0.27, 4.08)	3.13 (1.28, 7.66)			
Female	0.69 (0.23, 2.12)	1.01 (0.51, 1.99)			
Baseline FVC percent predicted					
<=70%	0.61 (0.16, 2.39)	1.39 (0.68, 2.84)			
>70%	1.01 (0.32, 3.20)	1.92 (0.89, 4.15)			
Baseline HRCT pattern					
UIP-like	0.88 (0.30, 2.56)	1.75 (0.88, 3.46)			
Other fibrotic patterns	0.73 (0.17, 3.12)	1.43 (0.64, 3.23)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Fatigue

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.86 (-5.03, 3.25)	3.90 (-0.29, 8.08)	-4.76 (-10.65, 1.13)
Age			
<65 years	-1.34 (-8.03, 4.78)	7.38 (1.00, 13.76)	
>=65 years	-0.45 (-6.31, 5.49)	1.71 (-3.74, 7.16)	
Sex			
Male	0.16 (-5.38, 5.85)	7.22 (1.98, 12.47)	
Female	-2.02 (-8.93, 4.61)	0.06 (-6.58, 6.71)	
Baseline FVC percent predicted			
<=70%	-1.96 (-7.89, 4.33)	2.46 (-2.75, 7.66)	
>70%	0.03 (-6.47, 6.01)	5.98 (-0.94, 12.90)	
Baseline HRCT pattern			
UIP-like	-0.53 (-5.44, 4.36)	4.37 (-0.86, 9.59)	
Other fibrotic patterns	-1.70 (-10.95, 7.14)	3.12 (-3.86, 10.10)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Fatigue

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.82 (0.33, 2.02)	1.68 (0.96, 2.97)	0.49 (0.17, 1.41)
Age			
<65 years	0.62 (0.10, 3.81)	3.02 (1.07, 8.50)	
>=65 years	0.92 (0.32, 2.60)	1.25 (0.62, 2.52)	
Sex			
Male	1.05 (0.26, 4.29)	3.38 (1.32, 8.69)	
Female	0.68 (0.21, 2.21)	1.01 (0.47, 2.14)	
Baseline FVC percent predicted			
<=70%	0.60 (0.15, 2.47)	1.43 (0.67, 3.09)	
>70%	1.01 (0.30, 3.40)	2.05 (0.88, 4.77)	
Baseline HRCT pattern			
UIP-like	0.87 (0.29, 2.66)	1.84 (0.88, 3.84)	
Other fibrotic patterns	0.71 (0.15, 3.33)	1.48 (0.61, 3.61)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Pyrexia

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.67 (0.33, 1.36)	0.89 (0.47, 1.69)	0.75 (0.29, 1.95)	0.5607	
Age					
<65 years	0.43 (0.16, 1.18)	0.75 (0.26, 2.16)			
>=65 years	1.05 (0.38, 2.92)	1.00 (0.45, 2.21)			
Sex					
Male	0.65 (0.22, 1.94)	0.91 (0.43, 1.95)			
Female	0.68 (0.27, 1.72)	0.84 (0.26, 2.69)			
Baseline FVC percent predicted					
<=70%	0.89 (0.37, 2.13)	0.98 (0.45, 2.14)			
>70%	0.48 (0.14, 1.59)	0.72 (0.24, 2.23)			
Baseline HRCT pattern					
UIP-like	0.82 (0.33, 2.02)	1.00 (0.48, 2.10)			
Other fibrotic patterns	0.48 (0.15, 1.53)	0.66 (0.19, 2.29)			
Underlying ILD diagnosis					
iNSIP	5.13 (0.27, 96.53)	1.91 (0.18, 20.49)			
Unclassifiable IIP	0.90 (0.13, 6.06)	0.94 (0.30, 2.90)			
HP	0.26 (0.01, 5.18)	1.77 (0.44, 7.16)			
Autoimmune ILD	0.41 (0.13, 1.23)	0.18 (0.02, 1.45)			
Other ILD	1.08 (0.26, 4.41)	0.85 (0.20, 3.55)			
Region					
Europe	2.26 (0.24, 20.96)	1.53 (0.51, 4.56)			
Asia	0.50 (0.21, 1.18)	0.75 (0.29, 1.91)			
Canada and USA	0.57 (0.02, 13.36)	0.41 (0.08, 2.05)			
Rest of the World	1.07 (0.16, 7.26)	NC (NC, NC)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Pyrexia

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-2.65 (-7.57, 2.17)	-0.62 (-4.07, 2.83)	-2.03 (-8.00, 3.93)
Age			
<65 years	-7.57 (-17.08, 1.40)	-1.47 (-6.83, 3.89)	
>=65 years	0.27 (-5.42, 6.10)	-0.01 (-4.55, 4.52)	
Sex			
Male	-2.39 (-9.03, 4.15)	-0.64 (-5.95, 4.67)	
Female	-3.01 (-10.80, 4.53)	-0.63 (-4.78, 3.53)	
Baseline FVC percent predicted			
<=70%	-0.99 (-8.73, 7.32)	-0.10 (-4.88, 4.69)	
>70%	-3.50 (-10.31, 2.38)	-1.40 (-6.23, 3.44)	
Baseline HRCT pattern			
UIP-like	-1.13 (-6.68, 4.38)	0.00 (-4.70, 4.70)	
Other fibrotic patterns	-6.44 (-17.35, 3.99)	-1.63 (-6.46, 3.21)	
Underlying ILD diagnosis			
iNSIP	5.45 (-4.01, 14.85)	1.49 (-3.84, 6.81)	
Unclassifiable IIP	-0.56 (-13.65, 11.63)	-0.63 (-11.59, 10.34)	
HP	-5.13 (-16.89, 6.81)	2.58 (-3.72, 8.88)	
Autoimmune ILD	-8.37 (-18.90, 1.84)	-5.60 (-11.38, 0.18)	
Other ILD	0.89 (-15.33, 20.06)	-1.41 (-13.61, 10.79)	
Region			
Europe	3.16 (-7.87, 13.09)	1.79 (-2.78, 6.36)	
Asia	-6.67 (-15.10, 1.53)	-2.98 (-12.57, 6.61)	
Canada and USA	-3.33 (-16.67, 15.30)	-4.26 (-11.61, 3.09)	
Rest of the World	0.30 (-10.42, 11.56)	0.00 (0.00, 0.00)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Pyrexia

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.65 (0.31, 1.39)	0.89 (0.45, 1.74)	0.74 (0.27, 2.03)
Age			
<65 years	0.39 (0.13, 1.19)	0.73 (0.24, 2.25)	
>=65 years	1.06 (0.36, 3.10)	1.00 (0.43, 2.32)	
Sex			
Male	0.64 (0.20, 2.01)	0.91 (0.40, 2.05)	
Female	0.66 (0.24, 1.80)	0.83 (0.25, 2.79)	
Baseline FVC percent predicted			
<=70%	0.88 (0.34, 2.29)	0.98 (0.43, 2.25)	
>70%	0.46 (0.13, 1.62)	0.71 (0.22, 2.31)	
Baseline HRCT pattern			
UIP-like	0.81 (0.31, 2.11)	1.00 (0.45, 2.21)	
Other fibrotic patterns	0.45 (0.13, 1.58)	0.65 (0.18, 2.36)	
Underlying ILD diagnosis			
iNSIP	NC (NC, NC)	1.94 (0.17, 21.91)	
Unclassifiable IIP	0.89 (0.12, 6.70)	0.93 (0.27, 3.25)	
HP	0.00 (NC, NC)	1.81 (0.42, 7.84)	
Autoimmune ILD	0.37 (0.11, 1.24)	0.17 (0.02, 1.43)	
Other ILD	1.09 (0.22, 5.36)	0.84 (0.17, 4.00)	
Region			
Europe	2.34 (0.23, 23.38)	1.56 (0.50, 4.87)	
Asia	0.46 (0.18, 1.19)	0.72 (0.26, 2.05)	
Canada and USA	0.00 (NC, NC)	0.39 (0.07, 2.10)	
Rest of the World	1.07 (0.14, 7.97)	NC (NC, NC)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Bronchitis

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.54, 1.89)	0.75 (0.53, 1.05)	1.35 (0.66, 2.75)	0.4102	
Age					
<65 years	1.51 (0.51, 4.43)	1.26 (0.73, 2.18)			
>=65 years	0.81 (0.37, 1.78)	0.52 (0.33, 0.83)			
Sex					
Male	1.05 (0.43, 2.54)	0.80 (0.49, 1.29)			
Female	0.97 (0.40, 2.35)	0.70 (0.43, 1.14)			
Baseline FVC percent predicted					
<=70%	1.23 (0.45, 3.38)	0.93 (0.61, 1.41)			
>70%	0.84 (0.38, 1.86)	0.49 (0.26, 0.91)			
Baseline HRCT pattern					
UIP-like	1.37 (0.59, 3.15)	0.72 (0.47, 1.10)			
Other fibrotic patterns	0.65 (0.24, 1.71)	0.80 (0.45, 1.45)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	0.69 (0.32, 1.45)	0.72 (0.47, 1.12)			
Asia	0.40 (0.08, 2.00)	1.20 (0.50, 2.88)			
Canada and USA	7.06 (0.86, 58.16)	0.56 (0.22, 1.43)			
Rest of the World	2.14 (0.20, 22.75)	0.61 (0.20, 1.84)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Bronchitis

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.07 (-5.17, 5.34)	-4.88 (-10.57, 0.82)	4.95 (-2.80, 12.70)
Age			
<65 years	3.07 (-5.48, 11.62)	3.83 (-5.24, 12.90)	
>=65 years	-1.78 (-8.67, 5.17)	-10.51 (-17.67, -3.34)	
Sex			
Male	0.35 (-7.03, 7.87)	-3.55 (-11.11, 4.01)	
Female	-0.23 (-8.10, 7.54)	-6.40 (-15.00, 2.21)	
Baseline FVC percent predicted			
<=70%	1.36 (-5.53, 8.99)	-1.31 (-9.03, 6.41)	
>70%	-1.71 (-10.02, 6.09)	-10.01 (-18.27, -1.75)	
Baseline HRCT pattern			
UIP-like	2.10 (-3.70, 8.06)	-5.83 (-13.22, 1.57)	
Other fibrotic patterns	-4.97 (-16.59, 6.41)	-3.31 (-12.17, 5.55)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	-8.63 (-26.06, 8.27)	-6.99 (-16.28, 2.30)	
Asia	-2.85 (-8.86, 2.56)	2.13 (-7.94, 12.20)	
Canada and USA	20.20 (0.88, 44.09)	-6.99 (-18.00, 4.03)	
Rest of the World	2.48 (-7.28, 13.43)	-8.01 (-25.10, 9.07)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Bronchitis

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.51, 2.00)	0.71 (0.47, 1.06)	1.43 (0.65, 3.17)
Age			
<65 years	1.56 (0.49, 4.98)	1.32 (0.68, 2.54)	
>=65 years	0.79 (0.34, 1.88)	0.46 (0.26, 0.80)	
Sex			
Male	1.05 (0.40, 2.75)	0.76 (0.43, 1.36)	
Female	0.97 (0.37, 2.55)	0.65 (0.36, 1.17)	
Baseline FVC percent predicted			
<=70%	1.25 (0.42, 3.69)	0.92 (0.55, 1.53)	
>70%	0.82 (0.34, 1.98)	0.43 (0.21, 0.88)	
Baseline HRCT pattern			
UIP-like	1.40 (0.57, 3.42)	0.67 (0.40, 1.12)	
Other fibrotic patterns	0.61 (0.20, 1.83)	0.77 (0.39, 1.55)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	0.61 (0.23, 1.63)	0.66 (0.38, 1.15)	
Asia	0.38 (0.07, 2.03)	1.23 (0.46, 3.31)	
Canada and USA	8.92 (0.91, 87.84)	0.52 (0.18, 1.49)	
Rest of the World	2.20 (0.19, 25.12)	0.55 (0.15, 2.04)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: COVID-19

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.98 (0.62, 1.54)				
Age					
<65 years	0.63 (0.30, 1.32)				
>=65 years	1.30 (0.72, 2.35)				
Sex					
Male	0.80 (0.41, 1.57)				
Female	1.17 (0.62, 2.19)				
Baseline FVC percent predicted					
<=70%	0.56 (0.28, 1.12)				
>70%	1.76 (0.87, 3.57)				
Baseline HRCT pattern					
UIP-like	1.08 (0.60, 1.94)				
Other fibrotic patterns	0.82 (0.40, 1.70)				
Underlying ILD diagnosis					
iNSIP	0.62 (0.23, 1.71)				
Unclassifiable IIP	1.26 (0.44, 3.62)				
HP	0.93 (0.33, 2.64)				
Autoimmune ILD	1.16 (0.44, 3.02)				
Other ILD	1.20 (0.41, 3.50)				
Region					
Europe	0.75 (0.29, 1.98)				
Asia	0.83 (0.44, 1.55)				
Canada and USA	1.18 (0.39, 3.59)				
Rest of the World	5.35 (0.65, 43.96)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: COVID-19

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.32 (-6.89, 6.26)		
Age			
<65 years	-6.71 (-17.59, 4.03)		
>=65 years	3.68 (-4.67, 12.14)		
Sex			
Male	-2.94 (-11.87, 6.08)		
Female	2.36 (-7.43, 12.08)		
Baseline FVC percent predicted			
<=70%	-8.23 (-17.46, 1.54)		
>70%	7.32 (-1.78, 16.03)		
Baseline HRCT pattern			
UIP-like	0.96 (-6.48, 8.46)		
Other fibrotic patterns	-3.65 (-17.08, 9.79)		
Underlying ILD diagnosis			
iNSIP	-6.59 (-22.17, 7.40)		
Unclassifiable IIP	3.61 (-13.56, 20.04)		
HP	-1.28 (-18.71, 17.85)		
Autoimmune ILD	1.57 (-9.09, 12.34)		
Other ILD	3.33 (-15.53, 24.39)		
Region			
Europe	-4.29 (-20.20, 10.27)		
Asia	-2.96 (-12.80, 6.88)		
Canada and USA	3.53 (-18.71, 29.48)		
Rest of the World	9.45 (-1.81, 22.43)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: COVID-19

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.97 (0.57, 1.66)		
Age			
<65 years	0.58 (0.25, 1.38)		
>=65 years	1.36 (0.68, 2.70)		
Sex			
Male	0.77 (0.36, 1.68)		
Female	1.20 (0.57, 2.53)		
Baseline FVC percent predicted			
<=70%	0.51 (0.23, 1.13)		
>70%	1.92 (0.86, 4.28)		
Baseline HRCT pattern			
UIP-like	1.09 (0.56, 2.14)		
Other fibrotic patterns	0.78 (0.32, 1.91)		
Underlying ILD diagnosis			
iNSIP	0.58 (0.18, 1.87)		
Unclassifiable IIP	1.32 (0.38, 4.58)		
HP	0.91 (0.26, 3.23)		
Autoimmune ILD	1.18 (0.40, 3.45)		
Other ILD	1.25 (0.34, 4.65)		
Region			
Europe	0.72 (0.23, 2.24)		
Asia	0.80 (0.38, 1.68)		
Canada and USA	1.23 (0.29, 5.16)		
Rest of the World	5.92 (0.66, 52.91)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Influenza

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.49, 2.07)	0.75 (0.32, 1.75)	1.35 (0.44, 4.11)	0.5975	
Age					
<65 years	0.42 (0.13, 1.31)	0.87 (0.22, 3.41)			
>=65 years	2.11 (0.74, 6.00)	0.68 (0.23, 2.04)			
Sex					
Male	1.57 (0.45, 5.41)	1.38 (0.45, 4.28)			
Female	0.78 (0.32, 1.90)	0.29 (0.06, 1.36)			
Baseline FVC percent predicted					
<=70%	0.46 (0.13, 1.69)	1.31 (0.46, 3.71)			
>70%	1.54 (0.59, 4.02)	0.17 (0.02, 1.39)			
Baseline HRCT pattern					
UIP-like	0.94 (0.43, 2.07)	1.14 (0.42, 3.09)			
Other fibrotic patterns	1.45 (0.25, 8.42)	0.20 (0.02, 1.67)			
Underlying ILD diagnosis					
iNSIP	5.13 (0.27, 96.53)	0.00 (NC, NC)			
Unclassifiable IIP	1.80 (0.17, 19.02)	0.52 (0.09, 3.00)			
HP	1.30 (0.08, 19.95)	0.71 (0.21, 2.42)			
Autoimmune ILD	0.56 (0.20, 1.60)	2.15 (0.20, 23.23)			
Other ILD	1.44 (0.32, 6.56)	NC (NC, NC)			
Region					
Europe	0.75 (0.16, 3.54)				
Asia	1.82 (0.70, 4.73)				
Canada and USA	1.72 (0.04, 83.12)				
Rest of the World	0.10 (0.01, 1.71)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Influenza

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.06 (-4.68, 4.81)	-0.91 (-3.58, 1.75)	0.97 (-4.47, 6.41)
Age			
<65 years	-6.30 (-15.23, 1.98)	-0.43 (-4.66, 3.80)	
>=65 years	3.98 (-1.70, 10.14)	-1.22 (-4.64, 2.21)	
Sex			
Male	1.96 (-3.90, 8.21)	1.09 (-2.66, 4.83)	
Female	-2.09 (-10.01, 5.64)	-3.24 (-6.99, 0.51)	
Baseline FVC percent predicted			
<=70%	-3.65 (-10.03, 2.90)	0.97 (-2.72, 4.67)	
>70%	3.10 (-4.24, 10.14)	-3.61 (-7.31, 0.08)	
Baseline HRCT pattern			
UIP-like	-0.45 (-6.52, 5.65)	0.49 (-3.13, 4.10)	
Other fibrotic patterns	1.42 (-6.72, 9.72)	-3.21 (-6.97, 0.56)	
Underlying ILD diagnosis			
iNSIP	5.45 (-4.01, 14.85)	-3.28 (-7.75, 1.19)	
Unclassifiable IIP	2.22 (-9.73, 13.95)	-2.87 (-10.72, 4.97)	
HP	0.77 (-10.20, 14.27)	-1.98 (-8.90, 4.94)	
Autoimmune ILD	-5.53 (-16.04, 4.80)	1.30 (-2.70, 5.31)	
Other ILD	3.67 (-11.94, 22.43)	2.63 (-2.46, 7.72)	
Region			
Europe	-1.84 (-14.75, 9.04)		
Asia	4.62 (-2.96, 12.43)		
Canada and USA	0.00 (NC, NC)		
Rest of the World	-10.87 (-23.04, -0.63)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Influenza

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.47, 2.17)	0.74 (0.31, 1.78)	1.36 (0.43, 4.37)
Age			
<65 years	0.39 (0.12, 1.32)	0.87 (0.21, 3.54)	
>=65 years	2.20 (0.73, 6.61)	0.67 (0.22, 2.09)	
Sex			
Male	1.60 (0.44, 5.83)	1.40 (0.44, 4.50)	
Female	0.76 (0.29, 2.01)	0.28 (0.06, 1.36)	
Baseline FVC percent predicted			
<=70%	0.44 (0.11, 1.72)	1.33 (0.45, 3.90)	
>70%	1.59 (0.57, 4.46)	0.16 (0.02, 1.37)	
Baseline HRCT pattern			
UIP-like	0.94 (0.40, 2.19)	1.15 (0.41, 3.23)	
Other fibrotic patterns	1.48 (0.24, 9.14)	0.19 (0.02, 1.67)	
Underlying ILD diagnosis			
iNSIP	NC (NC, NC)	0.00 (NC, NC)	
Unclassifiable IIP	1.84 (0.16, 21.22)	0.51 (0.08, 3.15)	
HP	1.31 (0.08, 21.84)	0.69 (0.19, 2.54)	
Autoimmune ILD	0.53 (0.17, 1.67)	2.18 (0.19, 24.45)	
Other ILD	1.50 (0.28, 8.12)	NC (NC, NC)	
Region			
Europe	0.74 (0.14, 3.88)		
Asia	1.91 (0.68, 5.37)		
Canada and USA	NC (NC, NC)		
Rest of the World	0.00 (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Nasopharyngitis

