Separater Anhang 4-G: Ergänzende Unterlagen

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1 Auswertungen zu Nerandomilast (als zu bewertendes Arzneimittel)

1.1 Auswertungen zur Studie FIBRONEER®-IPF

1.1.1 Database Lock 2

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H.1 Nerandomilast IPF HTA Analysis: DBL2 Analysis

H.1.1 Population with AF background

H.1.1.1 Efficacy Analysis

H.1.1.1.1 Time to event analyses

H.1.1.1.1.1 Analyses of composite endpoints

H.1.1.1.1.1.1 Time to first confirmed or suspected acute IPF exacerbation, respiratory hospitalisation or death

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

Subgroup Category	Placebo N	Placebo n (e/ h/ d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n (e/ h/ d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	306	71 (27/ 35/ 9)	23.2	18.53	305	74 (27/ 40/ 7)	24.3	19.89	1.15	(0.83, 1.59)	0.4095	
Age												0.6154
<65 years	69	13 (4/ 8/ 1)	18.8	14.15	63	11 (3/ 8/ 0)	17.5	13.76	0.96	(0.43, 2.14)	0.9179	
>=65 years	237	58 (23/ 27/ 8)	24.5	19.92	242	63 (24/ 32/ 7)	26.0	21.57	1.20	(0.84, 1.72)	0.3162	
Sex												0.4977
Male	269	68 (26/ 33/ 9)	25.3	20.47	255	65 (24/ 35/ 6)	25.5	21.00	1.14	(0.81, 1.61)	0.4407	
Female	37	3 (1/ 2/ 0)	8.1	5.89	50	9 (3/ 5/ 1)	18.0	14.38	1.83	(0.49, 6.78)	0.3674	
Baseline FVC percent predicted												0.1091
<=70%	109	34 (14/ 16/ 4)	31.2	26.48	112	44 (16/ 23/ 5)	39.3	36.90	1.44	(0.92, 2.26)	0.1105	
>70%	197	37 (13/ 19/ 5)	18.8	14.53	193	30 (11/ 17/ 2)	15.5	11.87	0.84	(0.52, 1.36)	0.4849	
Type of AF therapy												0.5620
Nintedanib	173	41 (16/ 20/ 5)	23.7	18.85	178	43 (14/ 24/ 5)	24.2	20.04	1.06	(0.69, 1.62)	0.7974	
Pirfenidone	133	30 (11/ 15/ 4)	22.6	18.12	127	31 (13/ 16/ 2)	24.4	19.68	1.29	(0.78, 2.13)	0.3287	
Region												0.2365
Europe	136	22 (11/ 10/ 1)	16.2	12.70	136	34 (14/ 16/ 4)	25.0	20.56	1.57	(0.92, 2.69)	0.0981	
Asia	72	21 (8/ 11/ 2)	29.2	24.00	79	20 (6/ 12/ 2)	25.3	20.89	1.11	(0.60, 2.06)	0.7481	
Canada and USA	75	23 (8/ 11/ 4)	30.7	25.00	56	11 (3/ 7/ 1)	19.6	15.07	0.63	(0.31, 1.30)	0.2121	
Rest of the World	23	5 (0/ 3/ 2)	21.7	16.51	34	9 (4/ 5/ 0)	26.5	23.67	1.55	(0.52, 4.67)	0.4347	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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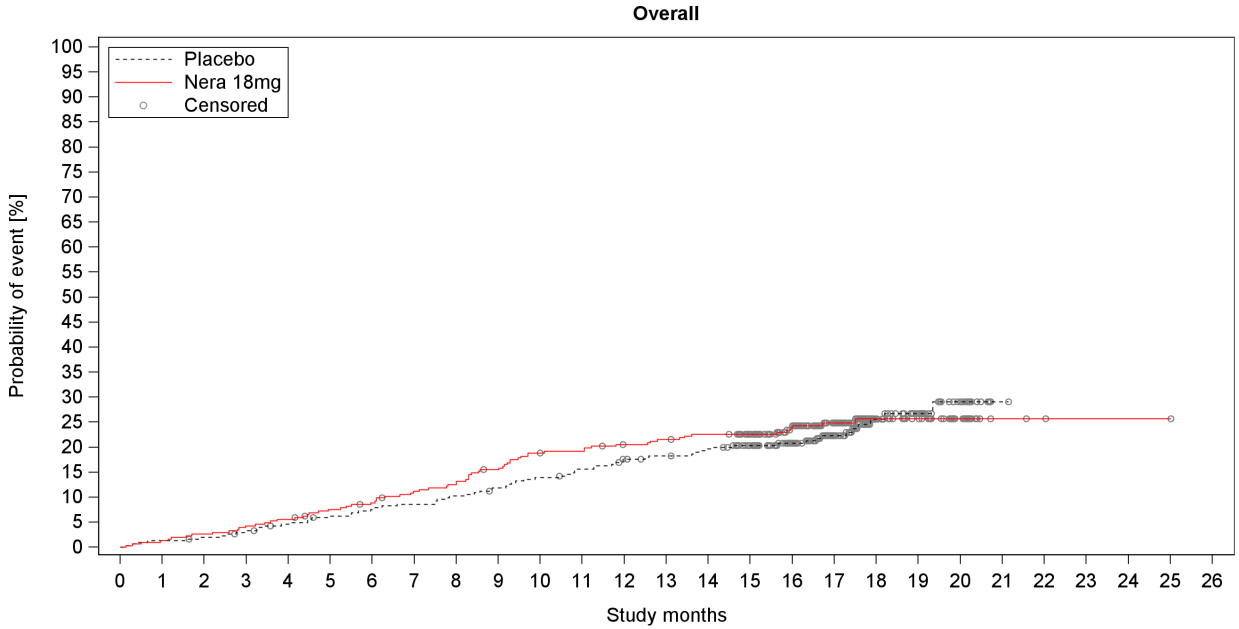

Number at risk (percentage relative to baseline)

Placebo	306	302	299	295	288	282	278	275	270	264	258	252	243	239	234	216	181	126	66	45	18	1	0	0	0	0	0
%	100.0	98.7	97.7	96.4	94.1	92.2	90.8	89.9	88.2	86.3	84.3	82.4	79.4	78.1	76.5	70.6	59.2	41.2	21.6	14.7	5.9	0.3	0.0	0.0	0.0	0.0	0.0
Nera 18mg	305	301	297	292	288	280	275	267	263	253	243	241	233	230	225	207	177	125	54	35	18	3	2	1	1	1	0
%	100.0	98.7	97.4	95.7	94.4	91.8	90.2	87.5	86.2	83.0	79.7	79.0	76.4	75.4	73.8	67.9	58.0	41.0	17.7	11.5	5.9	1.0	0.7	0.3	0.3	0.3	0.0