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.14 (0.68, 1.90)	1.12 (0.78, 1.60)	1.01 (0.54, 1.90)	0.9700	
Age					
<65 years	0.86 (0.38, 1.91)	1.04 (0.61, 1.79)			
>=65 years	1.38 (0.70, 2.72)	1.17 (0.72, 1.88)			
Sex					
Male	1.21 (0.60, 2.42)	0.89 (0.55, 1.43)			
Female	1.06 (0.49, 2.30)	1.51 (0.87, 2.62)			
Baseline FVC percent predicted					
<=70%	1.45 (0.68, 3.10)	1.27 (0.78, 2.09)			
>70%	0.90 (0.44, 1.83)	0.97 (0.58, 1.64)			
Baseline HRCT pattern					
UIP-like	0.86 (0.46, 1.62)	1.21 (0.80, 1.84)			
Other fibrotic patterns	2.13 (0.79, 5.80)	0.93 (0.47, 1.84)			
Underlying ILD diagnosis					
iNSIP	0.91 (0.26, 3.17)	1.27 (0.58, 2.80)			
Unclassifiable IIP	0.77 (0.29, 2.08)	1.22 (0.57, 2.58)			
HP	1.95 (0.60, 6.30)	1.06 (0.54, 2.09)			
Autoimmune ILD	1.16 (0.44, 3.02)	0.86 (0.43, 1.72)			
Other ILD	1.44 (0.22, 9.55)	2.26 (0.21, 23.98)			
Region					
Europe	1.06 (0.36, 3.09)	1.18 (0.70, 2.01)			
Asia	0.87 (0.45, 1.69)	0.88 (0.53, 1.45)			
Canada and USA	3.53 (0.34, 36.11)	2.40 (0.65, 8.91)			
Rest of the World	2.14 (0.41, 11.09)	0.00 (NC, NC)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Nasopharyngitis

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	1.46 (-4.58, 7.53)	1.76 (-3.73, 7.25)	-0.30 (-8.47, 7.87)
Age			
<65 years	-1.89 (-12.17, 8.18)	0.74 (-8.39, 9.86)	
>=65 years	3.53 (-4.08, 11.30)	2.21 (-4.66, 9.09)	
Sex			
Male	2.31 (-6.41, 11.15)	-1.87 (-9.48, 5.75)	
Female	0.63 (-7.96, 9.16)	5.96 (-1.93, 13.85)	
Baseline FVC percent predicted			
<=70%	4.22 (-4.34, 13.41)	3.38 (-3.53, 10.29)	
>70%	-1.21 (-10.12, 7.24)	-0.48 (-9.41, 8.45)	
Baseline HRCT pattern			
UIP-like	-1.64 (-8.78, 5.54)	3.40 (-3.97, 10.76)	
Other fibrotic patterns	8.85 (-2.77, 20.49)	-0.89 (-8.80, 7.02)	
Underlying ILD diagnosis			
iNSIP	-0.91 (-14.94, 11.19)	4.00 (-9.07, 17.06)	
Unclassifiable IIP	-4.44 (-21.93, 12.64)	3.88 (-10.82, 18.57)	
HP	9.74 (-7.22, 28.12)	0.94 (-10.05, 11.92)	
Autoimmune ILD	1.57 (-9.09, 12.34)	-2.41 (-13.38, 8.55)	
Other ILD	2.44 (-11.41, 19.88)	2.94 (-5.47, 11.35)	
Region			
Europe	0.71 (-14.45, 14.30)	2.60 (-5.59, 10.78)	
Asia	-2.01 (-11.53, 7.49)	-3.68 (-17.88, 10.52)	
Canada and USA	8.43 (-7.37, 31.17)	6.10 (-2.66, 14.86)	
Rest of the World	4.95 (-6.68, 17.65)	-2.56 (-7.52, 2.40)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Nasopharyngitis

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.15 (0.64, 2.07)	1.15 (0.75, 1.75)	1.01 (0.49, 2.07)
Age			
<65 years	0.84 (0.34, 2.09)	1.05 (0.55, 2.02)	
>=65 years	1.43 (0.67, 3.08)	1.20 (0.69, 2.09)	
Sex			
Male	1.24 (0.56, 2.74)	0.87 (0.49, 1.53)	
Female	1.07 (0.45, 2.54)	1.62 (0.85, 3.08)	
Baseline FVC percent predicted			
<=70%	1.52 (0.65, 3.57)	1.32 (0.74, 2.35)	
>70%	0.89 (0.40, 1.99)	0.97 (0.52, 1.81)	
Baseline HRCT pattern			
UIP-like	0.85 (0.42, 1.72)	1.26 (0.76, 2.10)	
Other fibrotic patterns	2.36 (0.77, 7.23)	0.92 (0.42, 1.99)	
Underlying ILD diagnosis			
iNSIP	0.90 (0.23, 3.59)	1.33 (0.52, 3.43)	
Unclassifiable IIP	0.73 (0.22, 2.42)	1.28 (0.50, 3.24)	
HP	2.19 (0.56, 8.59)	1.07 (0.48, 2.41)	
Autoimmune ILD	1.18 (0.40, 3.45)	0.83 (0.36, 1.91)	
Other ILD	1.48 (0.19, 11.26)	2.33 (0.20, 26.81)	
Region			
Europe	1.07 (0.31, 3.64)	1.22 (0.65, 2.28)	
Asia	0.85 (0.39, 1.84)	0.83 (0.41, 1.68)	
Canada and USA	3.87 (0.32, 46.18)	2.57 (0.63, 10.38)	
Rest of the World	2.26 (0.39, 13.00)	0.00 (NC, NC)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.07 (0.69, 1.66)	1.20 (0.76, 1.90)	0.89 (0.47, 1.69)	0.7309	
Age					
<65 years	0.75 (0.31, 1.82)	1.64 (0.76, 3.55)			
>=65 years	1.24 (0.75, 2.04)	0.98 (0.55, 1.77)			
Sex					
Male	1.05 (0.57, 1.90)	1.42 (0.78, 2.60)			
Female	1.10 (0.58, 2.09)	0.93 (0.45, 1.92)			
Baseline FVC percent predicted					
<=70%	1.00 (0.56, 1.78)	1.11 (0.66, 1.85)			
>70%	1.26 (0.64, 2.49)	1.52 (0.56, 4.16)			
Baseline HRCT pattern					
UIP-like	1.22 (0.71, 2.09)	1.33 (0.75, 2.38)			
Other fibrotic patterns	0.81 (0.38, 1.74)	0.99 (0.46, 2.12)			
Underlying ILD diagnosis					
iNSIP	2.00 (0.69, 5.83)	0.36 (0.10, 1.29)			
Unclassifiable IIP	1.50 (0.39, 5.84)	1.76 (0.57, 5.38)			
HP	1.73 (0.42, 7.17)	0.79 (0.29, 2.19)			
Autoimmune ILD	0.94 (0.46, 1.91)	1.88 (0.83, 4.24)			
Other ILD	0.43 (0.13, 1.41)	2.26 (0.44, 11.67)			
Region					
Europe	2.26 (0.65, 7.83)	1.47 (0.76, 2.84)			
Asia	0.78 (0.46, 1.34)	0.87 (0.37, 2.01)			
Canada and USA	2.65 (0.49, 14.31)	0.82 (0.23, 2.94)			
Rest of the World	1.07 (0.29, 4.01)	1.83 (0.33, 10.28)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	1.04 (-5.73, 7.82)	1.78 (-2.78, 6.34)	-0.74 (-8.90, 7.43)
Age			
<65 years	-2.96 (-12.74, 6.54)	4.79 (-2.39, 11.97)	
>=65 years	3.91 (-5.36, 13.21)	-0.16 (-6.00, 5.69)	
Sex			
Male	0.70 (-8.87, 10.36)	3.81 (-2.66, 10.28)	
Female	1.45 (-8.25, 11.06)	-0.59 (-6.93, 5.74)	
Baseline FVC percent predicted			
<=70%	-0.09 (-10.21, 10.51)	1.34 (-5.36, 8.04)	
>70%	2.98 (-6.15, 11.69)	2.27 (-3.12, 7.66)	
Baseline HRCT pattern			
UIP-like	2.94 (-5.00, 10.92)	2.91 (-2.92, 8.75)	
Other fibrotic patterns	-3.60 (-16.67, 9.45)	-0.08 (-7.35, 7.20)	
Underlying ILD diagnosis			
iNSIP	10.00 (-5.55, 23.76)	-8.43 (-18.36, 1.50)	
Unclassifiable IIP	4.17 (-11.05, 18.83)	6.06 (-5.30, 17.42)	
HP	5.64 (-9.32, 22.75)	-1.85 (-9.95, 6.26)	
Autoimmune ILD	-1.17 (-13.85, 11.59)	7.98 (-2.14, 18.10)	
Other ILD	-15.78 (-33.79, 5.78)	5.88 (-5.74, 17.49)	
Region			
Europe	9.48 (-5.13, 22.68)	4.14 (-2.87, 11.16)	
Asia	-4.88 (-15.62, 5.94)	-1.77 (-12.10, 8.57)	
Canada and USA	10.98 (-7.62, 34.85)	-1.28 (-9.62, 7.07)	
Rest of the World	0.61 (-12.31, 13.99)	4.25 (-8.00, 16.49)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.08 (0.65, 1.82)	1.22 (0.73, 2.03)	0.89 (0.43, 1.84)
Age			
<65 years	0.73 (0.27, 1.95)	1.73 (0.74, 4.05)	
>=65 years	1.30 (0.70, 2.40)	0.98 (0.51, 1.89)	
Sex			
Male	1.05 (0.52, 2.15)	1.48 (0.76, 2.91)	
Female	1.12 (0.53, 2.38)	0.93 (0.42, 2.05)	
Baseline FVC percent predicted			
<=70%	0.99 (0.49, 2.01)	1.13 (0.62, 2.03)	
>70%	1.30 (0.60, 2.85)	1.56 (0.54, 4.51)	
Baseline HRCT pattern			
UIP-like	1.26 (0.67, 2.37)	1.38 (0.72, 2.62)	
Other fibrotic patterns	0.77 (0.31, 1.94)	0.99 (0.43, 2.30)	
Underlying ILD diagnosis			
iNSIP	2.25 (0.66, 7.67)	0.33 (0.08, 1.29)	
Unclassifiable IIP	1.57 (0.35, 7.10)	1.88 (0.54, 6.51)	
HP	1.85 (0.38, 8.96)	0.78 (0.26, 2.35)	
Autoimmune ILD	0.92 (0.39, 2.19)	2.06 (0.81, 5.20)	
Other ILD	0.35 (0.09, 1.45)	2.41 (0.42, 13.98)	
Region			
Europe	2.52 (0.64, 10.01)	1.54 (0.74, 3.22)	
Asia	0.74 (0.38, 1.45)	0.85 (0.32, 2.22)	
Canada and USA	3.00 (0.45, 20.07)	0.81 (0.21, 3.17)	
Rest of the World	1.08 (0.25, 4.60)	1.91 (0.30, 12.22)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Respiratory tract infection

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.56 (0.75, 3.25)	1.33 (0.69, 2.55)	1.17 (0.44, 3.13)	0.7501	
Age					
<65 years	2.20 (0.59, 8.23)	2.09 (0.76, 5.76)			
>=65 years	1.32 (0.54, 3.23)	0.87 (0.35, 2.16)			
Sex					
Male	0.70 (0.26, 1.89)	1.43 (0.63, 3.26)			
Female	5.35 (1.21, 23.56)	1.17 (0.40, 3.41)			
Baseline FVC percent predicted					
<=70%	2.05 (0.50, 8.36)	1.31 (0.64, 2.70)			
>70%	1.26 (0.53, 2.96)	1.35 (0.31, 5.93)			
Baseline HRCT pattern					
UIP-like	1.60 (0.71, 3.58)	1.43 (0.55, 3.68)			
Other fibrotic patterns	1.45 (0.25, 8.42)	1.24 (0.51, 3.04)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	1.26 (0.32, 4.96)	1.16 (0.59, 2.27)			
Asia	1.49 (0.43, 5.12)	NC (NC, NC)			
Canada and USA	0.59 (0.07, 5.22)	2.06 (0.19, 22.18)			
Rest of the World	5.35 (0.65, 43.96)	NC (NC, NC)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Respiratory tract infection

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	2.77 (-1.89, 7.59)	1.49 (-1.91, 4.89)	1.28 (-4.55, 7.11)
Age			
<65 years	4.34 (-3.30, 12.27)	4.50 (-1.36, 10.36)	
>=65 years	1.82 (-4.39, 8.27)	-0.62 (-4.64, 3.41)	
Sex			
Male	-2.35 (-9.32, 4.56)	2.18 (-2.82, 7.17)	
Female	8.20 (1.77, 15.42)	0.68 (-3.83, 5.18)	
Baseline FVC percent predicted			
<=70%	2.67 (-2.86, 9.29)	1.95 (-3.18, 7.07)	
>70%	1.99 (-5.90, 9.47)	0.77 (-2.97, 4.51)	
Baseline HRCT pattern			
UIP-like	3.39 (-2.58, 9.59)	1.46 (-2.38, 5.29)	
Other fibrotic patterns	1.42 (-6.72, 9.72)	1.54 (-4.84, 7.92)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	1.93 (-11.53, 13.82)	1.52 (-5.34, 8.37)	
Asia	1.83 (-4.46, 8.34)	1.27 (-1.20, 3.73)	
Canada and USA	-4.12 (-20.47, 17.97)	1.54 (-3.42, 6.49)	
Rest of the World	9.45 (-1.81, 22.43)	0.00 (0.00, 0.00)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Respiratory tract infection

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.61 (0.73, 3.51)	1.35 (0.68, 2.69)	1.19 (0.42, 3.37)
Age			
<65 years	2.30 (0.58, 9.23)	2.19 (0.75, 6.41)	
>=65 years	1.34 (0.51, 3.51)	0.86 (0.33, 2.24)	
Sex			
Male	0.68 (0.23, 1.98)	1.46 (0.61, 3.51)	
Female	5.84 (1.26, 27.00)	1.18 (0.39, 3.60)	
Baseline FVC percent predicted			
<=70%	2.11 (0.49, 9.05)	1.34 (0.62, 2.91)	
>70%	1.29 (0.50, 3.28)	1.36 (0.30, 6.21)	
Baseline HRCT pattern			
UIP-like	1.66 (0.69, 3.95)	1.45 (0.54, 3.89)	
Other fibrotic patterns	1.48 (0.24, 9.14)	1.26 (0.48, 3.31)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	1.28 (0.29, 5.72)	1.18 (0.56, 2.49)	
Asia	1.51 (0.42, 5.53)	NC (NC, NC)	
Canada and USA	0.56 (0.05, 5.88)	2.09 (0.19, 23.63)	
Rest of the World	5.92 (0.66, 52.91)	NC (NC, NC)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Upper respiratory tract infection

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.71 (0.48, 1.06)	1.04 (0.61, 1.76)	0.69 (0.36, 1.33)	0.2698	
Age					
<65 years	0.63 (0.36, 1.10)	0.71 (0.31, 1.66)			
>=65 years	0.79 (0.45, 1.39)	1.32 (0.67, 2.61)			
Sex					
Male	0.46 (0.25, 0.87)	1.48 (0.62, 3.54)			
Female	1.02 (0.60, 1.74)	0.83 (0.42, 1.62)			
Baseline FVC percent predicted					
<=70%	0.47 (0.25, 0.88)	0.79 (0.38, 1.64)			
>70%	1.02 (0.59, 1.76)	1.42 (0.65, 3.09)			
Baseline HRCT pattern					
UIP-like	0.71 (0.45, 1.13)	0.92 (0.43, 1.97)			
Other fibrotic patterns	0.73 (0.33, 1.61)	1.16 (0.56, 2.40)			
Underlying ILD diagnosis					
iNSIP	0.73 (0.23, 2.35)	0.95 (0.33, 2.80)			
Unclassifiable IIP	1.26 (0.44, 3.62)	0.78 (0.16, 3.71)			
HP	0.13 (0.02, 0.96)	0.85 (0.35, 2.04)			
Autoimmune ILD	1.01 (0.55, 1.87)	1.50 (0.50, 4.55)			
Other ILD	0.60 (0.24, 1.49)	2.26 (0.21, 23.98)			
Region					
Europe	0.19 (0.04, 0.84)	1.53 (0.51, 4.56)			
Asia	0.88 (0.55, 1.41)	0.82 (0.29, 2.34)			
Canada and USA	0.98 (0.39, 2.45)	1.03 (0.50, 2.13)			
Rest of the World	0.71 (0.13, 4.06)	0.00 (NC, NC)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Upper respiratory tract infection

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-6.17 (-13.38, 1.10)	0.28 (-3.78, 4.33)	-6.45 (-14.74, 1.85)
Age			
<65 years	-10.73 (-23.18, 1.99)	-2.62 (-9.17, 3.94)	
>=65 years	-3.63 (-12.25, 5.11)	2.14 (-3.09, 7.37)	
Sex			
Male	-12.47 (-22.07, -2.63)	2.18 (-2.59, 6.96)	
Female	0.37 (-10.37, 11.05)	-1.89 (-8.62, 4.85)	
Baseline FVC percent predicted			
<=70%	-13.12 (-22.94, -2.64)	-1.65 (-6.70, 3.40)	
>70%	0.28 (-10.05, 10.23)	3.05 (-3.65, 9.74)	
Baseline HRCT pattern			
UIP-like	-6.55 (-15.26, 2.29)	-0.49 (-5.10, 4.12)	
Other fibrotic patterns	-5.11 (-17.98, 7.73)	1.51 (-6.02, 9.05)	
Underlying ILD diagnosis			
iNSIP	-3.41 (-17.96, 9.22)	-0.46 (-10.80, 9.88)	
Unclassifiable IIP	3.61 (-13.56, 20.04)	-1.31 (-9.69, 7.06)	
HP	-22.31 (-37.99, -4.97)	-1.71 (-10.79, 7.37)	
Autoimmune ILD	0.32 (-13.42, 14.09)	2.85 (-4.89, 10.60)	
Other ILD	-13.33 (-33.10, 9.86)	2.94 (-5.47, 11.35)	
Region			
Europe	-16.23 (-31.23, -3.15)	1.79 (-2.78, 6.36)	
Asia	-3.05 (-14.55, 8.53)	-1.62 (-10.36, 7.12)	
Canada and USA	-0.59 (-24.67, 26.62)	0.52 (-12.30, 13.34)	
Rest of the World	-1.87 (-13.36, 9.75)	-2.56 (-7.52, 2.40)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Upper respiratory tract infection

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.66 (0.41, 1.08)	1.04 (0.59, 1.84)	0.64 (0.30, 1.35)
Age			
<65 years	0.55 (0.27, 1.12)	0.69 (0.28, 1.73)	
>=65 years	0.76 (0.39, 1.47)	1.35 (0.65, 2.82)	
Sex			
Male	0.40 (0.19, 0.84)	1.52 (0.61, 3.81)	
Female	1.02 (0.52, 2.00)	0.81 (0.39, 1.71)	
Baseline FVC percent predicted			
<=70%	0.40 (0.19, 0.85)	0.77 (0.35, 1.70)	
>70%	1.02 (0.52, 2.00)	1.47 (0.63, 3.43)	
Baseline HRCT pattern			
UIP-like	0.66 (0.37, 1.16)	0.92 (0.41, 2.06)	
Other fibrotic patterns	0.68 (0.27, 1.76)	1.18 (0.52, 2.66)	
Underlying ILD diagnosis			
iNSIP	0.70 (0.19, 2.60)	0.95 (0.29, 3.12)	
Unclassifiable IIP	1.32 (0.38, 4.58)	0.77 (0.15, 3.99)	
HP	0.10 (0.01, 0.83)	0.83 (0.31, 2.22)	
Autoimmune ILD	1.02 (0.46, 2.24)	1.55 (0.47, 5.09)	
Other ILD	0.50 (0.15, 1.66)	2.33 (0.20, 26.81)	
Region			
Europe	0.16 (0.03, 0.79)	1.56 (0.50, 4.87)	
Asia	0.85 (0.46, 1.58)	0.81 (0.26, 2.53)	
Canada and USA	0.97 (0.26, 3.58)	1.04 (0.43, 2.50)	
Rest of the World	0.70 (0.11, 4.40)	0.00 (NC, NC)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Urinary tract infection

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.84 (0.43, 1.63)	1.04 (0.59, 1.86)	0.81 (0.33, 1.94)	0.6281	
Age					
<65 years	0.47 (0.04, 5.10)	0.62 (0.20, 1.91)			
>=65 years	0.92 (0.47, 1.81)	1.32 (0.67, 2.61)			
Sex					
Male	1.05 (0.22, 5.07)	0.99 (0.29, 3.36)			
Female	0.78 (0.38, 1.58)	1.07 (0.56, 2.04)			
Baseline FVC percent predicted					
<=70%	1.23 (0.45, 3.38)	0.91 (0.44, 1.89)			
>70%	0.61 (0.25, 1.46)	1.30 (0.50, 3.40)			
Baseline HRCT pattern					
UIP-like	0.77 (0.33, 1.77)	0.91 (0.39, 2.09)			
Other fibrotic patterns	0.97 (0.33, 2.85)	1.19 (0.53, 2.65)			
Underlying ILD diagnosis					
iNSIP	0.73 (0.25, 2.09)	0.64 (0.11, 3.67)			
Unclassifiable IIP	0.30 (0.03, 2.76)	1.04 (0.24, 4.44)			
HP	0.98 (0.24, 4.03)	1.24 (0.43, 3.53)			
Autoimmune ILD	1.35 (0.31, 5.82)	2.41 (0.77, 7.54)			
Other ILD	0.72 (0.07, 7.52)	0.00 (NC, NC)			
Region					
Europe	2.64 (0.58, 12.04)	0.74 (0.28, 1.94)			
Asia	0.17 (0.02, 1.35)	1.92 (0.18, 20.78)			
Canada and USA	0.59 (0.07, 5.22)	0.93 (0.40, 2.14)			
Rest of the World	0.92 (0.33, 2.51)	4.88 (0.57, 41.47)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Urinary tract infection

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-1.29 (-6.37, 3.76)	0.28 (-3.47, 4.03)	-1.57 (-7.88, 4.73)
Age			
<65 years	-1.27 (-7.30, 4.04)	-2.19 (-7.37, 3.00)	
>=65 years	-0.90 (-8.53, 6.81)	2.14 (-3.09, 7.37)	
Sex			
Male	0.12 (-4.95, 5.35)	-0.03 (-3.46, 3.40)	
Female	-3.14 (-12.28, 5.89)	0.72 (-6.21, 7.65)	
Baseline FVC percent predicted			
<=70%	1.36 (-5.53, 8.99)	-0.62 (-5.67, 4.43)	
>70%	-4.13 (-12.14, 3.23)	1.55 (-4.01, 7.10)	
Baseline HRCT pattern			
UIP-like	-1.75 (-7.64, 4.09)	-0.49 (-4.73, 3.76)	
Other fibrotic patterns	-0.28 (-11.05, 10.33)	1.52 (-5.47, 8.52)	
Underlying ILD diagnosis			
iNSIP	-4.09 (-19.32, 9.41)	-1.79 (-8.69, 5.11)	
Unclassifiable IIP	-5.83 (-19.48, 5.90)	0.25 (-8.61, 9.11)	
HP	-0.26 (-15.10, 16.55)	1.59 (-6.29, 9.47)	
Autoimmune ILD	1.49 (-6.75, 10.03)	6.43 (-1.61, 14.47)	
Other ILD	-1.56 (-14.57, 14.50)	-11.63 (-21.21, -2.05)	
Region			
Europe	8.21 (-5.08, 20.39)	-1.58 (-6.66, 3.51)	
Asia	-4.73 (-10.92, 0.44)	1.22 (-3.09, 5.52)	
Canada and USA	-4.12 (-20.47, 17.97)	-1.06 (-12.71, 10.59)	
Rest of the World	-1.26 (-16.23, 14.09)	9.94 (-2.55, 22.42)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Urinary tract infection

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.83 (0.41, 1.69)	1.05 (0.56, 1.94)	0.79 (0.31, 2.03)
Age			
<65 years	0.47 (0.04, 5.23)	0.61 (0.19, 1.97)	
>=65 years	0.91 (0.43, 1.95)	1.35 (0.65, 2.82)	
Sex			
Male	1.05 (0.21, 5.30)	0.99 (0.28, 3.48)	
Female	0.75 (0.33, 1.69)	1.08 (0.52, 2.22)	
Baseline FVC percent predicted			
<=70%	1.25 (0.42, 3.69)	0.91 (0.42, 1.99)	
>70%	0.58 (0.23, 1.51)	1.33 (0.48, 3.67)	
Baseline HRCT pattern			
UIP-like	0.76 (0.31, 1.85)	0.90 (0.38, 2.18)	
Other fibrotic patterns	0.97 (0.29, 3.17)	1.21 (0.50, 2.91)	
Underlying ILD diagnosis			
iNSIP	0.69 (0.21, 2.33)	0.62 (0.10, 3.87)	
Unclassifiable IIP	0.28 (0.03, 2.84)	1.04 (0.22, 4.90)	
HP	0.97 (0.20, 4.71)	1.26 (0.40, 3.91)	
Autoimmune ILD	1.37 (0.30, 6.37)	2.59 (0.77, 8.76)	
Other ILD	0.71 (0.06, 8.26)	0.00 (NC, NC)	
Region			
Europe	2.89 (0.57, 14.74)	0.73 (0.26, 2.01)	
Asia	0.16 (0.02, 1.33)	1.95 (0.17, 21.94)	
Canada and USA	0.56 (0.05, 5.88)	0.92 (0.35, 2.42)	
Rest of the World	0.90 (0.28, 2.94)	5.43 (0.58, 51.25)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Investigations
PT: C-reactive protein increased

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.85 (0.70, 4.91)				
Age					
<65 years					
>=65 years					
Sex					
Male	4.70 (1.04, 21.29)				
Female	0.49 (0.09, 2.60)				
Baseline FVC percent predicted					
<=70%	1.23 (0.37, 4.12)				
>70%	5.03 (0.62, 41.13)				
Baseline HRCT pattern					
UIP-like	2.05 (0.63, 6.67)				
Other fibrotic patterns	1.45 (0.25, 8.42)				
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	1.13 (0.20, 6.46)				
Asia	1.73 (0.52, 5.75)				
Canada and USA	1.72 (0.04, 83.12)				
Rest of the World	3.20 (0.13, 76.60)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Investigations
PT: C-reactive protein increased

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	2.30 (-1.47, 6.30)		
Age			
<65 years			
>=65 years			
Sex			
Male	6.38 (0.62, 13.09)		
Female	-1.94 (-7.63, 3.21)		
Baseline FVC percent predicted			
<=70%	0.97 (-5.10, 7.82)		
>70%	3.88 (-1.14, 9.25)		
Baseline HRCT pattern			
UIP-like	2.66 (-1.90, 7.63)		
Other fibrotic patterns	1.42 (-6.72, 9.72)		
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	0.66 (-11.43, 11.02)		
Asia	2.77 (-3.69, 9.52)		
Canada and USA	0.00 (NC, NC)		
Rest of the World	2.33 (-5.62, 12.06)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Investigations
PT: C-reactive protein increased

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.89 (0.69, 5.22)		
Age			
<65 years			
>=65 years			
Sex			
Male	5.03 (1.06, 23.82)		
Female	0.48 (0.09, 2.66)		
Baseline FVC percent predicted			
<=70%	1.24 (0.35, 4.42)		
>70%	5.24 (0.62, 44.22)		
Baseline HRCT pattern			
UIP-like	2.11 (0.62, 7.16)		
Other fibrotic patterns	1.48 (0.24, 9.14)		
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	1.14 (0.18, 7.17)		
Asia	1.79 (0.51, 6.29)		
Canada and USA	NC (NC, NC)		
Rest of the World	NC (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Investigations
PT: Weight decreased

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	2.08 (1.18, 3.67)	2.71 (1.62, 4.56)	0.77 (0.36, 1.65)	0.4983	
Age					
<65 years	1.89 (0.59, 6.03)	8.27 (1.97, 34.78)			
>=65 years	2.19 (1.15, 4.18)	2.04 (1.15, 3.62)			
Sex					
Male	1.81 (0.90, 3.62)	2.97 (1.44, 6.13)			
Female	2.72 (1.02, 7.30)	2.46 (1.17, 5.17)			
Baseline FVC percent predicted					
<=70%	1.42 (0.71, 2.83)	1.89 (1.00, 3.59)			
>70%	5.03 (1.52, 16.61)	4.87 (1.91, 12.39)			
Baseline HRCT pattern					
UIP-like	2.43 (1.24, 4.73)	4.71 (2.13, 10.41)			
Other fibrotic patterns	1.36 (0.45, 4.06)	1.44 (0.70, 2.98)			
Underlying ILD diagnosis					
iNSIP	1.82 (0.37, 8.90)	3.81 (1.13, 12.86)			
Unclassifiable IIP	4.95 (1.18, 20.85)	1.56 (0.63, 3.87)			
HP	0.33 (0.04, 2.76)	1.82 (0.75, 4.39)			
Autoimmune ILD	2.54 (0.83, 7.71)	5.37 (1.21, 23.76)			
Other ILD	2.16 (0.68, 6.87)	NC (NC, NC)			
Region					
Europe	3.02 (0.35, 25.98)	3.55 (1.59, 7.92)			
Asia	1.89 (0.96, 3.73)	2.47 (1.10, 5.58)			
Canada and USA	2.94 (0.80, 10.81)	1.29 (0.36, 4.59)			
Rest of the World	3.21 (0.35, 29.69)	NC (NC, NC)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Investigations
PT: Weight decreased

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	7.79 (1.93, 13.77)	9.32 (4.79, 13.85)	-1.53 (-8.98, 5.93)
Age			
<65 years	4.27 (-3.94, 12.64)	12.02 (5.87, 18.16)	
>=65 years	10.31 (2.09, 18.66)	7.92 (1.68, 14.17)	
Sex			
Male	7.63 (-1.28, 16.69)	10.00 (3.84, 16.16)	
Female	8.13 (0.41, 16.16)	8.53 (1.85, 15.22)	
Baseline FVC percent predicted			
<=70%	4.61 (-4.50, 14.27)	6.02 (0.16, 11.88)	
>70%	11.63 (4.29, 19.14)	14.02 (6.90, 21.15)	
Baseline HRCT pattern			
UIP-like	9.92 (2.73, 17.28)	12.62 (7.03, 18.21)	
Other fibrotic patterns	2.79 (-7.87, 13.46)	3.90 (-3.75, 11.54)	
Underlying ILD diagnosis			
iNSIP	4.09 (-8.51, 15.18)	13.83 (2.84, 24.83)	
Unclassifiable IIP	21.94 (4.97, 37.80)	6.75 (-6.39, 19.89)	
HP	-6.92 (-20.52, 7.78)	6.42 (-2.92, 15.76)	
Autoimmune ILD	8.65 (-1.53, 19.27)	9.92 (2.19, 17.66)	
Other ILD	12.89 (-6.03, 33.44)	7.89 (-0.68, 16.47)	
Region			
Europe	5.05 (-6.30, 15.56)	12.12 (5.28, 18.97)	
Asia	9.25 (-0.44, 18.88)	13.57 (2.27, 24.88)	
Canada and USA	19.41 (-3.04, 44.02)	1.67 (-6.70, 10.03)	
Rest of the World	4.80 (-5.44, 16.57)	0.00 (0.00, 0.00)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Investigations
PT: Weight decreased

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	2.27 (1.21, 4.26)	3.01 (1.71, 5.29)	0.75 (0.32, 1.76)
Age			
<65 years	1.98 (0.57, 6.82)	9.42 (2.15, 41.34)	
>=65 years	2.47 (1.19, 5.16)	2.23 (1.17, 4.24)	
Sex			
Male	1.97 (0.89, 4.36)	3.32 (1.51, 7.27)	
Female	2.98 (1.03, 8.58)	2.71 (1.20, 6.09)	
Baseline FVC percent predicted			
<=70%	1.50 (0.67, 3.32)	2.02 (1.00, 4.09)	
>70%	5.72 (1.63, 20.00)	5.70 (2.11, 15.43)	
Baseline HRCT pattern			
UIP-like	2.71 (1.29, 5.71)	5.42 (2.34, 12.57)	
Other fibrotic patterns	1.40 (0.42, 4.66)	1.51 (0.67, 3.39)	
Underlying ILD diagnosis			
iNSIP	1.90 (0.35, 10.33)	4.46 (1.19, 16.69)	
Unclassifiable IIP	6.45 (1.32, 31.49)	1.69 (0.59, 4.88)	
HP	0.30 (0.03, 2.85)	1.95 (0.73, 5.23)	
Autoimmune ILD	2.79 (0.83, 9.37)	5.97 (1.27, 28.14)	
Other ILD	2.53 (0.63, 10.11)	NC (NC, NC)	
Region			
Europe	3.18 (0.34, 29.65)	4.06 (1.70, 9.68)	
Asia	2.11 (0.96, 4.63)	2.91 (1.14, 7.44)	
Canada and USA	3.75 (0.77, 18.29)	1.31 (0.34, 5.11)	
Rest of the World	3.38 (0.34, 33.76)	NC (NC, NC)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.52, 1.97)	2.34 (1.47, 3.72)	0.43 (0.19, 0.97)	0.0424	
Age					0.2911
<65 years	1.57 (0.39, 6.37)	9.58 (2.30, 39.89)	0.16 (0.02, 1.21)	0.0764	
>=65 years	0.89 (0.41, 1.92)	1.66 (0.99, 2.77)	0.54 (0.21, 1.35)	0.1875	
Sex					0.9314
Male	0.87 (0.27, 2.77)	2.05 (1.10, 3.85)	0.42 (0.11, 1.58)	0.2018	
Female	1.07 (0.47, 2.41)	2.72 (1.36, 5.42)	0.39 (0.14, 1.14)	0.0867	
Baseline FVC percent predicted					0.5933
<=70%	0.92 (0.41, 2.10)	2.35 (1.27, 4.35)	0.39 (0.14, 1.10)	0.0743	
>70%	1.47 (0.44, 4.88)	2.33 (1.15, 4.72)	0.63 (0.16, 2.53)	0.5136	
Baseline HRCT pattern					0.5102
UIP-like	0.94 (0.43, 2.07)	2.64 (1.47, 4.74)	0.36 (0.13, 0.95)	0.0389	
Other fibrotic patterns	1.21 (0.34, 4.31)	1.87 (0.87, 4.04)	0.65 (0.15, 2.85)	0.5650	
Underlying ILD diagnosis					0.3648
iNSIP	1.45 (0.28, 7.56)	3.18 (0.92, 11.00)	0.46 (0.06, 3.60)	0.4580	
Unclassifiable IIP	0.45 (0.09, 2.31)	3.39 (1.02, 11.24)	0.13 (0.02, 1.01)	0.0513	
HP	0.43 (0.05, 3.96)	0.73 (0.33, 1.63)	0.59 (0.06, 6.20)	0.6609	
Autoimmune ILD	1.01 (0.31, 3.35)	16.10 (2.17, 119.16)	0.06 (0.01, 0.65)	0.0201	
Other ILD	2.88 (0.57, 14.54)	2.64 (0.73, 9.50)	1.09 (0.14, 8.59)	0.9342	
Region					0.6931
Europe	2.26 (0.24, 20.96)	2.59 (1.12, 5.98)	0.87 (0.08, 9.42)	0.9115	
Asia	0.72 (0.30, 1.72)	2.41 (1.13, 5.13)	0.30 (0.09, 0.95)	0.0405	
Canada and USA	0.44 (0.05, 3.64)	1.80 (0.81, 4.01)	0.24 (0.03, 2.34)	0.2214	
Rest of the World	9.61 (0.53, 173.44)	NC (NC, NC)	NC (NC, NC)	NC	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.07 (-4.93, 5.08)	9.32 (4.49, 14.14)	-9.25 (-16.20, -2.30)
Age			
<65 years	2.07 (-5.17, 9.40)	14.17 (7.70, 20.65)	-12.11 (-21.86, -2.36)
>=65 years	-1.02 (-8.02, 6.06)	6.58 (-0.05, 13.21)	-7.60 (-17.27, 2.07)
Sex			
Male	-0.67 (-6.88, 5.59)	7.74 (1.24, 14.24)	-8.41 (-17.41, 0.60)
Female	0.66 (-7.65, 8.90)	11.15 (3.97, 18.34)	-10.50 (-21.46, 0.46)
Baseline FVC percent predicted			
<=70%	-0.79 (-8.85, 7.82)	9.08 (2.87, 15.29)	-9.88 (-20.27, 0.52)
>70%	1.80 (-4.53, 7.82)	9.67 (2.02, 17.31)	-7.87 (-17.69, 1.96)
Baseline HRCT pattern			
UIP-like	-0.45 (-6.52, 5.65)	11.17 (4.90, 17.43)	-11.62 (-20.35, -2.88)
Other fibrotic patterns	1.33 (-8.42, 11.06)	6.29 (-1.20, 13.78)	-4.97 (-17.25, 7.32)
Underlying ILD diagnosis			
iNSIP	2.27 (-10.05, 12.90)	10.71 (0.29, 21.13)	-8.43 (-23.93, 7.06)
Unclassifiable IIP	-6.11 (-20.77, 7.20)	14.31 (2.46, 26.17)	-20.42 (-38.76, -2.09)
HP	-4.36 (-17.28, 9.90)	-3.89 (-13.77, 5.99)	-0.47 (-17.27, 16.33)
Autoimmune ILD	0.10 (-9.23, 9.50)	17.16 (8.50, 25.81)	-17.06 (-29.81, -4.30)
Other ILD	10.44 (-5.39, 29.53)	11.44 (-3.04, 25.93)	-1.00 (-23.68, 21.68)
Region			
Europe	3.16 (-7.87, 13.09)	7.58 (1.34, 13.81)	-4.42 (-16.60, 7.77)
Asia	-2.90 (-11.02, 5.07)	14.79 (2.98, 26.60)	-17.69 (-31.98, -3.40)
Canada and USA	-7.45 (-24.50, 15.12)	9.30 (-3.02, 21.62)	-16.75 (-40.08, 6.58)
Rest of the World	9.30 (-0.24, 21.60)	3.13 (-2.90, 9.15)	6.18 (-6.30, 18.65)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.49, 2.07)	2.60 (1.56, 4.35)	0.39 (0.16, 0.94)
Age			
<65 years	1.61 (0.37, 6.94)	11.19 (2.57, 48.65)	0.14 (0.02, 1.14)
>=65 years	0.88 (0.38, 2.04)	1.79 (0.99, 3.22)	0.49 (0.18, 1.38)
Sex			
Male	0.86 (0.26, 2.92)	2.24 (1.12, 4.50)	0.39 (0.09, 1.57)
Female	1.08 (0.44, 2.65)	3.09 (1.44, 6.62)	0.35 (0.11, 1.14)
Baseline FVC percent predicted			
<=70%	0.91 (0.37, 2.27)	2.60 (1.32, 5.14)	0.35 (0.11, 1.09)
>70%	1.50 (0.43, 5.26)	2.61 (1.19, 5.71)	0.57 (0.13, 2.53)
Baseline HRCT pattern			
UIP-like	0.94 (0.40, 2.19)	3.00 (1.57, 5.74)	0.31 (0.11, 0.91)
Other fibrotic patterns	1.23 (0.31, 4.80)	2.01 (0.86, 4.70)	0.61 (0.12, 3.05)
Underlying ILD diagnosis			
iNSIP	1.49 (0.26, 8.56)	3.58 (0.94, 13.71)	0.42 (0.05, 3.77)
Unclassifiable IIP	0.42 (0.07, 2.45)	3.99 (1.07, 14.90)	0.11 (0.01, 0.95)
HP	0.41 (0.04, 4.19)	0.70 (0.28, 1.74)	0.59 (0.05, 7.09)
Autoimmune ILD	1.02 (0.28, 3.67)	19.48 (2.51, 151.17)	0.05 (0.00, 0.59)
Other ILD	3.24 (0.54, 19.25)	3.01 (0.72, 12.60)	1.08 (0.11, 10.58)
Region			
Europe	2.34 (0.23, 23.38)	2.81 (1.15, 6.91)	0.83 (0.07, 9.83)
Asia	0.70 (0.27, 1.81)	2.88 (1.18, 7.02)	0.24 (0.07, 0.89)
Canada and USA	0.41 (0.04, 3.96)	2.01 (0.78, 5.17)	0.20 (0.02, 2.37)
Rest of the World	NC (NC, NC)	NC (NC, NC)	NC (NC, NC)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.23 (0.62, 2.42)	0.54 (0.28, 1.04)	2.27 (0.88, 5.85)	0.0901	
Age					
<65 years	1.18 (0.33, 4.24)	0.76 (0.28, 2.04)			
>=65 years	1.26 (0.57, 2.83)	0.41 (0.16, 1.02)			
Sex					
Male	1.05 (0.41, 2.69)	0.56 (0.25, 1.23)			
Female	1.46 (0.54, 3.96)	0.50 (0.15, 1.64)			
Baseline FVC percent predicted					
<=70%	2.46 (0.87, 6.95)	0.39 (0.16, 0.99)			
>70%	0.65 (0.25, 1.69)	0.79 (0.30, 2.06)			
Baseline HRCT pattern					
UIP-like	1.03 (0.44, 2.40)	0.75 (0.32, 1.74)			
Other fibrotic patterns	1.70 (0.52, 5.52)	0.33 (0.11, 1.00)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	1.66 (0.63, 4.40)	0.44 (0.17, 1.13)			
Asia	0.50 (0.09, 2.65)	0.72 (0.17, 3.12)			
Canada and USA	0.59 (0.07, 5.22)	0.59 (0.18, 1.92)			
Rest of the World	1.60 (0.28, 9.14)	NC (NC, NC)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	1.42 (-3.49, 6.40)	-3.34 (-6.82, 0.15)	4.76 (-1.29, 10.81)
Age			
<65 years	0.86 (-6.78, 8.39)	-1.58 (-7.30, 4.15)	
>=65 years	1.90 (-4.83, 8.83)	-4.51 (-8.85, -0.17)	
Sex			
Male	0.31 (-6.75, 7.52)	-4.01 (-9.31, 1.29)	
Female	2.60 (-4.65, 9.95)	-2.58 (-6.90, 1.74)	
Baseline FVC percent predicted			
<=70%	6.18 (-0.88, 14.25)	-4.71 (-9.19, -0.23)	
>70%	-3.01 (-10.56, 3.85)	-1.37 (-6.92, 4.17)	
Baseline HRCT pattern			
UIP-like	0.16 (-5.57, 5.96)	-1.46 (-5.70, 2.79)	
Other fibrotic patterns	4.36 (-5.91, 14.78)	-6.43 (-12.43, -0.42)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	8.25 (-7.93, 22.78)	-4.95 (-10.46, 0.57)	
Asia	-1.90 (-7.60, 3.32)	-1.47 (-8.02, 5.09)	
Canada and USA	-4.12 (-20.47, 17.97)	-4.17 (-13.28, 4.93)	
Rest of the World	2.63 (-8.54, 14.68)	0.00 (0.00, 0.00)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Musculoskeletal and connective tissue disorders
PT: Arthralgia