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

Placebo	0	0	1	2	4	5	5	5	5	6	6	7	10	12	13	29	63	115	171	191	217	234	235	235	235	235	235
%	0.0	0.0	0.3	0.7	1.3	1.6	1.6	1.6	1.6	2.0	2.0	2.3	3.3	3.9	4.2	9.5	20.6	37.6	55.9	62.4	70.9	76.5	76.8	76.8	76.8	76.8	76.8
Nera 18mg	0	0	0	0	0	2	3	4	4	5	5	6	10	10	12	30	57	107	177	196	213	228	229	230	230	230	231
%	0.0	0.0	0.0	0.0	0.0	0.7	1.0	1.3	1.3	1.6	1.6	2.0	3.3	3.3	3.9	9.8	18.7	35.1	58.0	64.3	69.8	74.8	75.1	75.4	75.4	75.4	75.7

Study: 1305-0014

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

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Figure H.1.1.1.1.1: 1

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H.1.1.1.1.1.2 Time to first confirmed acute IPF exacerbation or death

Table H.1.1.1.1.1.2: 1 Cox model for time to first confirmed acute IPF exacerbation or death over the whole trial - 18mg - FAS (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	306	44 (26/ 18)	14.4	10.85	305	39 (23/ 16)	12.8	9.75	0.92	(0.60, 1.42)	0.7172	
Age												0.7652
<65 years	69	7 (5/ 2)	10.1	7.36	63	5 (3/ 2)	7.9	5.95	0.79	(0.25, 2.48)	0.6799	
>=65 years	237	37 (21/ 16)	15.6	11.91	242	34 (20/ 14)	14.0	10.76	0.95	(0.59, 1.51)	0.8237	
Sex												0.2399
Male	269	43 (25/ 18)	16.0	12.16	255	33 (20/ 13)	12.9	9.88	0.88	(0.56, 1.38)	0.5696	
Female	37	1 (1/ 0)	2.7	1.93	50	6 (3/ 3)	12.0	9.12	3.22	(0.39, 26.93)	0.2799	
Baseline FVC percent predicted												0.7488
<=70%	109	24 (15/ 9)	22.0	17.45	112	23 (13/ 10)	20.5	17.06	0.95	(0.53, 1.68)	0.8531	
>70%	197	20 (11/ 9)	10.2	7.46	193	16 (10/ 6)	8.3	6.03	0.82	(0.42, 1.59)	0.5577	
Type of AF therapy												0.1734
Nintedanib	173	25 (15/ 10)	14.5	10.88	178	18 (12/ 6)	10.1	7.78	0.70	(0.38, 1.28)	0.2434	
Pirfenidone	133	19 (11/ 8)	14.3	10.80	127	21 (11/ 10)	16.5	12.46	1.28	(0.68, 2.39)	0.4440	
Region												0.2559
Europe	136	15 (11/ 4)	11.0	8.34	136	20 (11/ 9)	14.7	11.22	1.26	(0.65, 2.47)	0.4939	
Asia	72	14 (10/ 4)	19.4	15.21	79	7 (5/ 2)	8.9	6.70	0.50	(0.20, 1.25)	0.1375	
Canada and USA	75	13 (5/ 8)	17.3	12.91	56	7 (3/ 4)	12.5	9.11	0.70	(0.28, 1.76)	0.4500	
Rest of the World	23	2 (0/ 2)	8.7	6.06	34	5 (4/ 1)	14.7	12.39	2.29	(0.44, 11.93)	0.3240	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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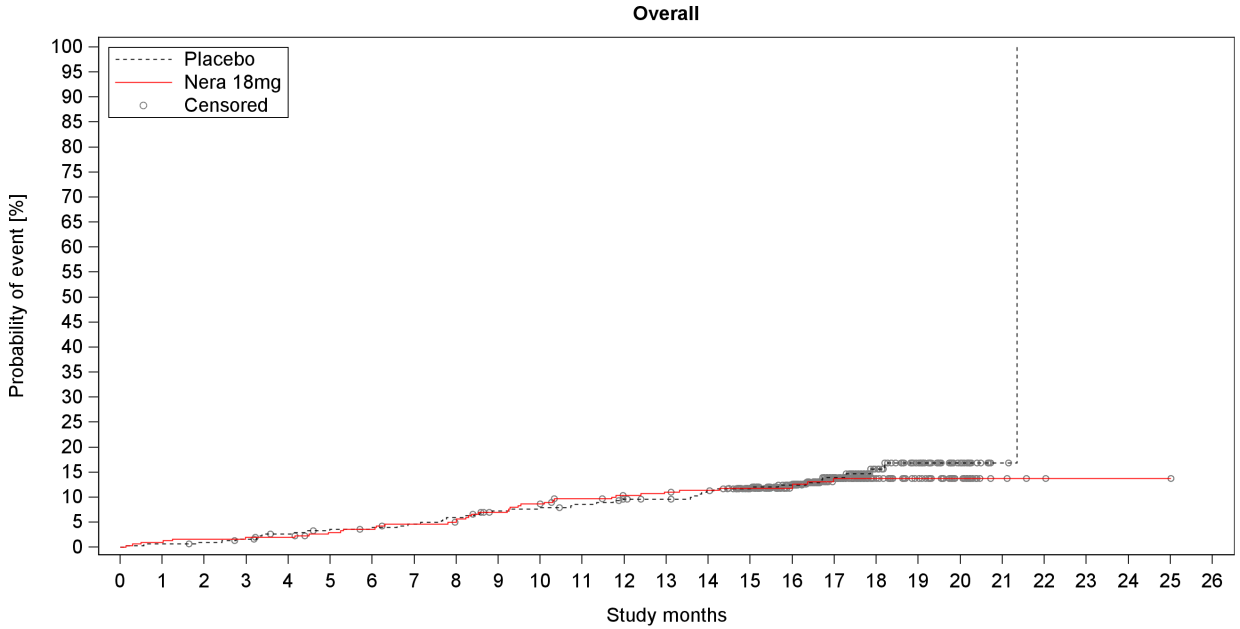

Number at risk (percentage relative to baseline)																										
Placebo	306	304	302	299	294	290	290	287	283	278	276	273	267	265	259	240	203	141	77	54	20	2	0	0	0	0	0
%	100.0	99.3	98.7	97.7	96.1	94.8	94.8	93.8	92.5	90.8	90.2	89.2	87.3	86.6	84.6	78.4	66.3	46.1	25.2	17.6	6.5	0.7	0.0	0.0	0.0	0.0	0.0
Nera 18mg	305	302	300	299	298	293	290	286	284	275	270	264	258	256	253	232	201	143	67	43	23	4	2	1	1	1	0
%	100.0	99.0	98.4	98.0	97.7	96.1	95.1	93.8	93.1	90.2	88.5	86.6	84.6	83.9	83.0	76.1	65.9	46.9	22.0	14.1	7.5	1.3	0.7	0.3	0.3	0.3	0.0
Number censored (percentage relative to number at risk at baseline)																											
Placebo	0	0	1	2	4	5	5	5	5	6	6	7	10	12	13	31	66	125	187	209	243	261	262	262	262	262	262
%	0.0	0.0	0.3	0.7	1.3	1.6	1.6	1.6	1.6	2.0	2.0	2.3	3.3	3.9	4.2	10.1	21.6	40.8	61.1	68.3	79.4	85.3	85.6	85.6	85.6	85.6	85.6
Nera 18mg	0	0	0	0	1	3	4	5	6	9	9	12	16	16	18	38	69	123	199	223	243	262	264	265	265	265	266
%	0.0	0.0	0.0	0.0	0.3	1.0	1.3	1.6	2.0	3.0	3.0	3.9	5.2	5.2	5.9	12.5	22.6	40.3	65.2	73.1	79.7	85.9	86.6	86.9	86.9	86.9	87.2