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.24 (0.60, 2.59)	0.52 (0.26, 1.04)	2.39 (0.87, 6.55)
Age			
<65 years	1.19 (0.31, 4.59)	0.75 (0.26, 2.13)	
>=65 years	1.29 (0.54, 3.10)	0.39 (0.15, 1.02)	
Sex			
Male	1.05 (0.38, 2.90)	0.53 (0.23, 1.24)	
Female	1.50 (0.51, 4.37)	0.49 (0.14, 1.66)	
Baseline FVC percent predicted			
<=70%	2.63 (0.87, 7.97)	0.37 (0.14, 0.99)	
>70%	0.63 (0.23, 1.76)	0.78 (0.28, 2.15)	
Baseline HRCT pattern			
UIP-like	1.03 (0.42, 2.54)	0.74 (0.30, 1.79)	
Other fibrotic patterns	1.78 (0.49, 6.40)	0.31 (0.10, 0.99)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	1.83 (0.58, 5.78)	0.42 (0.15, 1.13)	
Asia	0.49 (0.09, 2.71)	0.71 (0.15, 3.29)	
Canada and USA	0.56 (0.05, 5.88)	0.56 (0.16, 2.02)	
Rest of the World	1.65 (0.26, 10.39)	NC (NC, NC)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Musculoskeletal and connective tissue disorders
PT: Back pain

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	2.45 (1.04, 5.79)	1.03 (0.62, 1.72)	2.37 (0.87, 6.43)	0.0901	
Age					
<65 years	5.66 (0.70, 46.01)	1.13 (0.51, 2.49)			
>=65 years	1.93 (0.73, 5.07)	0.96 (0.49, 1.87)			
Sex					
Male	3.66 (0.78, 17.23)	0.73 (0.34, 1.53)			
Female	1.94 (0.69, 5.50)	1.43 (0.71, 2.88)			
Baseline FVC percent predicted					
<=70%	11.06 (1.43, 85.79)	1.14 (0.56, 2.32)			
>70%	1.12 (0.40, 3.12)	0.94 (0.46, 1.93)			
Baseline HRCT pattern					
UIP-like	2.22 (0.87, 5.70)	1.00 (0.51, 1.95)			
Other fibrotic patterns	3.88 (0.45, 33.77)	1.08 (0.50, 2.36)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	2.52 (0.74, 8.55)	0.95 (0.41, 2.23)			
Asia	1.98 (0.51, 7.72)	0.48 (0.17, 1.34)			
Canada and USA	0.57 (0.02, 13.36)	1.77 (0.74, 4.21)			
Rest of the World	3.20 (0.13, 76.60)	NC (NC, NC)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Musculoskeletal and connective tissue disorders
PT: Back pain

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	4.57 (0.28, 9.17)	0.28 (-3.92, 4.48)	4.30 (-1.81, 10.41)
Age			
<65 years	5.61 (-0.83, 12.95)	1.09 (-5.80, 7.98)	
>=65 years	4.02 (-1.98, 10.43)	-0.32 (-5.60, 4.96)	
Sex			
Male	4.58 (-0.82, 10.85)	-2.33 (-7.73, 3.08)	
Female	4.46 (-2.70, 11.86)	3.32 (-3.22, 9.85)	
Baseline FVC percent predicted			
<=70%	8.53 (2.74, 16.05)	0.92 (-4.22, 6.05)	
>70%	0.68 (-6.31, 7.23)	-0.59 (-7.64, 6.47)	
Baseline HRCT pattern			
UIP-like	4.64 (-0.82, 10.48)	0.00 (-5.17, 5.17)	
Other fibrotic patterns	4.50 (-3.21, 13.11)	0.72 (-6.41, 7.86)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	11.37 (-3.51, 24.79)	-0.31 (-5.94, 5.32)	
Asia	2.78 (-3.20, 9.15)	-6.83 (-16.13, 2.48)	
Canada and USA	-3.33 (-16.67, 15.30)	7.77 (-3.86, 19.39)	
Rest of the World	2.33 (-5.62, 12.06)	3.13 (-2.90, 9.15)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Musculoskeletal and connective tissue disorders
PT: Back pain

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	2.57 (1.04, 6.33)	1.04 (0.60, 1.80)	2.48 (0.86, 7.13)
Age			
<65 years	6.00 (0.71, 50.95)	1.15 (0.48, 2.71)	
>=65 years	2.02 (0.72, 5.61)	0.96 (0.46, 1.97)	
Sex			
Male	3.84 (0.78, 18.88)	0.71 (0.32, 1.59)	
Female	2.04 (0.67, 6.18)	1.48 (0.68, 3.21)	
Baseline FVC percent predicted			
<=70%	12.10 (1.51, 97.32)	1.15 (0.53, 2.48)	
>70%	1.13 (0.38, 3.36)	0.94 (0.42, 2.07)	
Baseline HRCT pattern			
UIP-like	2.34 (0.86, 6.31)	1.00 (0.49, 2.06)	
Other fibrotic patterns	4.06 (0.44, 37.39)	1.09 (0.46, 2.57)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	2.87 (0.73, 11.21)	0.95 (0.38, 2.36)	
Asia	2.04 (0.50, 8.38)	0.45 (0.14, 1.37)	
Canada and USA	0.00 (NC, NC)	1.93 (0.71, 5.25)	
Rest of the World	NC (NC, NC)	NC (NC, NC)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Nervous system disorders
PT: Headache

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.55, 1.85)	1.37 (0.85, 2.19)	0.74 (0.34, 1.59)	0.4404	
Age					
<65 years	0.47 (0.17, 1.32)	1.07 (0.54, 2.14)			
>=65 years	1.64 (0.73, 3.66)	1.63 (0.85, 3.12)			
Sex					
Male	1.05 (0.43, 2.54)	1.98 (0.76, 5.15)			
Female	0.97 (0.42, 2.24)	1.20 (0.70, 2.05)			
Baseline FVC percent predicted					
<=70%	1.23 (0.56, 2.71)	1.48 (0.77, 2.82)			
>70%	0.84 (0.33, 2.16)	1.25 (0.62, 2.50)			
Baseline HRCT pattern					
UIP-like	1.20 (0.57, 2.50)	1.40 (0.74, 2.64)			
Other fibrotic patterns	0.69 (0.23, 2.07)	1.32 (0.65, 2.68)			
Underlying ILD diagnosis					
iNSIP	0.36 (0.03, 3.87)	1.19 (0.34, 4.23)			
Unclassifiable IIP	0.23 (0.03, 1.92)	2.86 (0.84, 9.72)			
HP	1.63 (0.48, 5.54)	0.60 (0.28, 1.27)			
Autoimmune ILD	1.35 (0.49, 3.70)	1.88 (0.57, 6.18)			
Other ILD	1.92 (0.47, 7.84)	NC (NC, NC)			
Region					
Europe	1.01 (0.38, 2.67)	2.02 (0.94, 4.31)			
Asia	0.62 (0.21, 1.83)	0.38 (0.08, 1.92)			
Canada and USA	0.88 (0.09, 9.03)	1.54 (0.75, 3.19)			
Rest of the World	1.78 (0.45, 7.01)	0.41 (0.04, 3.72)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Nervous system disorders
PT: Headache

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.08 (-5.29, 5.46)	2.99 (-1.50, 7.48)	-2.91 (-9.91, 4.09)
Age			
<65 years	-6.37 (-15.67, 2.41)	0.77 (-6.89, 8.42)	
>=65 years	4.13 (-2.68, 11.22)	4.21 (-1.33, 9.75)	
Sex			
Male	0.35 (-7.03, 7.87)	3.31 (-1.22, 7.85)	
Female	-0.26 (-8.44, 7.83)	2.70 (-5.28, 10.68)	
Baseline FVC percent predicted			
<=70%	2.14 (-6.11, 11.01)	3.46 (-2.21, 9.13)	
>70%	-1.24 (-8.69, 5.63)	2.34 (-4.94, 9.63)	
Baseline HRCT pattern			
UIP-like	1.50 (-4.84, 7.94)	2.91 (-2.53, 8.36)	
Other fibrotic patterns	-3.36 (-14.21, 7.17)	3.10 (-4.68, 10.87)	
Underlying ILD diagnosis			
iNSIP	-3.18 (-14.78, 5.41)	1.26 (-7.79, 10.30)	
Unclassifiable IIP	-8.61 (-22.96, 3.75)	11.19 (-0.16, 22.53)	
HP	6.41 (-9.85, 24.41)	-7.26 (-17.63, 3.10)	
Autoimmune ILD	2.98 (-7.40, 13.53)	3.99 (-3.46, 11.44)	
Other ILD	7.67 (-8.89, 27.10)	13.16 (2.41, 23.91)	
Region			
Europe	0.09 (-15.73, 14.45)	6.22 (-0.27, 12.70)	
Asia	-2.87 (-10.03, 3.99)	-4.05 (-10.61, 2.52)	
Canada and USA	-0.78 (-16.22, 20.86)	7.90 (-5.09, 20.88)	
Rest of the World	5.11 (-7.68, 18.65)	-4.57 (-14.88, 5.74)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Nervous system disorders
PT: Headache

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.52, 1.96)	1.41 (0.84, 2.38)	0.72 (0.31, 1.67)
Age			
<65 years	0.44 (0.14, 1.35)	1.08 (0.50, 2.35)	
>=65 years	1.71 (0.72, 4.11)	1.71 (0.84, 3.46)	
Sex			
Male	1.05 (0.40, 2.75)	2.05 (0.75, 5.58)	
Female	0.97 (0.39, 2.43)	1.24 (0.66, 2.32)	
Baseline FVC percent predicted			
<=70%	1.26 (0.52, 3.04)	1.53 (0.76, 3.11)	
>70%	0.83 (0.30, 2.29)	1.28 (0.59, 2.78)	
Baseline HRCT pattern			
UIP-like	1.22 (0.54, 2.72)	1.45 (0.72, 2.89)	
Other fibrotic patterns	0.67 (0.20, 2.22)	1.37 (0.62, 3.03)	
Underlying ILD diagnosis			
iNSIP	0.35 (0.03, 4.02)	1.21 (0.31, 4.73)	
Unclassifiable IIP	0.21 (0.02, 1.93)	3.25 (0.86, 12.36)	
HP	1.75 (0.43, 7.18)	0.55 (0.23, 1.32)	
Autoimmune ILD	1.40 (0.46, 4.26)	1.96 (0.55, 6.96)	
Other ILD	2.10 (0.43, 10.31)	NC (NC, NC)	
Region			
Europe	1.01 (0.32, 3.18)	2.16 (0.94, 4.94)	
Asia	0.60 (0.19, 1.90)	0.37 (0.07, 1.96)	
Canada and USA	0.88 (0.07, 10.43)	1.70 (0.70, 4.11)	
Rest of the World	1.89 (0.42, 8.42)	0.39 (0.04, 3.91)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Anxiety

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.13 (0.68, 1.87)				
Age					
<65 years	1.11 (0.53, 2.35)				
>=65 years	1.13 (0.57, 2.25)				
Sex					
Male	0.70 (0.35, 1.38)				
Female	2.22 (0.95, 5.18)				
Baseline FVC percent predicted					
<=70%	1.14 (0.56, 2.31)				
>70%	1.14 (0.55, 2.38)				
Baseline HRCT pattern					
UIP-like	0.97 (0.54, 1.75)				
Other fibrotic patterns	1.75 (0.62, 4.93)				
Underlying ILD diagnosis					
iNSIP	0.48 (0.15, 1.61)				
Unclassifiable IIP	0.90 (0.24, 3.34)				
HP	0.98 (0.24, 4.03)				
Autoimmune ILD	1.78 (0.79, 3.96)				
Other ILD	1.44 (0.32, 6.56)				
Region					
Europe	0.66 (0.26, 1.67)				
Asia	0.90 (0.40, 2.03)				
Canada and USA	2.21 (0.68, 7.12)				
Rest of the World	3.21 (0.68, 15.05)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Anxiety

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	1.47 (-4.67, 7.62)		
Age			
<65 years	1.52 (-9.21, 12.06)		
>=65 years	1.29 (-6.22, 8.95)		
Sex			
Male	-4.71 (-13.62, 4.29)		
Female	8.08 (-0.33, 16.61)		
Baseline FVC percent predicted			
<=70%	1.68 (-7.25, 11.16)		
>70%	1.52 (-7.19, 9.80)		
Baseline HRCT pattern			
UIP-like	-0.32 (-7.77, 7.17)		
Other fibrotic patterns	5.82 (-5.33, 17.03)		
Underlying ILD diagnosis			
iNSIP	-7.73 (-22.47, 5.03)		
Unclassifiable IIP	-1.11 (-16.55, 13.56)		
HP	-0.26 (-15.10, 16.55)		
Autoimmune ILD	8.73 (-3.43, 20.84)		
Other ILD	3.67 (-11.94, 22.43)		
Region			
Europe	-6.79 (-22.98, 8.23)		
Asia	-1.03 (-9.41, 7.29)		
Canada and USA	16.08 (-6.89, 41.12)		
Rest of the World	9.61 (-2.98, 23.28)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Anxiety

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.15 (0.65, 2.04)		
Age			
<65 years	1.13 (0.48, 2.70)		
>=65 years	1.14 (0.53, 2.47)		
Sex			
Male	0.66 (0.30, 1.44)		
Female	2.43 (0.96, 6.18)		
Baseline FVC percent predicted			
<=70%	1.16 (0.52, 2.61)		
>70%	1.16 (0.51, 2.66)		
Baseline HRCT pattern			
UIP-like	0.97 (0.50, 1.90)		
Other fibrotic patterns	1.86 (0.59, 5.90)		
Underlying ILD diagnosis			
iNSIP	0.44 (0.12, 1.69)		
Unclassifiable IIP	0.89 (0.21, 3.85)		
HP	0.97 (0.20, 4.71)		
Autoimmune ILD	1.97 (0.77, 5.04)		
Other ILD	1.50 (0.28, 8.12)		
Region			
Europe	0.61 (0.20, 1.85)		
Asia	0.89 (0.36, 2.19)		
Canada and USA	2.71 (0.62, 11.92)		
Rest of the World	3.57 (0.68, 18.74)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Depression

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.94 (0.57, 1.55)	0.90 (0.37, 2.18)	1.04 (0.38, 2.89)	0.9336	
Age					
<65 years	1.35 (0.54, 3.37)	0.65 (0.15, 2.86)			
>=65 years	0.80 (0.44, 1.47)	1.09 (0.36, 3.32)			
Sex					
Male	0.58 (0.28, 1.20)	0.99 (0.20, 4.83)			
Female	1.56 (0.74, 3.27)	0.86 (0.30, 2.51)			
Baseline FVC percent predicted					
<=70%	0.91 (0.48, 1.71)	0.82 (0.25, 2.64)			
>70%	1.12 (0.49, 2.55)	1.01 (0.26, 3.98)			
Baseline HRCT pattern					
UIP-like	0.86 (0.46, 1.62)	0.78 (0.30, 2.05)			
Other fibrotic patterns	1.08 (0.47, 2.48)	1.98 (0.18, 21.60)			
Underlying ILD diagnosis					
iNSIP	0.36 (0.07, 1.89)				
Unclassifiable IIP	0.90 (0.28, 2.86)				
HP	0.87 (0.27, 2.80)				
Autoimmune ILD	1.13 (0.49, 2.60)				
Other ILD	1.80 (0.54, 6.05)				
Region					
Europe	0.86 (0.34, 2.18)	1.15 (0.36, 3.67)			
Asia	0.91 (0.44, 1.91)	NC (NC, NC)			
Canada and USA	2.35 (0.60, 9.29)	0.62 (0.15, 2.48)			
Rest of the World	0.43 (0.09, 2.09)	NC (NC, NC)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Depression

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.79 (-6.98, 5.40)	-0.31 (-2.85, 2.23)	-0.48 (-7.17, 6.21)
Age			
<65 years	2.93 (-6.51, 12.28)	-1.15 (-5.15, 2.85)	
>=65 years	-2.99 (-11.22, 5.35)	0.25 (-3.08, 3.58)	
Sex			
Male	-6.51 (-15.19, 2.21)	-0.02 (-2.69, 2.66)	
Female	5.24 (-3.67, 14.15)	-0.62 (-5.13, 3.88)	
Baseline FVC percent predicted			
<=70%	-1.52 (-11.08, 8.56)	-0.56 (-3.85, 2.74)	
>70%	1.02 (-7.05, 8.65)	0.04 (-3.94, 4.03)	
Baseline HRCT pattern			
UIP-like	-1.64 (-8.78, 5.54)	-0.97 (-4.70, 2.76)	
Other fibrotic patterns	1.09 (-11.42, 13.46)	0.79 (-1.90, 3.47)	
Underlying ILD diagnosis			
iNSIP	-6.36 (-19.68, 4.22)		
Unclassifiable IIP	-1.39 (-17.75, 14.30)		
HP	-2.05 (-18.49, 16.21)		
Autoimmune ILD	1.61 (-9.97, 13.25)		
Other ILD	8.89 (-9.16, 29.16)		
Region			
Europe	-2.41 (-18.57, 12.42)	0.49 (-3.74, 4.73)	
Asia	-1.05 (-9.97, 7.83)	0.00 (0.00, 0.00)	
Canada and USA	13.53 (-7.43, 38.15)	-2.77 (-10.64, 5.10)	
Rest of the World	-6.22 (-18.84, 6.21)	0.00 (0.00, 0.00)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Depression

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.93 (0.53, 1.64)	0.89 (0.36, 2.23)	1.04 (0.35, 3.05)
Age			
<65 years	1.39 (0.50, 3.85)	0.65 (0.14, 2.94)	
>=65 years	0.78 (0.39, 1.56)	1.09 (0.35, 3.44)	
Sex			
Male	0.54 (0.24, 1.23)	0.99 (0.20, 4.97)	
Female	1.65 (0.71, 3.83)	0.86 (0.28, 2.61)	
Baseline FVC percent predicted			
<=70%	0.89 (0.42, 1.88)	0.82 (0.24, 2.72)	
>70%	1.13 (0.46, 2.80)	1.02 (0.25, 4.14)	
Baseline HRCT pattern			
UIP-like	0.85 (0.42, 1.72)	0.77 (0.28, 2.11)	
Other fibrotic patterns	1.09 (0.41, 2.89)	2.00 (0.18, 22.34)	
Underlying ILD diagnosis			
iNSIP	0.34 (0.06, 1.95)		
Unclassifiable IIP	0.89 (0.23, 3.35)		
HP	0.85 (0.22, 3.32)		
Autoimmune ILD	1.15 (0.44, 3.02)		
Other ILD	2.00 (0.48, 8.35)		
Region			
Europe	0.84 (0.28, 2.54)	1.15 (0.34, 3.86)	
Asia	0.90 (0.39, 2.08)	NC (NC, NC)	
Canada and USA	2.77 (0.54, 14.23)	0.60 (0.14, 2.62)	
Rest of the World	0.40 (0.07, 2.18)	NC (NC, NC)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Insomnia

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.59 (0.63, 4.02)	1.00 (0.53, 1.88)	1.59 (0.52, 4.90)	0.4191	
Age					
<65 years	0.94 (0.20, 4.54)	1.74 (0.61, 4.95)			
>=65 years	2.11 (0.65, 6.83)	0.67 (0.28, 1.58)			
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%	0.74 (0.18, 3.01)	0.98 (0.47, 2.07)			
>70%	3.35 (0.73, 15.45)	1.01 (0.30, 3.43)			
Baseline HRCT pattern					
UIP-like	1.44 (0.47, 4.43)	1.45 (0.69, 3.06)			
Other fibrotic patterns	1.94 (0.37, 10.22)	0.28 (0.06, 1.34)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	3.80 (0.19, 76.95)	0.95 (0.24, 3.75)			
Asia	1.59 (0.54, 4.69)	0.96 (0.42, 2.18)			
Canada and USA	5.17 (0.22, 120.26)	1.03 (0.27, 3.95)			
Rest of the World	0.21 (0.01, 4.33)	NC (NC, NC)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Insomnia

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	1.85 (-2.04, 5.91)	-0.02 (-3.47, 3.43)	1.86 (-3.40, 7.13)
Age			
<65 years	-0.21 (-7.06, 6.38)	3.06 (-2.51, 8.63)	
>=65 years	3.18 (-2.03, 8.90)	-2.05 (-6.35, 2.26)	
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%	-1.11 (-6.80, 5.04)	-0.10 (-5.07, 4.86)	
>70%	4.53 (-1.23, 10.46)	0.05 (-4.39, 4.49)	
Baseline HRCT pattern			
UIP-like	1.38 (-3.27, 6.27)	2.43 (-2.35, 7.20)	
Other fibrotic patterns	2.94 (-5.48, 11.74)	-4.01 (-8.60, 0.57)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	3.77 (-5.40, 12.75)	-0.12 (-3.76, 3.51)	
Asia	2.76 (-4.13, 9.87)	-0.50 (-11.06, 10.06)	
Canada and USA	5.88 (-6.46, 26.98)	0.17 (-7.74, 8.08)	
Rest of the World	-4.35 (-14.53, 4.44)	0.00 (0.00, 0.00)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Psychiatric disorders
PT: Insomnia

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.62 (0.61, 4.25)	1.00 (0.51, 1.95)	1.62 (0.50, 5.26)
Age			
<65 years	0.94 (0.18, 4.80)	1.80 (0.60, 5.42)	
>=65 years	2.18 (0.64, 7.41)	0.66 (0.27, 1.62)	
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%	0.73 (0.17, 3.13)	0.98 (0.44, 2.18)	
>70%	3.52 (0.73, 16.94)	1.02 (0.29, 3.59)	
Baseline HRCT pattern			
UIP-like	1.46 (0.45, 4.69)	1.49 (0.68, 3.30)	
Other fibrotic patterns	2.00 (0.35, 11.32)	0.27 (0.06, 1.34)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	NC (NC, NC)	0.95 (0.23, 3.88)	
Asia	1.63 (0.52, 5.16)	0.96 (0.37, 2.45)	
Canada and USA	NC (NC, NC)	1.03 (0.25, 4.31)	
Rest of the World	0.00 (NC, NC)	NC (NC, NC)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.22 (0.80, 1.86)	0.78 (0.53, 1.15)	1.56 (0.88, 2.77)	0.1245	
Age					
<65 years	1.46 (0.73, 2.93)	0.68 (0.39, 1.20)			
>=65 years	1.10 (0.65, 1.88)	0.85 (0.51, 1.44)			
Sex					
Male	1.53 (0.84, 2.80)	0.99 (0.59, 1.65)			
Female	0.97 (0.54, 1.77)	0.58 (0.32, 1.05)			
Baseline FVC percent predicted					
<=70%	1.52 (0.85, 2.71)	0.68 (0.43, 1.09)			
>70%	1.00 (0.54, 1.84)	1.01 (0.52, 1.99)			
Baseline HRCT pattern					
UIP-like	0.90 (0.53, 1.53)	1.04 (0.62, 1.76)			
Other fibrotic patterns	2.18 (1.02, 4.66)	0.55 (0.31, 0.99)			
Underlying ILD diagnosis					
iNSIP	1.16 (0.41, 3.29)	0.64 (0.19, 2.14)			
Unclassifiable IIP	1.08 (0.36, 3.24)	0.95 (0.43, 2.12)			
HP	1.16 (0.51, 2.64)	0.84 (0.46, 1.54)			
Autoimmune ILD	1.12 (0.51, 2.46)	0.27 (0.06, 1.23)			
Other ILD	2.52 (0.82, 7.70)	1.01 (0.43, 2.35)			
Region					
Europe	1.51 (0.67, 3.39)	1.00 (0.59, 1.68)			
Asia	0.92 (0.47, 1.82)	0.96 (0.20, 4.62)			
Canada and USA	4.71 (1.44, 15.41)	0.58 (0.32, 1.05)			
Rest of the World	0.53 (0.17, 1.65)	0.00 (NC, NC)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	3.32 (-3.64, 10.27)	-3.36 (-8.59, 1.87)	6.68 (-2.03, 15.38)
Age			
<65 years	6.07 (-5.22, 17.10)	-6.06 (-15.00, 2.89)	
>=65 years	1.60 (-7.30, 10.58)	-1.93 (-8.36, 4.49)	
Sex			
Male	6.89 (-2.80, 16.61)	-0.16 (-7.38, 7.06)	
Female	-0.47 (-10.57, 9.58)	-7.08 (-14.64, 0.48)	
Baseline FVC percent predicted			
<=70%	7.47 (-2.83, 18.10)	-5.90 (-13.11, 1.31)	
>70%	-0.06 (-9.78, 9.25)	0.16 (-7.24, 7.55)	
Baseline HRCT pattern			
UIP-like	-1.54 (-9.53, 6.50)	0.49 (-5.77, 6.74)	
Other fibrotic patterns	14.77 (0.93, 28.00)	-9.70 (-18.86, -0.53)	
Underlying ILD diagnosis			
iNSIP	2.05 (-13.25, 15.63)	-3.59 (-13.13, 5.95)	
Unclassifiable IIP	1.11 (-15.66, 17.20)	-0.81 (-14.91, 13.29)	
HP	3.59 (-16.13, 24.20)	-3.49 (-15.30, 8.32)	
Autoimmune ILD	1.63 (-10.36, 13.66)	-6.65 (-13.52, 0.22)	
Other ILD	16.89 (-2.86, 37.58)	0.12 (-17.65, 17.89)	
Region			
Europe	8.92 (-8.65, 24.73)	-0.06 (-8.27, 8.14)	
Asia	-1.07 (-10.48, 8.32)	-0.15 (-6.23, 5.93)	
Canada and USA	37.06 (10.97, 59.99)	-13.93 (-28.54, 0.68)	
Rest of the World	-8.09 (-22.56, 6.75)	-5.13 (-12.05, 1.79)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.27 (0.77, 2.11)	0.75 (0.48, 1.17)	1.69 (0.86, 3.32)
Age			
<65 years	1.57 (0.69, 3.58)	0.63 (0.32, 1.24)	
>=65 years	1.12 (0.59, 2.13)	0.84 (0.46, 1.52)	
Sex			
Male	1.66 (0.81, 3.40)	0.99 (0.54, 1.79)	
Female	0.97 (0.47, 1.98)	0.54 (0.27, 1.06)	
Baseline FVC percent predicted			
<=70%	1.66 (0.82, 3.37)	0.64 (0.37, 1.11)	
>70%	1.00 (0.48, 2.05)	1.02 (0.48, 2.17)	
Baseline HRCT pattern			
UIP-like	0.89 (0.48, 1.65)	1.05 (0.58, 1.90)	
Other fibrotic patterns	2.63 (1.05, 6.57)	0.49 (0.25, 0.98)	
Underlying ILD diagnosis			
iNSIP	1.19 (0.36, 3.96)	0.61 (0.16, 2.28)	
Unclassifiable IIP	1.09 (0.30, 3.95)	0.95 (0.36, 2.50)	
HP	1.21 (0.40, 3.64)	0.80 (0.38, 1.70)	
Autoimmune ILD	1.14 (0.45, 2.88)	0.25 (0.05, 1.21)	
Other ILD	3.11 (0.80, 12.09)	1.01 (0.35, 2.94)	
Region			
Europe	1.69 (0.61, 4.69)	1.00 (0.53, 1.86)	
Asia	0.91 (0.42, 2.00)	0.96 (0.19, 4.91)	
Canada and USA	8.00 (1.74, 36.81)	0.48 (0.22, 1.06)	
Rest of the World	0.49 (0.14, 1.75)	0.00 (NC, NC)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.37 (0.75, 2.48)	0.91 (0.65, 1.28)	1.50 (0.75, 2.99)	0.2487	
Age					
<65 years	1.13 (0.36, 3.57)	1.16 (0.62, 2.17)			
>=65 years	1.49 (0.74, 3.00)	0.83 (0.55, 1.26)			
Sex					
Male	2.30 (0.83, 6.41)	1.18 (0.77, 1.81)			
Female	0.97 (0.46, 2.07)	0.58 (0.32, 1.05)			
Baseline FVC percent predicted					
<=70%	1.33 (0.64, 2.78)	0.66 (0.43, 1.02)			
>70%	1.68 (0.59, 4.75)	1.67 (0.90, 3.10)			
Baseline HRCT pattern					
UIP-like	2.05 (0.90, 4.66)	1.23 (0.79, 1.92)			
Other fibrotic patterns	0.75 (0.30, 1.90)	0.55 (0.31, 0.99)			
Underlying ILD diagnosis					
iNSIP	0.73 (0.23, 2.35)	0.95 (0.29, 3.13)			
Unclassifiable IIP	2.70 (0.29, 24.81)	1.23 (0.51, 2.94)			
HP	1.63 (0.48, 5.54)	0.85 (0.47, 1.52)			
Autoimmune ILD	1.01 (0.31, 3.35)	0.84 (0.41, 1.75)			
Other ILD	3.60 (0.76, 17.10)	0.93 (0.43, 1.99)			
Region					
Europe	1.89 (0.64, 5.58)	0.90 (0.58, 1.39)			
Asia	0.62 (0.21, 1.83)	1.20 (0.34, 4.31)			
Canada and USA	2.21 (0.68, 7.12)	0.81 (0.45, 1.46)			
Rest of the World	3.21 (0.35, 29.69)	1.22 (0.08, 18.73)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	2.80 (-2.65, 8.32)	-1.56 (-7.20, 4.08)	4.35 (-3.51, 12.22)
Age			
<65 years	0.79 (-7.38, 8.83)	1.99 (-6.29, 10.27)	
>=65 years	4.25 (-3.25, 11.93)	-3.42 (-10.96, 4.12)	
Sex			
Male	5.60 (-1.28, 12.99)	3.16 (-5.00, 11.31)	
Female	-0.31 (-9.05, 8.34)	-7.08 (-14.64, 0.48)	
Baseline FVC percent predicted			
<=70%	3.37 (-5.32, 12.66)	-7.48 (-15.18, 0.21)	
>70%	3.26 (-3.72, 9.98)	6.77 (-1.30, 14.83)	
Baseline HRCT pattern			
UIP-like	5.33 (-0.71, 11.65)	3.40 (-3.72, 10.52)	
Other fibrotic patterns	-3.46 (-15.30, 8.22)	-9.70 (-18.86, -0.53)	
Underlying ILD diagnosis			
iNSIP	-3.41 (-17.96, 9.22)	-0.38 (-9.90, 9.14)	
Unclassifiable IIP	4.72 (-7.69, 17.30)	3.19 (-10.15, 16.53)	
HP	6.41 (-9.85, 24.41)	-3.42 (-15.50, 8.65)	
Autoimmune ILD	0.10 (-9.23, 9.50)	-2.49 (-13.12, 8.13)	
Other ILD	14.44 (-2.37, 33.99)	-1.90 (-20.68, 16.89)	
Region			
Europe	8.87 (-6.59, 22.74)	-2.32 (-11.57, 6.93)	
Asia	-2.87 (-10.03, 3.99)	1.07 (-6.28, 8.42)	
Canada and USA	16.08 (-6.89, 41.12)	-5.15 (-19.66, 9.37)	
Rest of the World	4.80 (-5.44, 16.57)	0.56 (-7.25, 8.37)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Dyspnoea

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.41 (0.73, 2.71)	0.89 (0.59, 1.35)	1.58 (0.73, 3.42)
Age			
<65 years	1.14 (0.33, 3.89)	1.19 (0.58, 2.44)	
>=65 years	1.56 (0.72, 3.42)	0.80 (0.48, 1.32)	
Sex			
Male	2.44 (0.82, 7.27)	1.23 (0.72, 2.09)	
Female	0.97 (0.41, 2.26)	0.54 (0.27, 1.06)	
Baseline FVC percent predicted			
<=70%	1.38 (0.60, 3.19)	0.61 (0.36, 1.02)	
>70%	1.74 (0.57, 5.25)	1.80 (0.88, 3.67)	
Baseline HRCT pattern			
UIP-like	2.17 (0.90, 5.24)	1.28 (0.76, 2.17)	
Other fibrotic patterns	0.73 (0.25, 2.08)	0.49 (0.25, 0.98)	
Underlying ILD diagnosis			
iNSIP	0.70 (0.19, 2.60)	0.95 (0.26, 3.46)	
Unclassifiable IIP	2.84 (0.28, 28.59)	1.27 (0.46, 3.57)	
HP	1.75 (0.43, 7.18)	0.81 (0.39, 1.70)	
Autoimmune ILD	1.02 (0.28, 3.67)	0.82 (0.35, 1.92)	
Other ILD	4.25 (0.75, 23.98)	0.90 (0.33, 2.49)	
Region			
Europe	2.09 (0.60, 7.24)	0.87 (0.50, 1.51)	
Asia	0.60 (0.19, 1.90)	1.22 (0.31, 4.71)	
Canada and USA	2.71 (0.62, 11.92)	0.76 (0.35, 1.66)	
Rest of the World	3.38 (0.34, 33.76)	1.23 (0.07, 20.40)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Interstitial lung disease

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.64 (0.25, 1.63)	0.50 (0.33, 0.76)	1.29 (0.46, 3.58)	0.6275	
Age					
<65 years	0.19 (0.02, 1.58)	0.23 (0.09, 0.60)			
>=65 years	1.05 (0.35, 3.18)	0.68 (0.42, 1.10)			
Sex					
Male	0.15 (0.02, 1.19)	0.49 (0.29, 0.85)			
Female	1.46 (0.42, 5.02)	0.50 (0.25, 1.00)			
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like	0.68 (0.25, 1.88)	0.51 (0.32, 0.82)			
Other fibrotic patterns	0.48 (0.05, 5.22)	0.46 (0.18, 1.17)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe	0.38 (0.04, 4.02)	0.51 (0.21, 1.25)			
Asia	0.66 (0.19, 2.27)	0.48 (0.28, 0.84)			
Canada and USA	1.76 (0.12, 26.45)	0.41 (0.14, 1.25)			
Rest of the World	0.53 (0.05, 5.69)	0.73 (0.19, 2.83)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Interstitial lung disease

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-1.77 (-5.82, 2.12)	-8.48 (-13.51, -3.46)	6.71 (0.31, 13.12)
Age			
<65 years	-4.89 (-12.26, 1.19)	-12.11 (-19.29, -4.92)	
>=65 years	0.23 (-5.14, 5.76)	-5.70 (-12.59, 1.19)	
Sex			
Male	-5.13 (-11.08, -0.06)	-9.71 (-16.93, -2.49)	
Female	1.73 (-4.54, 8.14)	-7.10 (-13.97, -0.22)	
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like	-1.80 (-7.01, 3.30)	-10.19 (-17.16, -3.22)	
Other fibrotic patterns	-1.61 (-9.28, 5.35)	-5.64 (-12.15, 0.88)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	-3.11 (-14.72, 5.72)	-4.30 (-9.95, 1.35)	
Asia	-1.92 (-8.47, 4.35)	-19.12 (-32.85, -5.39)	
Canada and USA	2.55 (-11.64, 23.83)	-8.52 (-18.58, 1.54)	
Rest of the World	-2.02 (-12.38, 8.21)	-3.45 (-18.01, 11.12)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Respiratory, thoracic and mediastinal disorders
PT: Interstitial lung disease

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.63 (0.24, 1.66)	0.45 (0.28, 0.73)	1.39 (0.47, 4.10)
Age			
<65 years	0.18 (0.02, 1.57)	0.20 (0.07, 0.55)	
>=65 years	1.06 (0.33, 3.36)	0.63 (0.36, 1.11)	
Sex			
Male	0.14 (0.02, 1.17)	0.44 (0.24, 0.82)	
Female	1.49 (0.41, 5.42)	0.46 (0.22, 1.00)	
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like	0.67 (0.23, 1.93)	0.45 (0.26, 0.79)	
Other fibrotic patterns	0.48 (0.04, 5.39)	0.43 (0.16, 1.17)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	0.37 (0.03, 4.18)	0.49 (0.19, 1.27)	
Asia	0.65 (0.18, 2.36)	0.37 (0.18, 0.78)	
Canada and USA	1.81 (0.11, 30.97)	0.37 (0.11, 1.26)	
Rest of the World	0.52 (0.05, 5.99)	0.70 (0.15, 3.20)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Vascular disorders
PT: Hypertension

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.11 (0.48, 2.56)	1.06 (0.53, 2.12)	1.04 (0.35, 3.08)	0.9382	
Age					
<65 years	0.71 (0.16, 3.07)	1.12 (0.43, 2.91)			
>=65 years	1.40 (0.50, 3.94)	0.95 (0.35, 2.58)			
Sex					
Male	0.35 (0.07, 1.69)	1.15 (0.40, 3.36)			
Female	2.19 (0.69, 6.89)	1.01 (0.41, 2.47)			
Baseline FVC percent predicted					
<=70%	0.77 (0.26, 2.27)	0.98 (0.42, 2.31)			
>70%	2.52 (0.52, 12.20)	1.22 (0.38, 3.90)			
Baseline HRCT pattern					
UIP-like	1.17 (0.44, 3.15)	0.88 (0.32, 2.37)			
Other fibrotic patterns	0.97 (0.20, 4.63)	1.28 (0.49, 3.32)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Vascular disorders
PT: Hypertension