Study: 1305-0014

Figure H.1.1.1.1.1.2: 1 Time to first confirmed acute IPF exacerbation or death over the whole trial, Kaplan-Meier estimate - 18mg - FAS (AF background)

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Figure H.1.1.1.1.2: 1

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H.1.1.1.1.1.3 Time to first confirmed or suspected acute IPF exacerbation or death

Table H.1.1.1.1.1.3: 1 Cox model for time to first confirmed or suspected acute IPF exacerbation or death over the whole trial - 18mg - FAS (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	306	47 (30/ 17)	15.4	11.64	305	42 (29/ 13)	13.8	10.55	0.94	(0.62, 1.42)	0.7540	
Age												0.7410
<65 years	69	7 (5/ 2)	10.1	7.36	63	5 (3/ 2)	7.9	5.95	0.78	(0.25, 2.47)	0.6741	
>=65 years	237	40 (25/ 15)	16.9	12.96	242	37 (26/ 11)	15.3	11.78	0.96	(0.61, 1.51)	0.8658	
Sex												0.2528
Male	269	46 (29/ 17)	17.1	13.07	255	36 (26/ 10)	14.1	10.83	0.90	(0.58, 1.39)	0.6334	
Female	37	1 (1/ 0)	2.7	1.93	50	6 (3/ 3)	12.0	9.13	3.18	(0.38, 26.56)	0.2849	
Baseline FVC percent predicted												0.3054
<=70%	109	24 (15/ 9)	22.0	17.46	112	26 (18/ 8)	23.2	19.51	1.10	(0.63, 1.93)	0.7323	
>70%	197	23 (15/ 8)	11.7	8.63	193	16 (11/ 5)	8.3	6.04	0.71	(0.37, 1.34)	0.2895	
Type of AF therapy												0.1682
Nintedanib	173	27 (18/ 9)	15.6	11.81	178	20 (15/ 5)	11.2	8.66	0.72	(0.40, 1.28)	0.2562	
Pirfenidone	133	20 (12/ 8)	15.0	11.41	127	22 (14/ 8)	17.3	13.15	1.29	(0.70, 2.38)	0.4110	
Region												0.1990
Europe	136	16 (12/ 4)	11.8	8.92	136	21 (14/ 7)	15.4	11.86	1.25	(0.65, 2.39)	0.5071	
Asia	72	14 (10/ 4)	19.4	15.21	79	8 (6/ 2)	10.1	7.66	0.58	(0.24, 1.40)	0.2247	
Canada and USA	75	15 (8/ 7)	20.0	15.07	56	7 (3/ 4)	12.5	9.11	0.60	(0.25, 1.48)	0.2693	
Rest of the World	23	2 (0/ 2)	8.7	6.06	34	6 (6/ 0)	17.6	15.04	2.89	(0.58, 14.45)	0.1963	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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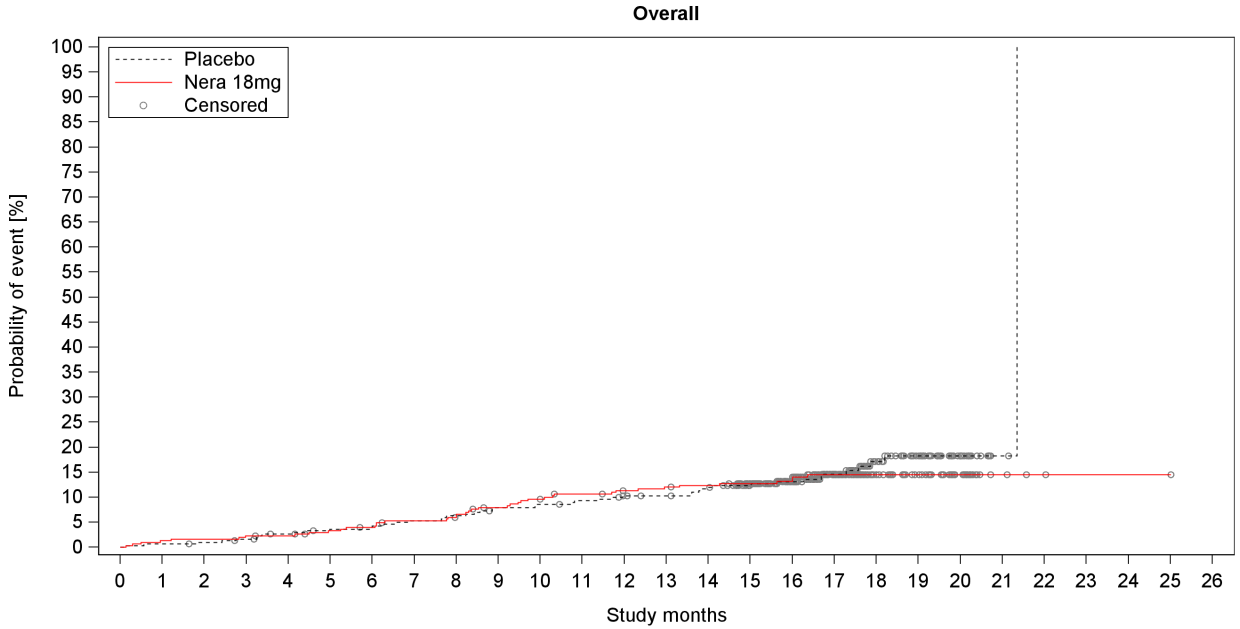

Number at risk (percentage relative to baseline)

Placebo	306	304	302	299	294	290	289	285	282	276	274	271	265	263	257	238	201	140	76	53	20	2	0	0	0	0	0
%	100.0	99.3	98.7	97.7	96.1	94.8	94.4	93.1	92.2	90.2	89.5	88.6	86.6	85.9	84.0	77.8	65.7	45.8	24.8	17.3	6.5	0.7	0.0	0.0	0.0	0.0	0.0
Nera 18mg	305	301	300	298	297	292	289	284	281	273	268	263	257	255	252	231	199	142	67	43	23	4	2	1	1	1	0
%	100.0	98.7	98.4	97.7	97.4	95.7	94.8	93.1	92.1	89.5	87.9	86.2	84.3	83.6	82.6	75.7	65.2	46.6	22.0	14.1	7.5	1.3	0.7	0.3	0.3	0.3	0.0