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.50 (-3.71, 4.75)	0.29 (-2.93, 3.50)	0.21 (-5.10, 5.52)
Age			
<65 years	-1.41 (-8.69, 5.39)	0.69 (-5.14, 6.52)	
>=65 years	1.74 (-3.88, 7.66)	-0.18 (-3.88, 3.51)	
Sex			
Male	-3.37 (-9.17, 1.95)	0.52 (-3.37, 4.42)	
Female	4.48 (-2.26, 11.56)	0.04 (-5.22, 5.29)	
Baseline FVC percent predicted			
<=70%	-1.57 (-8.29, 5.64)	-0.08 (-4.47, 4.31)	
>70%	2.92 (-2.56, 8.41)	0.79 (-3.86, 5.44)	
Baseline HRCT pattern			
UIP-like	0.76 (-4.34, 6.00)	-0.49 (-4.10, 3.13)	
Other fibrotic patterns	-0.14 (-8.88, 8.42)	1.54 (-4.50, 7.58)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC and PT over the whole trial
SOC: Vascular disorders
PT: Hypertension

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.12 (0.46, 2.68)	1.07 (0.52, 2.19)	1.05 (0.34, 3.26)
Age			
<65 years	0.70 (0.15, 3.21)	1.13 (0.41, 3.12)	
>=65 years	1.43 (0.48, 4.24)	0.95 (0.34, 2.67)	
Sex			
Male	0.34 (0.07, 1.70)	1.16 (0.38, 3.52)	
Female	2.30 (0.68, 7.69)	1.01 (0.39, 2.61)	
Baseline FVC percent predicted			
<=70%	0.76 (0.24, 2.39)	0.98 (0.40, 2.42)	
>70%	2.59 (0.51, 13.13)	1.23 (0.37, 4.12)	
Baseline HRCT pattern			
UIP-like	1.18 (0.42, 3.34)	0.87 (0.31, 2.45)	
Other fibrotic patterns	0.97 (0.19, 4.98)	1.30 (0.47, 3.60)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.43 (0.23, 0.83)				
Age					
<65 years	0.51 (0.20, 1.33)				
>=65 years	0.37 (0.15, 0.91)				
Sex					
Male	0.33 (0.14, 0.80)				
Female	0.65 (0.24, 1.76)				
Baseline FVC percent predicted					
<=70%	0.53 (0.27, 1.07)				
>70%	0.34 (0.07, 1.69)				
Baseline HRCT pattern					
UIP-like	0.31 (0.14, 0.71)				
Other fibrotic patterns	0.97 (0.29, 3.19)				
Underlying ILD diagnosis					
iNSIP	0.55 (0.13, 2.30)				
Unclassifiable IIP	1.35 (0.24, 7.63)				
HP	0.19 (0.02, 1.43)				
Autoimmune ILD	0.13 (0.02, 0.99)				
Other ILD	0.82 (0.27, 2.52)				
Region					
Europe	0.75 (0.23, 2.43)				
Asia	0.43 (0.19, 1.01)				
Canada and USA	0.25 (0.01, 4.50)				
Rest of the World	0.12 (0.01, 2.14)				

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-7.16 (-12.68, -1.80)		
Age			
<65 years	-6.43 (-16.09, 2.80)		
>=65 years	-7.68 (-14.61, -0.98)		
Sex			
Male	-10.97 (-19.29, -2.82)		
Female	-2.99 (-10.46, 4.19)		
Baseline FVC percent predicted			
<=70%	-9.07 (-18.39, 0.78)		
>70%	-3.19 (-9.27, 1.72)		
Baseline HRCT pattern			
UIP-like	-10.01 (-16.76, -3.51)		
Other fibrotic patterns	-0.24 (-10.40, 9.76)		
Underlying ILD diagnosis			
iNSIP	-4.55 (-18.08, 6.63)		
Unclassifiable IIP	1.94 (-11.57, 14.95)		
HP	-14.62 (-29.59, 1.46)		
Autoimmune ILD	-9.84 (-19.33, -1.56)		
Other ILD	-3.44 (-21.75, 17.58)		
Region			
Europe	-3.07 (-17.69, 9.84)		
Asia	-8.55 (-17.24, -0.10)		
Canada and USA	-10.00 (-25.62, 9.56)		
Rest of the World	-8.70 (-20.32, 1.05)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC and PT over the whole trial
SOC: General disorders and administration site conditions
PT: Condition aggravated

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.40 (0.20, 0.81)		
Age			
<65 years	0.48 (0.17, 1.36)		
>=65 years	0.34 (0.13, 0.90)		
Sex			
Male	0.29 (0.11, 0.76)		
Female	0.63 (0.22, 1.83)		
Baseline FVC percent predicted			
<=70%	0.48 (0.22, 1.07)		
>70%	0.32 (0.06, 1.71)		
Baseline HRCT pattern			
UIP-like	0.28 (0.12, 0.67)		
Other fibrotic patterns	0.97 (0.27, 3.51)		
Underlying ILD diagnosis			
iNSIP	0.52 (0.11, 2.46)		
Unclassifiable IIP	1.38 (0.22, 8.76)		
HP	0.16 (0.02, 1.36)		
Autoimmune ILD	0.11 (0.01, 0.94)		
Other ILD	0.79 (0.20, 3.05)		
Region			
Europe	0.73 (0.20, 2.71)		
Asia	0.39 (0.15, 1.00)		
Canada and USA	0.00 (NC, NC)		
Rest of the World	0.00 (NC, NC)		

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.97 (0.55, 1.68)	1.50 (0.81, 2.76)	0.65 (0.28, 1.48)	0.2994	
Age					
<65 years	0.94 (0.28, 3.14)	2.18 (0.70, 6.76)			
>=65 years	0.99 (0.54, 1.85)	1.27 (0.60, 2.68)			
Sex					
Male	0.87 (0.39, 1.93)	1.85 (0.81, 4.26)			
Female	1.06 (0.49, 2.30)	1.13 (0.45, 2.86)			
Baseline FVC percent predicted					
<=70%	1.23 (0.63, 2.39)	1.12 (0.57, 2.17)			
>70%	0.73 (0.28, 1.96)	7.10 (0.89, 56.96)			
Baseline HRCT pattern					
UIP-like	1.03 (0.51, 2.08)	1.36 (0.64, 2.90)			
Other fibrotic patterns	0.86 (0.35, 2.10)	1.79 (0.62, 5.18)			
Underlying ILD diagnosis					
iNSIP	1.64 (0.54, 4.94)	0.48 (0.12, 1.82)			
Unclassifiable IIP	1.35 (0.24, 7.63)	NC (NC, NC)			
HP	0.65 (0.06, 6.83)	1.41 (0.33, 6.13)			
Autoimmune ILD	0.71 (0.29, 1.76)	1.79 (0.68, 4.70)			
Other ILD	0.58 (0.12, 2.74)	2.26 (0.21, 23.98)			
Region					
Europe	2.64 (0.58, 12.04)	1.79 (0.78, 4.10)			
Asia	0.74 (0.37, 1.49)	1.15 (0.37, 3.63)			
Canada and USA	0.88 (0.09, 9.03)	1.03 (0.07, 16.13)			
Rest of the World	0.71 (0.13, 4.06)	1.22 (0.18, 8.18)			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-0.36 (-6.11, 5.40)	2.40 (-1.22, 6.01)	-2.76 (-9.55, 4.04)
Age			
<65 years	-0.34 (-8.34, 7.39)	3.89 (-1.46, 9.24)	
>=65 years	-0.07 (-8.16, 8.12)	1.54 (-3.28, 6.36)	
Sex			
Male	-1.34 (-9.31, 6.71)	3.86 (-1.22, 8.94)	
Female	0.63 (-7.96, 9.16)	0.69 (-4.43, 5.80)	
Baseline FVC percent predicted			
<=70%	2.91 (-6.41, 12.76)	0.90 (-4.56, 6.36)	
>70%	-2.05 (-9.39, 4.65)	4.42 (0.45, 8.40)	
Baseline HRCT pattern			
UIP-like	0.23 (-6.31, 6.83)	1.94 (-2.75, 6.63)	
Other fibrotic patterns	-1.94 (-14.01, 9.99)	3.14 (-2.52, 8.80)	
Underlying ILD diagnosis			
iNSIP	6.36 (-8.69, 19.71)	-5.15 (-14.24, 3.94)	
Unclassifiable IIP	1.94 (-11.57, 14.95)	7.81 (1.24, 14.39)	
HP	-1.79 (-13.87, 12.05)	1.39 (-4.51, 7.29)	
Autoimmune ILD	-4.08 (-15.24, 7.07)	5.38 (-3.45, 14.20)	
Other ILD	-5.89 (-21.75, 12.79)	2.94 (-5.47, 11.35)	
Region			
Europe	8.21 (-5.08, 20.39)	4.30 (-1.65, 10.25)	
Asia	-3.88 (-13.17, 5.37)	1.02 (-7.06, 9.09)	
Canada and USA	-0.78 (-16.22, 20.86)	0.04 (-4.00, 4.09)	
Rest of the World	-1.87 (-13.36, 9.75)	1.12 (-9.75, 12.00)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.2.4: 2 Indirect treatment comparison for the proportion of patients with frequent serious AEs by SOC and PT over the whole trial
SOC: Infections and infestations
PT: Pneumonia

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.96 (0.52, 1.78)	1.53 (0.80, 2.94)	0.63 (0.26, 1.54)
Age			
<65 years	0.94 (0.26, 3.37)	2.27 (0.69, 7.43)	
>=65 years	0.99 (0.49, 2.02)	1.29 (0.58, 2.86)	
Sex			
Male	0.86 (0.35, 2.07)	1.93 (0.80, 4.68)	
Female	1.07 (0.45, 2.54)	1.14 (0.43, 3.04)	
Baseline FVC percent predicted			
<=70%	1.27 (0.59, 2.75)	1.13 (0.55, 2.33)	
>70%	0.72 (0.25, 2.05)	7.43 (0.90, 61.26)	
Baseline HRCT pattern			
UIP-like	1.03 (0.47, 2.24)	1.39 (0.62, 3.11)	
Other fibrotic patterns	0.84 (0.30, 2.34)	1.85 (0.60, 5.67)	
Underlying ILD diagnosis			
iNSIP	1.76 (0.50, 6.18)	0.45 (0.11, 1.89)	
Unclassifiable IIP	1.38 (0.22, 8.76)	NC (NC, NC)	
HP	0.64 (0.06, 7.39)	1.43 (0.31, 6.60)	
Autoimmune ILD	0.68 (0.24, 1.89)	1.90 (0.66, 5.48)	
Other ILD	0.54 (0.10, 3.03)	2.33 (0.20, 26.81)	
Region			
Europe	2.89 (0.57, 14.74)	1.88 (0.77, 4.56)	
Asia	0.71 (0.32, 1.58)	1.17 (0.34, 4.00)	
Canada and USA	0.88 (0.07, 10.43)	1.03 (0.06, 16.82)	
Rest of the World	0.70 (0.11, 4.40)	1.23 (0.16, 9.28)	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Only adverse events reported in study 1305-0023 that met the minimum occurrence threshold (incidence in either arm >= 5% or both incidence >=1% and >=10 patients affected in either arm) are presented.
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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M.1.3 Further analysis

M.1.3.1 Further safety analysis

Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.18 (0.95, 1.46)	1.70 (1.51, 1.91)	0.70 (0.54, 0.89)	0.0038	
Age					0.0131
<65 years	0.86 (0.59, 1.25)	1.91 (1.53, 2.38)	0.45 (0.29, 0.70)	0.0003	
>=65 years	1.41 (1.08, 1.84)	1.60 (1.39, 1.84)	0.88 (0.65, 1.19)	0.4017	
Sex					0.8815
Male	1.19 (0.87, 1.62)	1.68 (1.43, 1.97)	0.71 (0.50, 1.00)	0.0524	
Female	1.17 (0.87, 1.58)	1.72 (1.44, 2.05)	0.68 (0.48, 0.96)	0.0299	
Baseline FVC percent predicted					0.7220
<=70%	1.13 (0.83, 1.53)	1.58 (1.36, 1.82)	0.71 (0.51, 1.00)	0.0527	
>70%	1.24 (0.91, 1.68)	1.90 (1.55, 2.32)	0.65 (0.45, 0.94)	0.0221	
Baseline HRCT pattern					0.1724
UIP-like	1.28 (0.99, 1.65)	1.64 (1.42, 1.89)	0.78 (0.58, 1.05)	0.0972	
Other fibrotic patterns	0.97 (0.64, 1.46)	1.81 (1.47, 2.23)	0.54 (0.34, 0.85)	0.0075	
Underlying ILD diagnosis					0.4025
iNSIP	1.12 (0.63, 1.97)	2.54 (1.68, 3.84)	0.44 (0.22, 0.89)	0.0219	
Unclassifiable IIP	1.18 (0.74, 1.89)	2.19 (1.57, 3.06)	0.54 (0.30, 0.96)	0.0349	
HP	0.99 (0.58, 1.71)	1.39 (1.15, 1.69)	0.71 (0.40, 1.27)	0.2506	
Autoimmune ILD	1.23 (0.85, 1.79)	1.54 (1.25, 1.91)	0.80 (0.52, 1.23)	0.3067	
Other ILD	1.54 (0.92, 2.59)	1.57 (1.15, 2.15)	0.98 (0.53, 1.80)	0.9478	
Region					0.6121
Europe	1.39 (0.82, 2.38)	1.91 (1.56, 2.34)	0.73 (0.41, 1.30)	0.2818	
Asia	1.10 (0.82, 1.47)	1.64 (1.34, 2.00)	0.67 (0.47, 0.96)	0.0269	
Canada and USA	0.99 (0.57, 1.74)	1.17 (0.99, 1.39)	0.85 (0.47, 1.52)	0.5790	
Rest of the World	1.56 (0.88, 2.76)	3.83 (1.88, 7.80)	0.41 (0.16, 1.01)	0.0539	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	7.18 (-2.04, 16.23)	34.49 (27.82, 41.16)	-27.31 (-38.63, -16.00)
Age			
<65 years	-5.81 (-20.00, 8.67)	39.04 (28.15, 49.93)	-44.84 (-62.85, -26.84)
>=65 years	15.66 (3.79, 26.93)	32.16 (23.78, 40.54)	-16.50 (-30.79, -2.21)
Sex			
Male	7.11 (-5.63, 19.56)	34.08 (24.99, 43.16)	-26.96 (-42.49, -11.43)
Female	7.11 (-6.10, 19.98)	34.96 (25.13, 44.79)	-27.84 (-44.18, -11.51)
Baseline FVC percent predicted			
<=70%	5.16 (-8.03, 18.19)	30.82 (22.12, 39.51)	-25.66 (-41.39, -9.93)
>70%	9.12 (-3.76, 21.50)	39.62 (29.28, 49.96)	-30.50 (-46.83, -14.18)
Baseline HRCT pattern			
UIP-like	10.74 (-0.26, 21.39)	33.01 (24.62, 41.40)	-22.27 (-35.96, -8.57)
Other fibrotic patterns	-1.28 (-17.73, 15.25)	36.94 (25.98, 47.90)	-38.22 (-58.02, -18.42)
Underlying ILD diagnosis			
iNSIP	3.86 (-15.38, 21.99)	45.49 (29.89, 61.10)	-41.63 (-65.98, -17.28)
Unclassifiable IIP	8.06 (-13.86, 28.89)	50.19 (35.01, 65.37)	-42.13 (-68.35, -15.91)
HP	-0.26 (-22.46, 22.31)	23.85 (11.09, 36.61)	-24.11 (-49.87, 1.66)
Autoimmune ILD	9.13 (-7.10, 24.72)	29.60 (16.53, 42.67)	-20.47 (-41.05, 0.12)
Other ILD	21.11 (-4.09, 42.89)	30.72 (11.84, 49.61)	-9.61 (-39.75, 20.53)
Region			
Europe	12.78 (-7.19, 30.95)	38.34 (28.20, 48.48)	-25.56 (-47.16, -3.96)
Asia	4.27 (-8.97, 17.29)	37.04 (24.93, 49.15)	-32.77 (-50.64, -14.91)
Canada and USA	-0.39 (-27.84, 26.66)	12.65 (-0.54, 25.85)	-13.05 (-43.32, 17.23)
Rest of the World	15.93 (-3.91, 34.25)	50.80 (30.73, 70.88)	-34.88 (-62.57, -7.18)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.34 (0.92, 1.96)	5.36 (3.72, 7.72)	0.25 (0.15, 0.42)
Age			
<65 years	0.78 (0.42, 1.45)	6.05 (3.45, 10.62)	0.13 (0.06, 0.30)
>=65 years	1.89 (1.16, 3.06)	5.16 (3.18, 8.36)	0.37 (0.18, 0.73)
Sex			
Male	1.34 (0.79, 2.28)	5.33 (3.24, 8.79)	0.25 (0.12, 0.52)
Female	1.33 (0.78, 2.29)	5.39 (3.17, 9.19)	0.25 (0.12, 0.53)
Baseline FVC percent predicted			
<=70%	1.23 (0.72, 2.13)	4.65 (2.89, 7.49)	0.27 (0.13, 0.55)
>70%	1.45 (0.86, 2.47)	6.54 (3.71, 11.53)	0.22 (0.10, 0.48)
Baseline HRCT pattern			
UIP-like	1.55 (0.99, 2.43)	5.22 (3.27, 8.35)	0.30 (0.15, 0.57)
Other fibrotic patterns	0.95 (0.47, 1.91)	5.64 (3.16, 10.06)	0.17 (0.07, 0.42)
Underlying ILD diagnosis			
iNSIP	1.19 (0.50, 2.80)	7.17 (3.26, 15.78)	0.17 (0.05, 0.53)
Unclassifiable IIP	1.38 (0.56, 3.41)	16.30 (5.58, 47.59)	0.08 (0.02, 0.34)
HP	0.99 (0.38, 2.59)	3.54 (1.71, 7.33)	0.28 (0.08, 0.93)
Autoimmune ILD	1.45 (0.74, 2.83)	4.42 (2.14, 9.14)	0.33 (0.12, 0.88)
Other ILD	2.36 (0.83, 6.69)	4.64 (1.61, 13.36)	0.51 (0.11, 2.25)
Region			
Europe	1.72 (0.73, 4.04)	5.67 (3.38, 9.49)	0.30 (0.11, 0.82)
Asia	1.19 (0.69, 2.04)	13.64 (4.52, 41.13)	0.09 (0.03, 0.30)
Canada and USA	0.98 (0.30, 3.24)	2.27 (0.94, 5.51)	0.43 (0.10, 1.91)
Rest of the World	2.01 (0.83, 4.84)	10.06 (3.32, 30.45)	0.20 (0.05, 0.82)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.41 (0.46, 4.38)	3.39 (1.70, 6.75)	0.42 (0.11, 1.57)	0.1955	
Age					
<65 years	0.94 (0.06, 14.84)	4.06 (1.20, 13.80)			
>=65 years	1.58 (0.46, 5.47)	3.11 (1.34, 7.19)			
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like	1.23 (0.38, 3.95)	6.67 (2.01, 22.09)			
Other fibrotic patterns	2.91 (0.12, 70.15)	1.98 (0.83, 4.75)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.93 (-2.41, 4.41)	7.22 (3.47, 10.97)	-6.29 (-11.36, -1.22)
Age			
<65 years	-0.07 (-5.46, 5.05)	7.59 (1.87, 13.31)	
>=65 years	1.67 (-3.27, 6.98)	7.03 (2.09, 11.97)	
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like	0.73 (-3.81, 5.43)	8.25 (3.89, 12.61)	
Other fibrotic patterns	1.52 (-4.28, 8.10)	5.51 (-1.30, 12.32)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.43 (0.45, 4.56)	3.66 (1.78, 7.54)	0.39 (0.10, 1.53)
Age			
<65 years	0.94 (0.06, 15.32)	4.41 (1.23, 15.72)	
>=65 years	1.61 (0.44, 5.83)	3.35 (1.38, 8.12)	
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like	1.24 (0.37, 4.15)	7.28 (2.13, 24.89)	
Other fibrotic patterns	NC (NC, NC)	2.11 (0.82, 5.41)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain upper