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

Placebo	0	0	1	2	4	5	5	5	5	6	6	7	10	12	13	31	66	124	185	207	240	258	259	259	259	259	259
%	0.0	0.0	0.3	0.7	1.3	1.6	1.6	1.6	1.6	2.0	2.0	2.3	3.3	3.9	4.2	10.1	21.6	40.5	60.5	67.6	78.4	84.3	84.6	84.6	84.6	84.6	84.6
Nera 18mg	0	0	0	0	1	3	4	5	6	8	8	10	14	14	16	36	67	121	196	220	240	259	261	262	262	262	263
%	0.0	0.0	0.0	0.0	0.3	1.0	1.3	1.6	2.0	2.6	2.6	3.3	4.6	4.6	5.2	11.8	22.0	39.7	64.3	72.1	78.7	84.9	85.6	85.9	85.9	85.9	86.2

Study: 1305-0014

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

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Figure H.1.1.1.1.1.3: 1

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H.1.1.1.1.1.4 Time to first respiratory hospitalisation or death

Table H.1.1.1.1.1.4: 1 Cox model for time to first respiratory hospitalisation or death over the whole trial - 18mg - FAS (AF 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	306	66 (55/ 11)	21.6	16.99	305	68 (61/ 7)	22.3	18.01	1.14	(0.81, 1.60)	0.4568	
Age												0.4027
<65 years	69	12 (11/ 1)	17.4	13.05	63	9 (9/ 0)	14.3	11.03	0.82	(0.35, 1.96)	0.6598	
>=65 years	237	54 (44/ 10)	22.8	18.21	242	59 (52/ 7)	24.4	19.93	1.23	(0.85, 1.78)	0.2729	
Sex												0.4918
Male	269	63 (52/ 11)	23.4	18.66	255	59 (53/ 6)	23.1	18.74	1.12	(0.79, 1.61)	0.5172	
Female	37	3 (3/ 0)	8.1	5.89	50	9 (8/ 1)	18.0	14.35	1.81	(0.49, 6.72)	0.3743	
Baseline FVC percent predicted												0.1722
<=70%	109	31 (26/ 5)	28.4	23.48	112	39 (34/ 5)	34.8	31.49	1.41	(0.88, 2.26)	0.1581	
>70%	197	35 (29/ 6)	17.8	13.64	193	29 (27/ 2)	15.0	11.43	0.87	(0.53, 1.43)	0.5942	
Type of AF therapy												0.9487
Nintedanib	173	37 (30/ 7)	21.4	16.78	178	41 (36/ 5)	23.0	18.89	1.13	(0.72, 1.76)	0.5964	
Pirfenidone	133	29 (25/ 4)	21.8	17.26	127	27 (25/ 2)	21.3	16.81	1.15	(0.68, 1.96)	0.5959	
Region												0.4184
Europe	136	21 (19/ 2)	15.4	12.02	136	31 (27/ 4)	22.8	18.47	1.49	(0.86, 2.60)	0.1569	
Asia	72	21 (19/ 2)	29.2	23.79	79	20 (18/ 2)	25.3	20.89	1.14	(0.61, 2.12)	0.6869	
Canada and USA	75	19 (14/ 5)	25.3	19.96	56	9 (8/ 1)	16.1	12.01	0.65	(0.29, 1.44)	0.2900	
Rest of the World	23	5 (3/ 2)	21.7	16.51	34	8 (8/ 0)	23.5	20.48	1.24	(0.40, 3.82)	0.7103	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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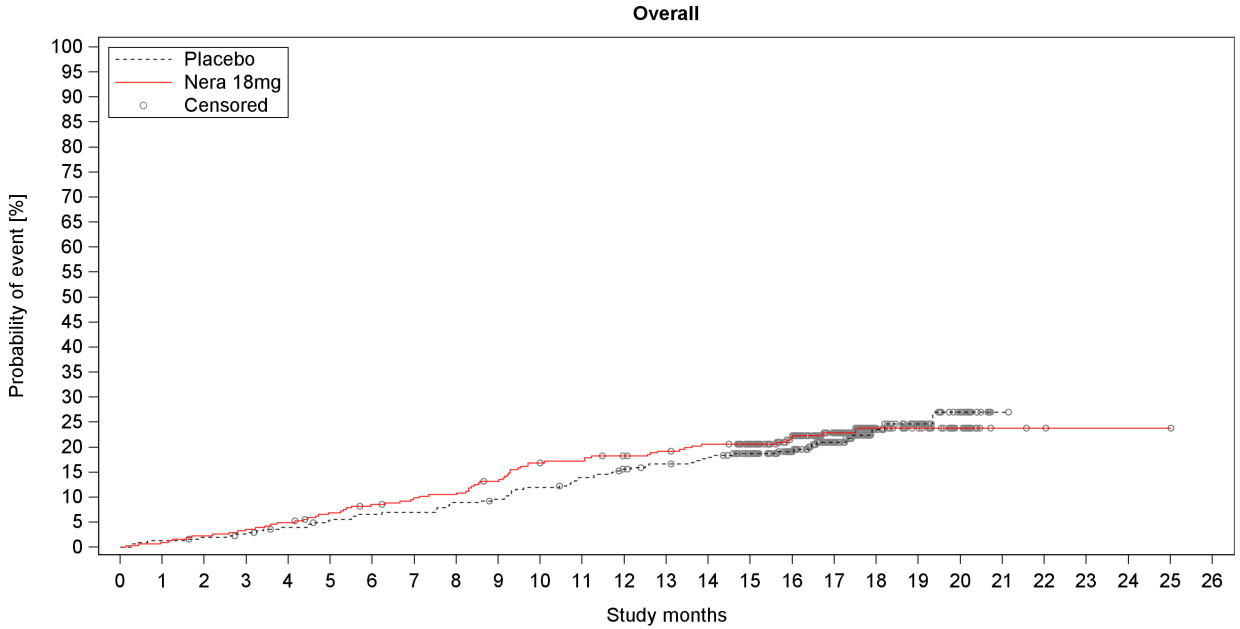

Number at risk (percentage relative to baseline)

Placebo	306	302	299	296	290	284	281	280	274	271	264	257	249	244	239	221	186	128	67	46	18	1	0	0	0	0	0
%	100.0	98.7	97.7	96.7	94.8	92.8	91.8	91.5	89.5	88.6	86.3	84.0	81.4	79.7	78.1	72.2	60.8	41.8	21.9	15.0	5.9	0.3	0.0	0.0	0.0	0.0	0.0
Nera 18mg	305	302	298	294	290	282	276	271	269	260	249	247	240	236	230	211	181	127	54	35	18	3	2	1	1	1	0
%	100.0	99.0	97.7	96.4	95.1	92.5	90.5	88.9	88.2	85.2	81.6	81.0	78.7	77.4	75.4	69.2	59.3	41.6	17.7	11.5	5.9	1.0	0.7	0.3	0.3	0.3	0.0

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

Placebo	0	0	1	2	4	5	5	5	5	6	6	7	10	12	13	29	63	117	175	195	222	239	240	240	240	240	240
%	0.0	0.0	0.3	0.7	1.3	1.6	1.6	1.6	1.6	2.0	2.0	2.3	3.3	3.9	4.2	9.5	20.6	38.2	57.2	63.7	72.5	78.1	78.4	78.4	78.4	78.4	78.4
Nera 18mg	0	0	0	0	0	2	3	4	4	5	5	6	10	11	13	32	59	111	183	202	219	234	235	236	236	236	237
%	0.0	0.0	0.0	0.0	0.0	0.7	1.0	1.3	1.3	1.6	1.6	2.0	3.3	3.6	4.3	10.5	19.3	36.4	60.0	66.2	71.8	76.7	77.0	77.4	77.4	77.4	77.7

Study: 1305-0014

Figure H.1.1.1.1.1.4: 1 Time to first respiratory hospitalisation or death over the whole trial, Kaplan-Meier estimate - 18mg - FAS (AF background)

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Figure H.1.1.1.1.1.4: 1

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

Table H.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 (AF 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	306	95 (86/ 9)	31.0	26.50	305	95 (90/ 5)	31.1	26.73	1.03	(0.78, 1.38)	0.8133	
Age												0.3310
<65 years	69	18 (17/ 1)	26.1	21.22	63	13 (13/ 0)	20.6	16.61	0.75	(0.37, 1.54)	0.4382	
>=65 years	237	77 (69/ 8)	32.5	28.14	242	82 (77/ 5)	33.9	29.58	1.11	(0.81, 1.52)	0.5147	
Sex												0.3691
Male	269	90 (81/ 9)	33.5	29.04	255	82 (78/ 4)	32.2	27.67	1.01	(0.75, 1.37)	0.9317	
Female	37	5 (5/ 0)	13.5	10.29	50	13 (12/ 1)	26.0	21.97	1.66	(0.59, 4.67)	0.3369	
Baseline FVC percent predicted												0.1627
<=70%	109	39 (34/ 5)	35.8	31.57	112	47 (43/ 4)	42.0	40.38	1.28	(0.84, 1.96)	0.2535	
>70%	197	56 (52/ 4)	28.4	23.83	193	48 (47/ 1)	24.9	20.08	0.85	(0.58, 1.25)	0.4148	
Type of AF therapy												0.5399
Nintedanib	173	51 (45/ 6)	29.5	24.71	178	57 (54/ 3)	32.0	27.76	1.12	(0.77, 1.63)	0.5587	
Pirfenidone	133	44 (41/ 3)	33.1	28.92	127	38 (36/ 2)	29.9	25.30	0.93	(0.60, 1.45)	0.7616	
Region												0.1259
Europe	136	36 (34/ 2)	26.5	22.15	136	42 (39/ 3)	30.9	26.51	1.17	(0.75, 1.83)	0.4925	
Asia	72	25 (23/ 2)	34.7	29.63	79	31 (29/ 2)	39.2	36.16	1.35	(0.79, 2.30)	0.2743	
Canada and USA	75	28 (25/ 3)	37.3	33.74	56	12 (12/ 0)	21.4	16.41	0.50	(0.26, 0.99)	0.0473	
Rest of the World	23	6 (4/ 2)	26.1	20.97	34	10 (10/ 0)	29.4	26.20	1.29	(0.46, 3.56)	0.6291	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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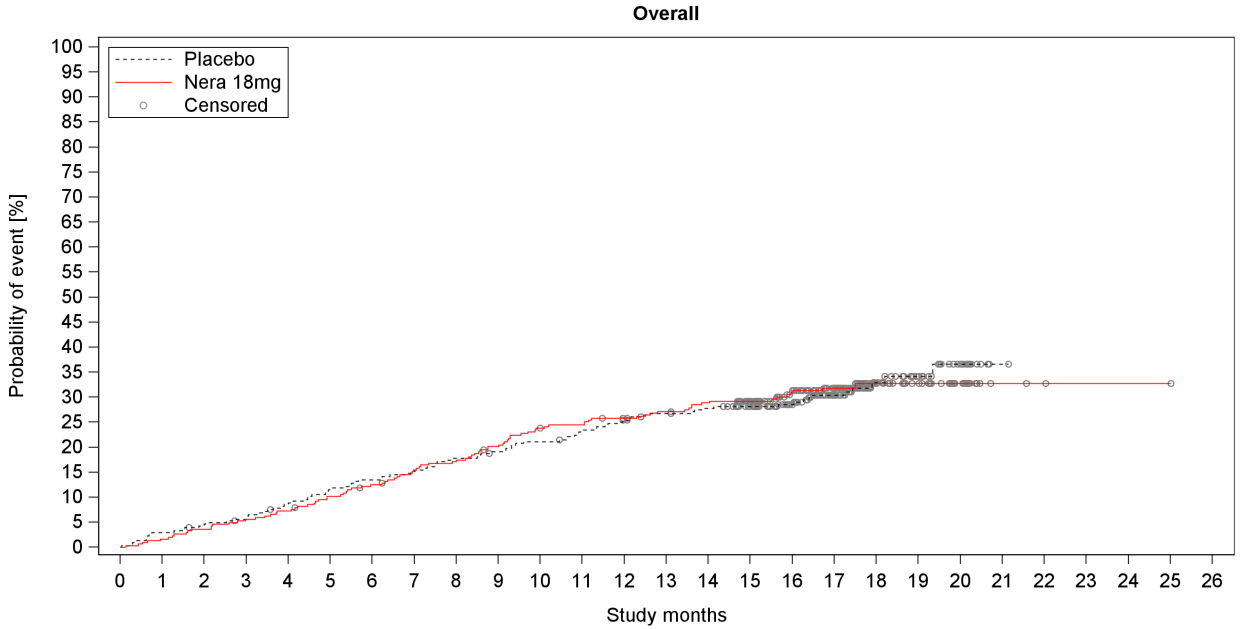

Number at risk (percentage relative to baseline)

Placebo	306	297	292	287	277	267	262	257	249	244	238	231	223	217	213	198	167	114	57	37	14	1	0	0	0	0	0
%	100.0	97.1	95.4	93.8	90.5	87.3	85.6	84.0	81.4	79.7	77.8	75.5	72.9	70.9	69.6	64.7	54.6	37.3	18.6	12.1	4.6	0.3	0.0	0.0	0.0	0.0	0.0
Nera 18mg	305	300	294	288	283	273	265	255	250	240	229	226	218	213	206	189	161	115	49	33	17	3	2	1	1	1	0
%	100.0	98.4	96.4	94.4	92.8	89.5	86.9	83.6	82.0	78.7	75.1	74.1	71.5	69.8	67.5	62.0	52.8	37.7	16.1	10.8	5.6	1.0	0.7	0.3	0.3	0.3	0.0

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

Placebo	0	0	1	2	3	3	3	3	3	4	4	5	6	8	9	23	53	102	156	175	197	210	211	211	211	211	211
%	0.0	0.0	0.3	0.7	1.0	1.0	1.0	1.0	1.0	1.3	1.3	1.6	2.0	2.6	2.9	7.5	17.3	33.3	51.0	57.2	64.4	68.6	69.0	69.0	69.0	69.0	69.0
Nera 18mg	0	0	0	0	0	1	2	3	3	4	4	5	9	10	12	28	52	96	161	177	193	207	208	209	209	209	210
%	0.0	0.0	0.0	0.0	0.0	0.3	0.7	1.0	1.0	1.3	1.3	1.6	3.0	3.3	3.9	9.2	17.0	31.5	52.8	58.0	63.3	67.9	68.2	68.5	68.5	68.5	68.9