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.33, 3.08)	4.70 (2.11, 10.47)	0.21 (0.05, 0.85)	0.0282	
Age					
<65 years					
>=65 years					
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like					
Other fibrotic patterns					
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain upper

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.02 (-3.38, 3.45)	7.82 (4.25, 11.40)	-7.80 (-12.74, -2.86)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Abdominal pain upper

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.32, 3.18)	5.11 (2.23, 11.72)	0.20 (0.05, 0.81)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.55 (1.09, 2.22)	2.82 (2.32, 3.42)	0.55 (0.37, 0.83)	0.0042	
Age					0.0185
<65 years	0.94 (0.51, 1.76)	3.45 (2.39, 4.96)	0.27 (0.13, 0.56)	0.0004	
>=65 years	2.01 (1.29, 3.14)	2.56 (2.03, 3.22)	0.79 (0.48, 1.30)	0.3505	
Sex					0.5941
Male	1.38 (0.84, 2.25)	2.78 (2.14, 3.60)	0.50 (0.29, 0.86)	0.0131	
Female	1.77 (1.05, 3.01)	2.86 (2.13, 3.84)	0.62 (0.34, 1.13)	0.1208	
Baseline FVC percent predicted					0.4483
<=70%	1.37 (0.87, 2.16)	2.76 (2.14, 3.56)	0.50 (0.30, 0.84)	0.0087	
>70%	2.00 (1.11, 3.62)	2.90 (2.14, 3.93)	0.69 (0.35, 1.34)	0.2746	
Baseline HRCT pattern					0.4199
UIP-like	1.69 (1.11, 2.55)	2.75 (2.17, 3.49)	0.61 (0.38, 0.99)	0.0444	
Other fibrotic patterns	1.23 (0.61, 2.51)	2.94 (2.09, 4.14)	0.42 (0.19, 0.92)	0.0308	
Underlying ILD diagnosis					0.7779
iNSIP	1.58 (0.66, 3.79)	3.15 (1.89, 5.26)	0.50 (0.18, 1.38)	0.1808	
Unclassifiable IIP	1.98 (0.76, 5.15)	4.17 (2.27, 7.66)	0.48 (0.15, 1.48)	0.1983	
HP	1.63 (0.73, 3.61)	2.59 (1.85, 3.62)	0.63 (0.26, 1.49)	0.2913	
Autoimmune ILD	1.08 (0.58, 2.02)	2.40 (1.67, 3.46)	0.45 (0.22, 0.92)	0.0298	
Other ILD	2.88 (1.12, 7.41)	2.78 (1.60, 4.81)	1.04 (0.35, 3.09)	0.9482	
Region					0.3616
Europe	2.42 (0.97, 6.04)	3.47 (2.48, 4.85)	0.70 (0.26, 1.85)	0.4673	
Asia	1.09 (0.64, 1.84)	2.84 (1.94, 4.16)	0.38 (0.20, 0.73)	0.0038	
Canada and USA	1.76 (0.75, 4.18)	1.75 (1.30, 2.36)	1.01 (0.40, 2.51)	0.9864	
Rest of the World	2.50 (1.05, 5.91)	5.48 (2.06, 14.57)	0.46 (0.12, 1.67)	0.2363	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	9.71 (1.92, 17.36)	46.61 (39.88, 53.34)	-36.90 (-47.15, -26.66)
Age			
<65 years	-1.10 (-12.92, 10.60)	50.56 (40.14, 60.99)	-51.66 (-67.37, -35.94)
>=65 years	16.79 (6.51, 26.71)	44.49 (35.74, 53.23)	-27.70 (-41.06, -14.34)
Sex			
Male	7.16 (-3.72, 17.92)	47.19 (38.03, 56.35)	-40.03 (-54.20, -25.85)
Female	12.40 (1.24, 23.17)	45.91 (35.99, 55.84)	-33.51 (-48.30, -18.72)
Baseline FVC percent predicted			
<=70%	8.17 (-3.54, 19.95)	45.52 (36.68, 54.37)	-37.35 (-52.05, -22.64)
>70%	12.50 (2.22, 22.21)	48.17 (37.79, 58.54)	-35.67 (-50.08, -21.26)
Baseline HRCT pattern			
UIP-like	12.15 (2.70, 21.38)	47.57 (39.08, 56.06)	-35.42 (-48.05, -22.80)
Other fibrotic patterns	4.02 (-9.68, 17.48)	45.05 (34.06, 56.05)	-41.03 (-58.50, -23.56)
Underlying ILD diagnosis			
iNSIP	8.64 (-8.21, 23.62)	45.88 (30.45, 61.30)	-37.24 (-59.41, -15.07)
Unclassifiable IIP	13.61 (-5.04, 30.82)	57.00 (41.97, 72.03)	-43.39 (-66.79, -19.99)
HP	12.82 (-7.78, 33.18)	48.23 (35.26, 61.20)	-35.41 (-59.66, -11.17)
Autoimmune ILD	1.73 (-11.91, 15.34)	39.88 (26.09, 53.68)	-38.15 (-57.54, -18.77)
Other ILD	26.11 (3.89, 46.89)	45.47 (26.03, 64.91)	-19.36 (-48.35, 9.63)
Region			
Europe	17.69 (0.39, 32.78)	50.37 (40.67, 60.07)	-32.68 (-51.56, -13.81)
Asia	1.68 (-9.22, 12.53)	50.85 (37.31, 64.38)	-49.17 (-66.53, -31.80)
Canada and USA	17.84 (-8.47, 43.41)	32.64 (17.12, 48.17)	-14.80 (-45.03, 15.43)
Rest of the World	19.51 (2.05, 35.97)	45.99 (26.34, 65.64)	-26.48 (-52.43, -0.52)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.76 (1.12, 2.77)	7.55 (5.35, 10.65)	0.23 (0.13, 0.41)
Age			
<65 years	0.93 (0.43, 2.01)	9.50 (5.36, 16.86)	0.10 (0.04, 0.26)
>=65 years	2.52 (1.42, 4.48)	6.78 (4.38, 10.49)	0.37 (0.18, 0.77)
Sex			
Male	1.51 (0.81, 2.83)	7.77 (4.85, 12.45)	0.19 (0.09, 0.43)
Female	2.08 (1.07, 4.05)	7.33 (4.42, 12.14)	0.28 (0.12, 0.65)
Baseline FVC percent predicted			
<=70%	1.53 (0.83, 2.84)	7.15 (4.57, 11.18)	0.21 (0.10, 0.46)
>70%	2.33 (1.15, 4.74)	8.17 (4.76, 14.04)	0.29 (0.12, 0.70)
Baseline HRCT pattern			
UIP-like	1.98 (1.16, 3.38)	7.93 (5.11, 12.31)	0.25 (0.12, 0.50)
Other fibrotic patterns	1.30 (0.54, 3.12)	7.12 (4.07, 12.46)	0.18 (0.06, 0.52)
Underlying ILD diagnosis			
iNSIP	1.75 (0.60, 5.10)	7.56 (3.38, 16.91)	0.23 (0.06, 0.88)
Unclassifiable IIP	2.35 (0.73, 7.59)	13.67 (5.46, 34.19)	0.17 (0.04, 0.76)
HP	1.94 (0.65, 5.74)	8.42 (4.22, 16.78)	0.23 (0.06, 0.83)
Autoimmune ILD	1.11 (0.50, 2.46)	5.43 (2.82, 10.46)	0.20 (0.07, 0.57)
Other ILD	4.13 (1.20, 14.25)	7.14 (2.68, 19.03)	0.58 (0.12, 2.81)
Region			
Europe	3.03 (1.00, 9.14)	9.45 (5.56, 16.06)	0.32 (0.09, 1.09)
Asia	1.11 (0.57, 2.15)	9.55 (4.58, 19.93)	0.12 (0.04, 0.31)
Canada and USA	2.30 (0.64, 8.31)	4.14 (1.98, 8.65)	0.56 (0.13, 2.44)
Rest of the World	3.22 (1.10, 9.38)	11.25 (3.23, 39.19)	0.29 (0.06, 1.48)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.91 (0.87, 4.18)	3.02 (2.10, 4.34)	0.63 (0.27, 1.50)	0.2971	
Age					
<65 years	1.26 (0.29, 5.45)	3.32 (1.79, 6.16)			
>=65 years	2.28 (0.89, 5.83)	2.87 (1.83, 4.50)			
Sex					
Male	4.18 (0.91, 19.26)	2.75 (1.55, 4.89)			
Female	1.25 (0.48, 3.24)	3.23 (2.03, 5.14)			
Baseline FVC percent predicted					
<=70%	2.05 (0.77, 5.43)	2.73 (1.75, 4.26)			
>70%	1.96 (0.52, 7.38)	3.60 (1.92, 6.73)			
Baseline HRCT pattern					
UIP-like	3.33 (1.11, 10.00)	3.47 (2.10, 5.74)			
Other fibrotic patterns	0.78 (0.22, 2.76)	2.54 (1.51, 4.28)			
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	3.67 (-0.82, 8.38)	20.15 (14.25, 26.05)	-16.48 (-23.95, -9.00)
Age			
<65 years	0.93 (-6.12, 7.91)	21.12 (11.93, 30.32)	
>=65 years	5.53 (-0.70, 12.22)	19.58 (11.89, 27.26)	
Sex			
Male	5.48 (-0.10, 11.98)	13.88 (6.64, 21.12)	
Female	1.65 (-5.82, 9.15)	27.53 (18.20, 36.87)	
Baseline FVC percent predicted			
<=70%	5.33 (-1.93, 13.51)	19.72 (11.84, 27.60)	
>70%	2.76 (-3.23, 8.63)	20.71 (11.86, 29.55)	
Baseline HRCT pattern			
UIP-like	5.91 (0.79, 11.59)	20.39 (13.16, 27.62)	
Other fibrotic patterns	-1.75 (-11.67, 7.84)	19.74 (9.68, 29.80)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Nausea

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.98 (0.86, 4.55)	3.89 (2.53, 5.98)	0.51 (0.20, 1.30)
Age			
<65 years	1.27 (0.28, 5.85)	4.33 (2.11, 8.88)	
>=65 years	2.42 (0.89, 6.57)	3.67 (2.14, 6.29)	
Sex			
Male	4.43 (0.92, 21.33)	3.24 (1.69, 6.22)	
Female	1.27 (0.46, 3.55)	4.71 (2.64, 8.41)	
Baseline FVC percent predicted			
<=70%	2.17 (0.76, 6.21)	3.51 (2.05, 6.01)	
>70%	2.01 (0.51, 7.99)	4.64 (2.26, 9.53)	
Baseline HRCT pattern			
UIP-like	3.55 (1.13, 11.14)	4.46 (2.50, 7.98)	
Other fibrotic patterns	0.76 (0.19, 2.97)	3.29 (1.73, 6.25)	
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Vomiting

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.30 (0.49, 3.42)	3.99 (2.36, 6.75)	0.33 (0.11, 0.98)	0.0461	
Age					0.0736
<65 years	0.24 (0.03, 2.07)	4.18 (1.65, 10.61)	0.06 (0.01, 0.60)	0.0171	
>=65 years	2.81 (0.76, 10.36)	3.96 (2.09, 7.49)	0.71 (0.17, 3.03)	0.6437	
Sex					0.1861
Male	2.09 (0.39, 11.18)	2.47 (1.12, 5.46)	0.85 (0.13, 5.41)	0.8593	
Female	0.97 (0.29, 3.26)	5.54 (2.70, 11.37)	0.18 (0.04, 0.72)	0.0155	
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					0.6030
UIP-like	0.88 (0.30, 2.56)	2.85 (1.56, 5.19)	0.31 (0.09, 1.05)	0.0603	
Other fibrotic patterns	6.79 (0.36, 128.91)	8.93 (2.78, 28.68)	0.76 (0.03, 18.04)	0.8655	
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					0.9525
Europe	0.75 (0.05, 11.70)	3.22 (1.51, 6.86)	0.23 (0.01, 4.02)	0.3172	
Asia	2.31 (0.61, 8.70)	11.54 (1.54, 86.64)	0.20 (0.02, 2.23)	0.1913	
Canada and USA	0.34 (0.02, 6.78)	2.80 (1.26, 6.21)	0.12 (0.01, 2.70)	0.1835	
Rest of the World	1.07 (0.07, 16.57)	NC (NC, NC)	NC (NC, NC)	NC	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Vomiting

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.94 (-2.81, 4.79)	14.44 (9.61, 19.27)	-13.51 (-19.65, -7.36)
Age			
<65 years	-3.68 (-10.67, 2.13)	13.13 (5.92, 20.35)	-16.82 (-26.46, -7.17)
>=65 years	3.90 (-1.07, 9.53)	15.49 (9.02, 21.95)	-11.58 (-19.94, -3.23)
Sex			
Male	1.88 (-2.99, 7.32)	6.65 (1.12, 12.19)	-4.77 (-12.34, 2.79)
Female	-0.13 (-6.54, 6.17)	23.56 (15.58, 31.55)	-23.69 (-33.90, -13.49)
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like	-0.53 (-5.44, 4.36)	11.65 (5.45, 17.86)	-12.18 (-20.09, -4.28)
Other fibrotic patterns	4.55 (-1.86, 12.53)	19.03 (11.38, 26.68)	-14.48 (-24.99, -3.98)
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	-0.61 (-11.11, 7.70)	12.09 (5.05, 19.13)	-12.70 (-24.45, -0.96)
Asia	3.71 (-2.44, 10.33)	13.87 (5.56, 22.19)	-10.16 (-20.65, 0.32)
Canada and USA	-6.67 (-21.32, 12.38)	18.21 (5.28, 31.15)	-24.88 (-46.12, -3.64)
Rest of the World	0.15 (-9.21, 10.05)	18.75 (5.23, 32.27)	-18.60 (-35.20, -2.00)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Gastrointestinal disorders
PT: Vomiting

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.31 (0.48, 3.58)	4.70 (2.65, 8.33)	0.28 (0.09, 0.89)
Age			
<65 years	0.23 (0.02, 2.07)	4.84 (1.79, 13.13)	0.05 (0.00, 0.53)
>=65 years	2.92 (0.76, 11.27)	4.73 (2.35, 9.52)	0.62 (0.14, 2.83)
Sex			
Male	2.13 (0.38, 11.87)	2.66 (1.14, 6.20)	0.80 (0.12, 5.45)
Female	0.97 (0.27, 3.46)	7.37 (3.33, 16.28)	0.13 (0.03, 0.59)
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like	0.87 (0.29, 2.66)	3.25 (1.67, 6.32)	0.27 (0.07, 0.98)
Other fibrotic patterns	NC (NC, NC)	11.09 (3.27, 37.64)	NC (NC, NC)
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	0.75 (0.05, 12.37)	3.69 (1.62, 8.43)	0.20 (0.01, 3.77)
Asia	2.40 (0.60, 9.56)	13.43 (1.70, 106.07)	0.18 (0.01, 2.15)
Canada and USA	0.00 (NC, NC)	3.51 (1.36, 9.02)	NC (NC, NC)
Rest of the World	1.07 (0.06, 17.68)	NC (NC, NC)	NC (NC, NC)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.14 (0.45, 2.89)	3.72 (1.94, 7.10)	0.31 (0.10, 0.95)	0.0409	
Age					0.8977
<65 years	1.89 (0.35, 10.03)	7.40 (1.74, 31.38)	0.25 (0.03, 2.32)	0.2252	
>=65 years	0.88 (0.27, 2.81)	2.90 (1.38, 6.09)	0.30 (0.08, 1.20)	0.0891	
Sex					0.3954
Male	0.87 (0.27, 2.77)	4.12 (1.73, 9.80)	0.21 (0.05, 0.90)	0.0352	
Female	1.94 (0.36, 10.40)	3.22 (1.21, 8.57)	0.60 (0.09, 4.21)	0.6105	
Baseline FVC percent predicted					0.9719
<=70%	0.92 (0.21, 4.02)	3.32 (1.55, 7.13)	0.28 (0.05, 1.46)	0.1297	
>70%	1.26 (0.36, 4.34)	4.74 (1.39, 16.11)	0.27 (0.05, 1.52)	0.1357	
Baseline HRCT pattern					0.9954
UIP-like	1.03 (0.37, 2.86)	3.00 (1.38, 6.52)	0.34 (0.09, 1.24)	0.1017	
Other fibrotic patterns	1.94 (0.18, 20.87)	5.62 (1.69, 18.71)	0.34 (0.02, 4.94)	0.4334	
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					0.5018
Europe	1.51 (0.14, 16.07)	1.91 (0.59, 6.21)	0.79 (0.06, 11.11)	0.8617	
Asia	0.99 (0.36, 2.73)	8.66 (2.74, 27.36)	0.11 (0.02, 0.53)	0.0056	
Canada and USA	1.72 (0.04, 83.12)	1.37 (0.32, 5.91)	1.25 (0.02, 78.93)	0.9146	
Rest of the World	1.07 (0.02, 52.68)	2.44 (0.23, 25.67)	0.44 (0.00, 41.64)	0.7225	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.49 (-3.37, 4.41)	9.03 (4.99, 13.06)	-8.54 (-14.14, -2.94)
Age			
<65 years	2.14 (-4.43, 8.93)	10.58 (4.68, 16.48)	-8.44 (-17.36, 0.47)
>=65 years	-0.53 (-5.77, 4.78)	8.15 (2.75, 13.55)	-8.68 (-16.23, -1.13)
Sex			
Male	-0.67 (-6.88, 5.59)	10.58 (4.84, 16.31)	-11.24 (-19.72, -2.77)
Female	1.78 (-3.45, 7.34)	7.21 (1.61, 12.81)	-5.43 (-13.20, 2.35)
Baseline FVC percent predicted			
<=70%	-0.26 (-5.67, 5.76)	9.63 (4.05, 15.22)	-9.90 (-17.89, -1.90)
>70%	0.99 (-5.21, 6.80)	8.12 (2.46, 13.78)	-7.13 (-15.38, 1.12)
Baseline HRCT pattern			
UIP-like	0.12 (-4.89, 5.19)	7.77 (2.65, 12.88)	-7.65 (-14.83, -0.47)
Other fibrotic patterns	1.47 (-5.65, 8.94)	11.09 (4.55, 17.63)	-9.62 (-19.42, 0.17)
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	1.27 (-9.46, 10.49)	2.47 (-1.91, 6.86)	-1.20 (-12.09, 9.69)
Asia	-0.06 (-7.28, 7.13)	30.23 (18.89, 41.57)	-30.29 (-43.73, -16.86)
Canada and USA	0.00 (NC, NC)	1.62 (-5.82, 9.06)	-1.62 (NC, NC)
Rest of the World	0.00 (NC, NC)	3.69 (-6.06, 13.43)	-3.69 (NC, NC)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.14 (0.43, 3.01)	4.10 (2.07, 8.12)	0.28 (0.08, 0.91)
Age			
<65 years	1.93 (0.34, 10.82)	8.29 (1.87, 36.67)	0.23 (0.02, 2.27)
>=65 years	0.87 (0.26, 2.93)	3.17 (1.44, 7.01)	0.28 (0.06, 1.17)
Sex			
Male	0.86 (0.26, 2.92)	4.63 (1.85, 11.58)	0.19 (0.04, 0.86)
Female	1.98 (0.36, 11.05)	3.48 (1.24, 9.75)	0.57 (0.08, 4.22)
Baseline FVC percent predicted			
<=70%	0.92 (0.20, 4.21)	3.69 (1.63, 8.36)	0.25 (0.04, 1.40)
>70%	1.27 (0.35, 4.63)	5.16 (1.45, 18.40)	0.25 (0.04, 1.51)
Baseline HRCT pattern			
UIP-like	1.03 (0.35, 3.00)	3.26 (1.43, 7.45)	0.31 (0.08, 1.22)
Other fibrotic patterns	1.97 (0.17, 22.26)	6.34 (1.81, 22.23)	0.31 (0.02, 4.76)
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe	1.53 (0.13, 17.48)	1.96 (0.58, 6.65)	0.78 (0.05, 11.92)
Asia	0.99 (0.33, 2.93)	12.63 (3.64, 43.87)	0.08 (0.02, 0.41)
Canada and USA	NC (NC, NC)	1.40 (0.30, 6.49)	NC (NC, NC)
Rest of the World	NC (NC, NC)	2.53 (0.22, 29.29)	NC (NC, NC)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders
PT: Hepatic function abnormal