Study: 1305-0014

Figure H.1.1.1.1.1.5: 1 Time to first non-elective hospitalisation for any cause or death over the whole trial, Kaplan-Meier estimate - 18mg - FAS (AF background)

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Figure H.1.1.1.1.5: 1

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H.1.1.1.1.2 Analyses of single endpoints

H.1.1.1.1.2.1 Time to death

Table H.1.1.1.1.2.1: 1 Cox model for time to death over the whole trial
- 18mg - FAS (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	306	30	9.8	7.15	305	23	7.5	5.54	0.81	(0.47, 1.40)	0.4481	
Age												0.6392
<65 years	69	4	5.8	4.13	63	2	3.2	2.31	0.55	(0.10, 3.02)	0.4941	
>=65 years	237	26	11.0	8.06	242	21	8.7	6.39	0.85	(0.48, 1.51)	0.5774	
Sex												0.1956
Male	269	29	10.8	7.89	255	17	6.7	4.88	0.68	(0.38, 1.25)	0.2149	
Female	37	1	2.7	1.93	50	6	12.0	9.00	2.95	(0.35, 24.78)	0.3196	
Baseline FVC percent predicted												0.4601
<=70%	109	16	14.7	11.06	112	15	13.4	10.49	0.97	(0.48, 1.97)	0.9304	
>70%	197	14	7.1	5.10	193	8	4.1	2.94	0.63	(0.26, 1.52)	0.3067	
Type of AF therapy												0.3363
Nintedanib	173	17	9.8	7.20	178	11	6.2	4.58	0.63	(0.30, 1.35)	0.2378	
Pirfenidone	133	13	9.8	7.09	127	12	9.4	6.85	1.09	(0.49, 2.40)	0.8400	
Region												0.1510
Europe	136	9	6.6	4.93	136	13	9.6	7.00	1.31	(0.56, 3.09)	0.5291	
Asia	72	9	12.5	9.03	79	2	2.5	1.84	0.24	(0.05, 1.11)	0.0678	
Canada and USA	75	10	13.3	9.60	56	4	7.1	5.06	0.53	(0.16, 1.69)	0.2823	
Rest of the World	23	2	8.7	6.06	34	4	11.8	9.65	2.09	(0.38, 11.60)	0.4003	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment,
continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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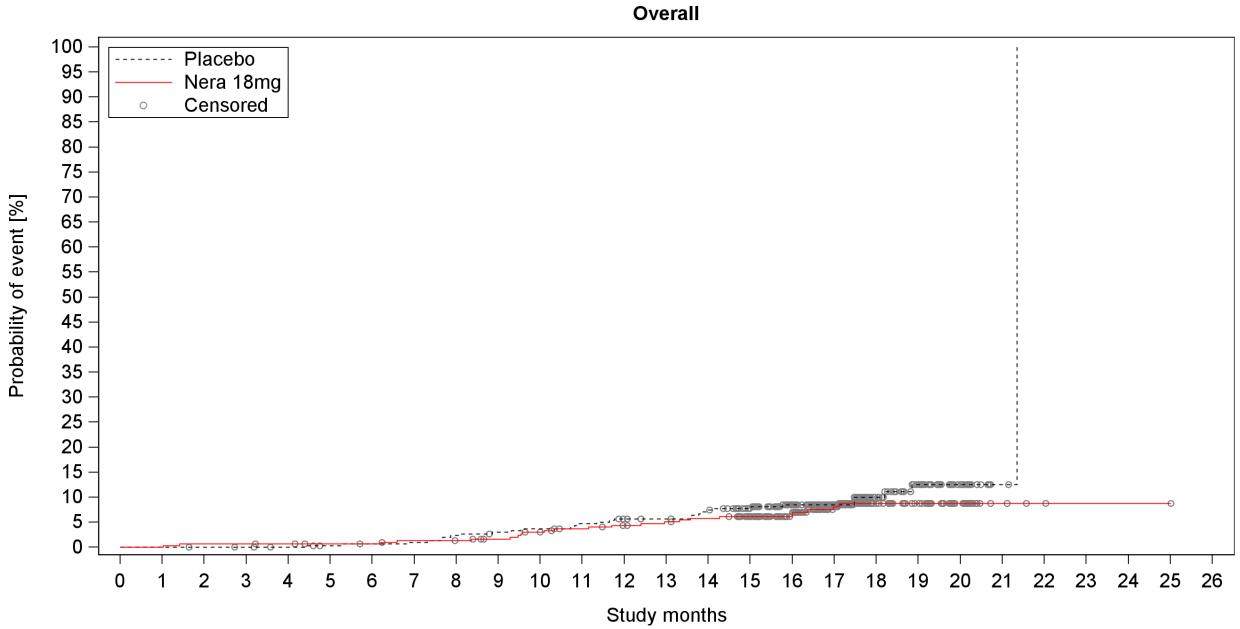

Number at risk (percentage relative to baseline)

Placebo	306	306	305	304	302	299	298	297	293	290	288	284	278	276	270	251	213	151	83	57	21	2	0	0	0	0	0
%	100.0	100.0	99.7	99.3	98.7	97.7	97.4	97.1	95.8	94.8	94.1	92.8	90.8	90.2	88.2	82.0	69.6	49.3	27.1	18.6	6.9	0.7	0.0	0.0	0.0	0.0	0.0
Nera 18mg	305	305	303	303	302	300	299	296	295	291	286	281	275	272	268	246	212	151	68	44	23	4	2	1	1	1	0
%	100.0	100.0	99.3	99.3	99.0	98.4	98.0	97.0	96.7	95.4	93.8	92.1	90.2	89.2	87.9	80.7	69.5	49.5	22.3	14.4	7.5	1.3	0.7	0.3	0.3	0.3	0.0

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

Placebo	0	0	1	2	4	6	6	6	6	7	7	8	11	13	14	32	68	130	196	220	256	275	276	276	276	276	276
%	0.0	0.0	0.3	0.7	1.3	2.0	2.0	2.0	2.0	2.3	2.3	2.6	3.6	4.2	4.6	10.5	22.2	42.5	64.1	71.9	83.7	89.9	90.2	90.2	90.2	90.2	90.2
Nera 18mg	0	0	0	0	1	3	4	5	6	9	10	13	17	18	20	41	75	132	214	238	259	278	280	281	281	281	282
%	0.0	0.0	0.0	0.0	0.3	1.0	1.3	1.6	2.0	3.0	3.3	4.3	5.6	5.9	6.6	13.4	24.6	43.3	70.2	78.0	84.9	91.1	91.8	92.1	92.1	92.1	92.5

Study: 1305-0014

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

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Figure H.1.1.1.1.2.1: 1

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H.1.1.1.1.2.2 Time to first confirmed acute IPF exacerbation

Table H.1.1.1.1.2.2: 1 Cox model for time to first confirmed acute IPF exacerbation over the whole trial - 18mg - FAS (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	306	26	8.5	6.41	305	23	7.5	5.75	0.92	(0.53, 1.62)	0.7848	
Age												0.6055
<65 years	69	5	7.2	5.26	63	3	4.8	3.57	0.66	(0.16, 2.75)	0.5660	
>=65 years	237	21	8.9	6.76	242	20	8.3	6.33	0.99	(0.54, 1.83)	0.9768	
Sex												0.5611
Male	269	25	9.3	7.07	255	20	7.8	5.99	0.90	(0.50, 1.63)	0.7354	
Female	37	1	2.7	1.93	50	3	6.0	4.56	1.81	(0.19, 17.50)	0.6083	
Baseline FVC percent predicted												0.9058
<=70%	109	15	13.8	10.91	112	13	11.6	9.65	0.86	(0.41, 1.81)	0.6922	
>70%	197	11	5.6	4.10	193	10	5.2	3.77	0.92	(0.39, 2.17)	0.8510	
Type of AF therapy												0.4786
Nintedanib	173	15	8.7	6.53	178	12	6.7	5.19	0.77	(0.36, 1.65)	0.5079	
Pirfenidone	133	11	8.3	6.26	127	11	8.7	6.53	1.17	(0.50, 2.70)	0.7214	
Region												0.8283
Europe	136	11	8.1	6.11	136	11	8.1	6.17	0.96	(0.41, 2.21)	0.9147	
Asia	72	10	13.9	10.86	79	5	6.3	4.79	0.50	(0.17, 1.47)	0.2057	
Canada and USA	75	5	6.7	4.97	56	3	5.4	3.90	0.82	(0.20, 3.43)	0.7842	
Rest of the World	23	0	0.0	0.00	34	4	11.8	9.91	>10	(NC, NC)	0.9856	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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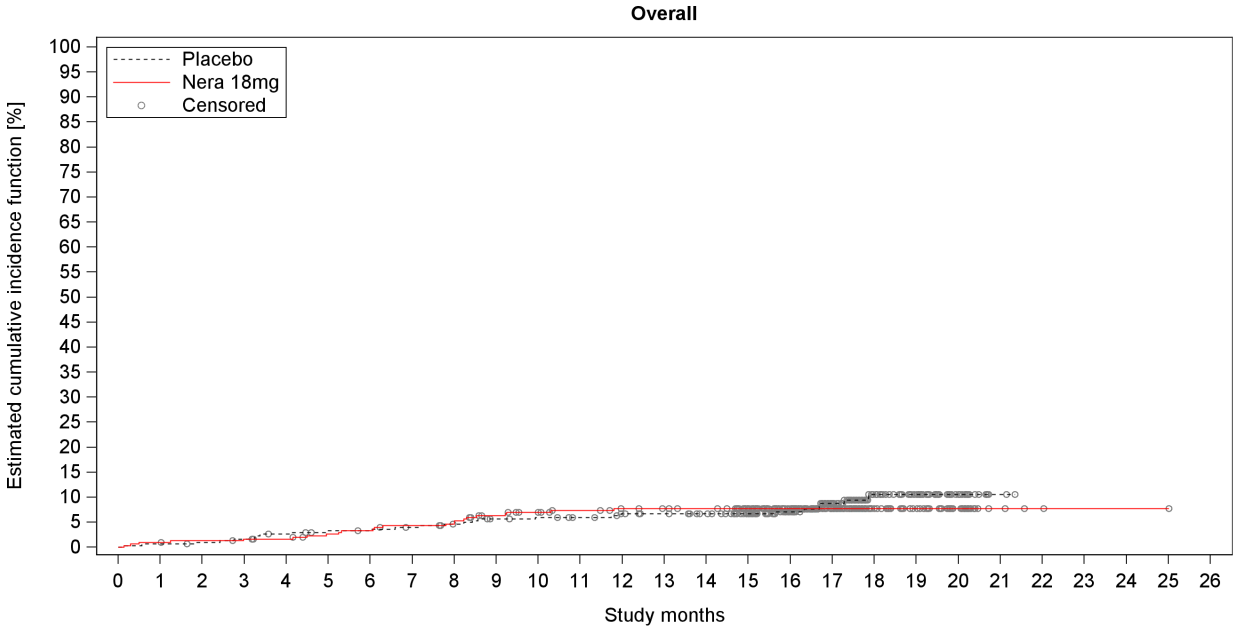

Number at risk (percentage relative to baseline)

Placebo	306	304	302	299	294	290	290	287	283	278	276	273	267	264	259	240	203	141	77	54	20	2	0	0	0	0	0
%	100.0	99.3	98.7	97.7	96.1	94.8	94.8	93.8	92.5	90.8	90.2	89.2	87.3	86.3	84.6	78.4	66.3	46.1	25.2	17.6	6.5	0.7	0.0	0.0	0.0	0.0	0.0
Nera 18mg	305	302	300	299	298	293	290	286	284	275	270	264	258	256	253	232	201	143	67	43	23	4	2	1	1	1	0
%	100.0	99.0	98.4	98.0	97.7	96.1	95.1	93.8	93.1	90.2	88.5	86.6	84.6	83.9	83.0	76.1	65.9	46.9	22.0	14.1	7.5	1.3	0.7	0.3	0.3	0.3	0.0

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

Placebo	0	0	1	2	4	6	6	7	9	11	12	15	19	22	27	46	82	141	203	226	260	278	280	280	280	280	280
%	0.0	0.0	0.3	0.7	1.3	2.0	2.0	2.3	2.9	3.6	3.9	4.9	6.2	7.2	8.8	15.0	26.8	46.1	66.3	73.9	85.0	90.8	91.5	91.5	91.5	91.5	91.5
Nera 18mg	0	0	1	1	2	4	5	6	7	11	14	19	24	26	29	50	81	139	215	239	259	278	280	281	281	281	282
%	0.0	0.0	0.3	0.3	0.7	1.3	1.6	2.0	2.3	3.6	4.6	6.2	7.9	8.5	9.5	16.4	26.6	45.6	70.5	78.4	84.9	91.1	91.8	92.1	92.1	92.1	92.5

Study: 1305-0014

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

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Figure H.1.1.1.1.2.2: 1

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H.1.1.1.1.2.3 Time to first confirmed or suspected acute IPF exacerbation