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.26, 3.98)	6.31 (1.89, 21.13)	0.16 (0.03, 1.00)	0.0494	
Age					
<65 years					
>=65 years					
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like					
Other fibrotic patterns					
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders
PT: Hepatic function abnormal

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.02 (-2.94, 2.99)	4.82 (2.12, 7.52)	-4.80 (-8.81, -0.79)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Hepatobiliary disorders
PT: Hepatic function abnormal

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.25, 4.09)	6.64 (1.94, 22.65)	0.15 (0.02, 0.98)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.52, 1.97)	2.34 (1.47, 3.72)	0.43 (0.19, 0.97)	0.0424	
Age					0.2911
<65 years	1.57 (0.39, 6.37)	9.58 (2.30, 39.89)	0.16 (0.02, 1.21)	0.0764	
>=65 years	0.89 (0.41, 1.92)	1.66 (0.99, 2.77)	0.54 (0.21, 1.35)	0.1875	
Sex					0.9314
Male	0.87 (0.27, 2.77)	2.05 (1.10, 3.85)	0.42 (0.11, 1.58)	0.2018	
Female	1.07 (0.47, 2.41)	2.72 (1.36, 5.42)	0.39 (0.14, 1.14)	0.0867	
Baseline FVC percent predicted					0.5933
<=70%	0.92 (0.41, 2.10)	2.35 (1.27, 4.35)	0.39 (0.14, 1.10)	0.0743	
>70%	1.47 (0.44, 4.88)	2.33 (1.15, 4.72)	0.63 (0.16, 2.53)	0.5136	
Baseline HRCT pattern					0.5102
UIP-like	0.94 (0.43, 2.07)	2.64 (1.47, 4.74)	0.36 (0.13, 0.95)	0.0389	
Other fibrotic patterns	1.21 (0.34, 4.31)	1.87 (0.87, 4.04)	0.65 (0.15, 2.85)	0.5650	
Underlying ILD diagnosis					0.3648
iNSIP	1.45 (0.28, 7.56)	3.18 (0.92, 11.00)	0.46 (0.06, 3.60)	0.4580	
Unclassifiable IIP	0.45 (0.09, 2.31)	3.39 (1.02, 11.24)	0.13 (0.02, 1.01)	0.0513	
HP	0.43 (0.05, 3.96)	0.73 (0.33, 1.63)	0.59 (0.06, 6.20)	0.6609	
Autoimmune ILD	1.01 (0.31, 3.35)	16.10 (2.17, 119.16)	0.06 (0.01, 0.65)	0.0201	
Other ILD	2.88 (0.57, 14.54)	2.64 (0.73, 9.50)	1.09 (0.14, 8.59)	0.9342	
Region					0.6931
Europe	2.26 (0.24, 20.96)	2.59 (1.12, 5.98)	0.87 (0.08, 9.42)	0.9115	
Asia	0.72 (0.30, 1.72)	2.41 (1.13, 5.13)	0.30 (0.09, 0.95)	0.0405	
Canada and USA	0.44 (0.05, 3.64)	1.80 (0.81, 4.01)	0.24 (0.03, 2.34)	0.2214	
Rest of the World	9.61 (0.53, 173.44)	NC (NC, NC)	NC (NC, NC)	NC	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.07 (-4.93, 5.08)	9.32 (4.49, 14.14)	-9.25 (-16.20, -2.30)
Age			
<65 years	2.07 (-5.17, 9.40)	14.17 (7.70, 20.65)	-12.11 (-21.86, -2.36)
>=65 years	-1.02 (-8.02, 6.06)	6.58 (-0.05, 13.21)	-7.60 (-17.27, 2.07)
Sex			
Male	-0.67 (-6.88, 5.59)	7.74 (1.24, 14.24)	-8.41 (-17.41, 0.60)
Female	0.66 (-7.65, 8.90)	11.15 (3.97, 18.34)	-10.50 (-21.46, 0.46)
Baseline FVC percent predicted			
<=70%	-0.79 (-8.85, 7.82)	9.08 (2.87, 15.29)	-9.88 (-20.27, 0.52)
>70%	1.80 (-4.53, 7.82)	9.67 (2.02, 17.31)	-7.87 (-17.69, 1.96)
Baseline HRCT pattern			
UIP-like	-0.45 (-6.52, 5.65)	11.17 (4.90, 17.43)	-11.62 (-20.35, -2.88)
Other fibrotic patterns	1.33 (-8.42, 11.06)	6.29 (-1.20, 13.78)	-4.97 (-17.25, 7.32)
Underlying ILD diagnosis			
iNSIP	2.27 (-10.05, 12.90)	10.71 (0.29, 21.13)	-8.43 (-23.93, 7.06)
Unclassifiable IIP	-6.11 (-20.77, 7.20)	14.31 (2.46, 26.17)	-20.42 (-38.76, -2.09)
HP	-4.36 (-17.28, 9.90)	-3.89 (-13.77, 5.99)	-0.47 (-17.27, 16.33)
Autoimmune ILD	0.10 (-9.23, 9.50)	17.16 (8.50, 25.81)	-17.06 (-29.81, -4.30)
Other ILD	10.44 (-5.39, 29.53)	11.44 (-3.04, 25.93)	-1.00 (-23.68, 21.68)
Region			
Europe	3.16 (-7.87, 13.09)	7.58 (1.34, 13.81)	-4.42 (-16.60, 7.77)
Asia	-2.90 (-11.02, 5.07)	14.79 (2.98, 26.60)	-17.69 (-31.98, -3.40)
Canada and USA	-7.45 (-24.50, 15.12)	9.30 (-3.02, 21.62)	-16.75 (-40.08, 6.58)
Rest of the World	9.30 (-0.24, 21.60)	3.13 (-2.90, 9.15)	6.18 (-6.30, 18.65)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 1 Indirect treatment comparison for the proportion of patients with specific AEs over the whole trial

SOC: Metabolism and nutrition disorders
PT: Decreased appetite

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.49, 2.07)	2.60 (1.56, 4.35)	0.39 (0.16, 0.94)
Age			
<65 years	1.61 (0.37, 6.94)	11.19 (2.57, 48.65)	0.14 (0.02, 1.14)
>=65 years	0.88 (0.38, 2.04)	1.79 (0.99, 3.22)	0.49 (0.18, 1.38)
Sex			
Male	0.86 (0.26, 2.92)	2.24 (1.12, 4.50)	0.39 (0.09, 1.57)
Female	1.08 (0.44, 2.65)	3.09 (1.44, 6.62)	0.35 (0.11, 1.14)
Baseline FVC percent predicted			
<=70%	0.91 (0.37, 2.27)	2.60 (1.32, 5.14)	0.35 (0.11, 1.09)
>70%	1.50 (0.43, 5.26)	2.61 (1.19, 5.71)	0.57 (0.13, 2.53)
Baseline HRCT pattern			
UIP-like	0.94 (0.40, 2.19)	3.00 (1.57, 5.74)	0.31 (0.11, 0.91)
Other fibrotic patterns	1.23 (0.31, 4.80)	2.01 (0.86, 4.70)	0.61 (0.12, 3.05)
Underlying ILD diagnosis			
iNSIP	1.49 (0.26, 8.56)	3.58 (0.94, 13.71)	0.42 (0.05, 3.77)
Unclassifiable IIP	0.42 (0.07, 2.45)	3.99 (1.07, 14.90)	0.11 (0.01, 0.95)
HP	0.41 (0.04, 4.19)	0.70 (0.28, 1.74)	0.59 (0.05, 7.09)
Autoimmune ILD	1.02 (0.28, 3.67)	19.48 (2.51, 151.17)	0.05 (0.00, 0.59)
Other ILD	3.24 (0.54, 19.25)	3.01 (0.72, 12.60)	1.08 (0.11, 10.58)
Region			
Europe	2.34 (0.23, 23.38)	2.81 (1.15, 6.91)	0.83 (0.07, 9.83)
Asia	0.70 (0.27, 1.81)	2.88 (1.18, 7.02)	0.24 (0.07, 0.89)
Canada and USA	0.41 (0.04, 3.96)	2.01 (0.78, 5.17)	0.20 (0.02, 2.37)
Rest of the World	NC (NC, NC)	NC (NC, NC)	NC (NC, NC)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 2 Indirect treatment comparison for the proportion of patients with specific serious AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.33, 3.08)	2.49 (0.98, 6.35)	0.40 (0.09, 1.74)	0.2234	
Age					
<65 years					
>=65 years					
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like					
Other fibrotic patterns					
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 2 Indirect treatment comparison for the proportion of patients with specific serious AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.02 (-3.38, 3.45)	2.71 (0.05, 5.36)	-2.68 (-7.00, 1.64)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 2 Indirect treatment comparison for the proportion of patients with specific serious AEs over the whole trial

SOC: Gastrointestinal disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.01 (0.32, 3.18)	2.56 (0.98, 6.69)	0.39 (0.09, 1.76)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 2 Indirect treatment comparison for the proportion of patients with specific serious AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	0.25 (0.03, 2.24)	2.99 (0.97, 9.18)	0.08 (0.01, 0.98)	0.0483	
Age					
<65 years					
>=65 years					
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like					
Other fibrotic patterns					
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 2 Indirect treatment comparison for the proportion of patients with specific serious AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	-1.35 (-4.11, 1.00)	2.41 (0.08, 4.73)	-3.75 (-7.21, -0.30)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 2 Indirect treatment comparison for the proportion of patients with specific serious AEs over the whole trial

SOC: Hepatobiliary disorders

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	0.25 (0.03, 2.24)	3.07 (0.98, 9.61)	0.08 (0.01, 0.97)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 3 Indirect treatment comparison for the proportion of patients with Diarrhoea with CTCAE grade <3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.55 (1.09, 2.22)	2.61 (2.12, 3.22)	0.59 (0.39, 0.90)	0.0138	
Age					0.0086
<65 years	0.94 (0.51, 1.76)	3.52 (2.37, 5.24)	0.27 (0.13, 0.56)	0.0005	
>=65 years	2.01 (1.29, 3.14)	2.25 (1.76, 2.89)	0.89 (0.54, 1.49)	0.6673	
Sex					0.5288
Male	1.38 (0.84, 2.25)	2.63 (1.99, 3.47)	0.52 (0.30, 0.92)	0.0243	
Female	1.77 (1.05, 3.01)	2.59 (1.88, 3.56)	0.69 (0.37, 1.27)	0.2298	
Baseline FVC percent predicted					0.2537
<=70%	1.37 (0.87, 2.16)	2.75 (2.08, 3.65)	0.50 (0.29, 0.85)	0.0107	
>70%	2.00 (1.11, 3.62)	2.44 (1.78, 3.34)	0.82 (0.42, 1.61)	0.5654	
Baseline HRCT pattern					0.2833
UIP-like	1.69 (1.11, 2.55)	2.43 (1.89, 3.14)	0.69 (0.43, 1.13)	0.1386	
Other fibrotic patterns	1.23 (0.61, 2.51)	2.98 (2.06, 4.30)	0.41 (0.19, 0.92)	0.0312	
Underlying ILD diagnosis					0.7394
iNSIP	1.58 (0.66, 3.79)	3.02 (1.75, 5.21)	0.52 (0.19, 1.47)	0.2177	
Unclassifiable IIP	1.98 (0.76, 5.15)	3.56 (1.92, 6.61)	0.56 (0.18, 1.74)	0.3132	
HP	1.63 (0.73, 3.61)	2.12 (1.47, 3.05)	0.77 (0.32, 1.84)	0.5534	
Autoimmune ILD	1.08 (0.58, 2.02)	2.49 (1.67, 3.71)	0.43 (0.21, 0.91)	0.0273	
Other ILD	2.88 (1.12, 7.41)	2.83 (1.57, 5.10)	1.02 (0.33, 3.10)	0.9749	
Region					0.2353
Europe	2.42 (0.97, 6.04)	3.29 (2.28, 4.73)	0.73 (0.27, 1.97)	0.5398	
Asia	1.09 (0.64, 1.84)	2.66 (1.80, 3.91)	0.41 (0.21, 0.79)	0.0073	
Canada and USA	1.76 (0.75, 4.18)	1.43 (1.01, 2.04)	1.23 (0.49, 3.12)	0.6626	
Rest of the World	2.50 (1.05, 5.91)	6.91 (2.22, 21.48)	0.36 (0.09, 1.50)	0.1615	

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 3 Indirect treatment comparison for the proportion of patients with Diarrhoea with CTCAE grade <3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	9.71 (1.92, 17.36)	38.48 (31.54, 45.43)	-28.78 (-39.16, -18.39)
Age			
<65 years	-1.10 (-12.92, 10.60)	45.85 (35.32, 56.38)	-46.94 (-62.73, -31.16)
>=65 years	16.79 (6.51, 26.71)	34.00 (24.86, 43.13)	-17.21 (-30.83, -3.59)
Sex			
Male	7.16 (-3.72, 17.92)	40.50 (31.06, 49.95)	-33.34 (-47.70, -18.98)
Female	12.40 (1.24, 23.17)	36.10 (25.87, 46.32)	-23.69 (-38.69, -8.70)
Baseline FVC percent predicted			
<=70%	8.17 (-3.54, 19.95)	39.96 (30.97, 48.95)	-31.78 (-46.58, -16.99)
>70%	12.50 (2.22, 22.21)	36.40 (25.48, 47.33)	-23.90 (-38.71, -9.09)
Baseline HRCT pattern			
UIP-like	12.15 (2.70, 21.38)	36.89 (27.99, 45.80)	-24.74 (-37.65, -11.84)
Other fibrotic patterns	4.02 (-9.68, 17.48)	41.10 (30.04, 52.17)	-37.08 (-54.60, -19.56)
Underlying ILD diagnosis			
iNSIP	8.64 (-8.21, 23.62)	39.70 (24.07, 55.33)	-31.07 (-53.38, -8.76)
Unclassifiable IIP	13.61 (-5.04, 30.82)	46.06 (30.20, 61.92)	-32.45 (-56.39, -8.51)
HP	12.82 (-7.78, 33.18)	32.69 (18.65, 46.73)	-19.87 (-44.70, 4.96)
Autoimmune ILD	1.73 (-11.91, 15.34)	37.20 (23.34, 51.05)	-35.46 (-54.90, -16.03)
Other ILD	26.11 (3.89, 46.89)	42.53 (22.86, 62.21)	-16.42 (-45.56, 12.72)
Region			
Europe	17.69 (0.39, 32.78)	42.02 (32.08, 51.96)	-24.33 (-43.34, -5.33)
Asia	1.68 (-9.22, 12.53)	45.79 (31.79, 59.79)	-44.10 (-61.83, -26.38)
Canada and USA	17.84 (-8.47, 43.41)	17.63 (1.08, 34.17)	0.21 (-30.55, 30.98)
Rest of the World	19.51 (2.05, 35.97)	45.43 (26.23, 64.64)	-25.92 (-51.54, -0.30)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 3 Indirect treatment comparison for the proportion of patients with Diarrhoea with CTCAE grade <3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	1.76 (1.12, 2.77)	5.28 (3.77, 7.39)	0.33 (0.19, 0.59)
Age			
<65 years	0.93 (0.43, 2.01)	8.01 (4.50, 14.27)	0.12 (0.04, 0.30)
>=65 years	2.52 (1.42, 4.48)	4.22 (2.78, 6.43)	0.60 (0.29, 1.22)
Sex			
Male	1.51 (0.81, 2.83)	5.70 (3.60, 9.03)	0.26 (0.12, 0.58)
Female	2.08 (1.07, 4.05)	4.86 (2.96, 7.97)	0.43 (0.19, 0.98)
Baseline FVC percent predicted			
<=70%	1.53 (0.83, 2.84)	5.71 (3.66, 8.89)	0.27 (0.13, 0.57)
>70%	2.33 (1.15, 4.74)	4.75 (2.84, 7.97)	0.49 (0.20, 1.18)
Baseline HRCT pattern			
UIP-like	1.98 (1.16, 3.38)	4.84 (3.17, 7.37)	0.41 (0.21, 0.81)
Other fibrotic patterns	1.30 (0.54, 3.12)	6.19 (3.53, 10.85)	0.21 (0.07, 0.59)
Underlying ILD diagnosis			
iNSIP	1.75 (0.60, 5.10)	5.97 (2.67, 13.34)	0.29 (0.08, 1.12)
Unclassifiable IIP	2.35 (0.73, 7.59)	8.12 (3.36, 19.65)	0.29 (0.07, 1.26)
HP	1.94 (0.65, 5.74)	3.94 (2.09, 7.43)	0.49 (0.14, 1.73)
Autoimmune ILD	1.11 (0.50, 2.46)	4.94 (2.56, 9.52)	0.22 (0.08, 0.63)
Other ILD	4.13 (1.20, 14.25)	6.35 (2.39, 16.82)	0.65 (0.13, 3.15)
Region			
Europe	3.03 (1.00, 9.14)	6.78 (4.00, 11.49)	0.45 (0.13, 1.52)
Asia	1.11 (0.57, 2.15)	7.23 (3.56, 14.69)	0.15 (0.06, 0.40)
Canada and USA	2.30 (0.64, 8.31)	2.04 (1.03, 4.04)	1.13 (0.26, 4.83)
Rest of the World	3.22 (1.10, 9.38)	13.60 (3.47, 53.37)	0.24 (0.04, 1.34)

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 4 Indirect treatment comparison for the proportion of patients with Diarrhoea with CTCAE grade >=3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk ratio (95% CI)	Nin 150bid vs Placebo Risk ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk ratio (95% CI)	p-value	Interaction p-value
Overall	1.01 (0.02, 50.63)	5.48 (2.33, 12.91)	0.18 (0.00, 10.13)	0.4078	
Age					
<65 years					
>=65 years					
Sex					
Male					
Female					
Baseline FVC percent predicted					
<=70%					
>70%					
Baseline HRCT pattern					
UIP-like					
Other fibrotic patterns					
Underlying ILD diagnosis					
iNSIP					
Unclassifiable IIP					
HP					
Autoimmune ILD					
Other ILD					
Region					
Europe					
Asia					
Canada and USA					
Rest of the World					

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 4 Indirect treatment comparison for the proportion of patients with Diarrhoea with CTCAE grade >=3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Risk difference (95% CI)	Nin 150bid vs Placebo Risk difference (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Risk difference (95% CI)
Overall	0.00 (NC, NC)	8.13 (4.60, 11.65)	-8.13 (NC, NC)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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Table M.1.3.1: 4 Indirect treatment comparison for the proportion of patients with Diarrhoea with CTCAE grade >=3 over the whole trial

SOC: Gastrointestinal disorders
PT: Diarrhoea

Subgroup Category	Nera 18mg vs Placebo Odds ratio (95% CI)	Nin 150bid vs Placebo Odds ratio (95% CI)	Indirect Bucher comparison Nera 18mg vs Nin 150bid Odds ratio (95% CI)
Overall	NC (NC, NC)	5.98 (2.47, 14.47)	NC (NC, NC)
Age			
<65 years			
>=65 years			
Sex			
Male			
Female			
Baseline FVC percent predicted			
<=70%			
>70%			
Baseline HRCT pattern			
UIP-like			
Other fibrotic patterns			
Underlying ILD diagnosis			
iNSIP			
Unclassifiable IIP			
HP			
Autoimmune ILD			
Other ILD			
Region			
Europe			
Asia			
Canada and USA			
Rest of the World			

Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0023. Estimates for the comparison of Nintedanib versus Placebo are based on trial 1199-0247.
An indirect treatment comparison is only performed if both contributing comparisons are available. NC: Not calculable.
Estimates for the comparison of Nintedanib versus Placebo are only presented if a corresponding estimate for Nerandomilast versus Placebo is available. Interaction p-value based on the Cochran's Q-Test for homogeneity (treatment by subgroup interaction).
Subgroup analyses for the ITC are only performed in case of a significant p-value for the overall comparison (at 5% level).

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