Table H.1.1.1.1.2.3: 1 Cox model for time to first confirmed or suspected acute IPF exacerbation over the whole trial - 18mg - FAS (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	306	30	9.8	7.43	305	29	9.5	7.28	1.01	(0.60, 1.68)	0.9766	
Age												0.5084
<65 years	69	5	7.2	5.26	63	3	4.8	3.57	0.65	(0.15, 2.71)	0.5499	
>=65 years	237	25	10.5	8.10	242	26	10.7	8.28	1.08	(0.62, 1.88)	0.7751	
Sex												0.6666
Male	269	29	10.8	8.24	255	26	10.2	7.82	1.02	(0.60, 1.73)	0.9554	
Female	37	1	2.7	1.93	50	3	6.0	4.57	1.69	(0.18, 16.34)	0.6488	
Baseline FVC percent predicted												0.3356
<=70%	109	15	13.8	10.91	112	18	16.1	13.51	1.22	(0.61, 2.43)	0.5708	
>70%	197	15	7.6	5.63	193	11	5.7	4.15	0.73	(0.34, 1.60)	0.4351	
Type of AF therapy												0.3080
Nintedanib	173	18	10.4	7.88	178	15	8.4	6.50	0.80	(0.40, 1.59)	0.5219	
Pirfenidone	133	12	9.0	6.85	127	14	11.0	8.37	1.37	(0.63, 2.97)	0.4275	
Region												0.7028
Europe	136	12	8.8	6.69	136	14	10.3	7.91	1.10	(0.51, 2.39)	0.8058	
Asia	72	10	13.9	10.86	79	6	7.6	5.75	0.60	(0.22, 1.68)	0.3323	
Canada and USA	75	8	10.7	8.05	56	3	5.4	3.90	0.50	(0.13, 1.90)	0.3121	
Rest of the World	23	0	0.0	0.00	34	6	17.6	15.04	>10	(NC, NC)	0.9839	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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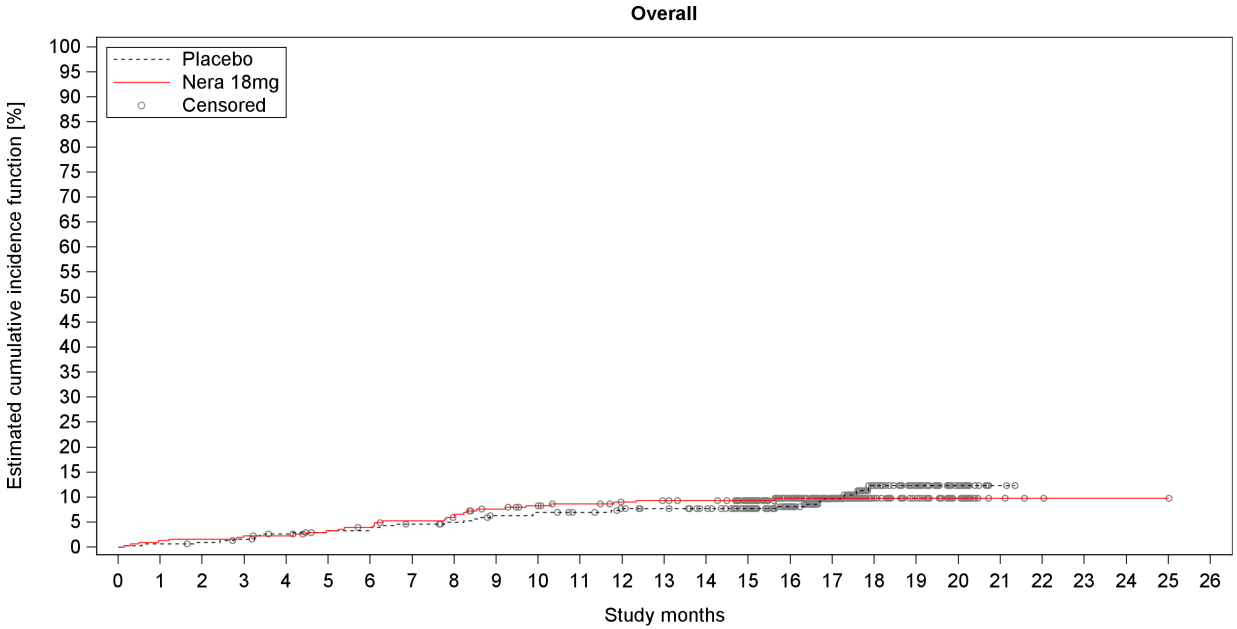

Number at risk (percentage relative to baseline)

Placebo	306	304	302	299	294	290	289	285	282	276	274	271	265	262	257	238	201	140	76	53	20	2	0	0	0	0	0
%	100.0	99.3	98.7	97.7	96.1	94.8	94.4	93.1	92.2	90.2	89.5	88.6	86.6	85.6	84.0	77.8	65.7	45.8	24.8	17.3	6.5	0.7	0.0	0.0	0.0	0.0	0.0
Nera 18mg	305	301	300	298	297	292	289	284	281	273	268	263	257	255	252	231	199	142	67	43	23	4	2	1	1	1	0
%	100.0	98.7	98.4	97.7	97.4	95.7	94.8	93.1	92.1	89.5	87.9	86.2	84.3	83.6	82.6	75.7	65.2	46.6	22.0	14.1	7.5	1.3	0.7	0.3	0.3	0.3	0.0

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

Placebo	0	0	1	2	4	6	6	7	9	11	11	14	18	21	26	45	81	139	200	223	256	274	276	276	276	276	276
%	0.0	0.0	0.3	0.7	1.3	2.0	2.0	2.3	2.9	3.6	3.6	4.6	5.9	6.9	8.5	14.7	26.5	45.4	65.4	72.9	83.7	89.5	90.2	90.2	90.2	90.2	90.2
Nera 18mg	0	0	0	0	1	3	4	5	6	9	12	16	21	22	25	46	77	134	209	233	253	272	274	275	275	275	276
%	0.0	0.0	0.0	0.0	0.3	1.0	1.3	1.6	2.0	3.0	3.9	5.2	6.9	7.2	8.2	15.1	25.2	43.9	68.5	76.4	83.0	89.2	89.8	90.2	90.2	90.2	90.5

Study: 1305-0014

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

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Figure H.1.1.1.1.2.3: 1

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H.1.1.1.1.2.4 Time to first respiratory hospitalisation

Table H.1.1.1.1.2.4: 1 Cox model for time to first respiratory hospitalisation over the whole trial - 18mg - FAS (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	306	55	18.0	14.16	305	61	20.0	16.15	1.22	(0.84,	1.75)	0.2954	
Age													0.4328
<65 years	69	11	15.9	11.96	63	9	14.3	11.03	0.90	(0.37,	2.17)	0.8103	
>=65 years	237	44	18.6	14.84	242	52	21.5	17.56	1.32	(0.88,	1.98)	0.1732	
Sex													0.6638
Male	269	52	19.3	15.41	255	53	20.8	16.83	1.21	(0.83,	1.78)	0.3238	
Female	37	3	8.1	5.89	50	8	16.0	12.75	1.65	(0.44,	6.25)	0.4613	
Baseline FVC percent predicted													0.3120
<=70%	109	26	23.9	19.69	112	34	30.4	27.46	1.43	(0.86,	2.40)	0.1674	
>70%	197	29	14.7	11.31	193	27	14.0	10.64	0.98	(0.58,	1.66)	0.9501	
Type of AF therapy													0.9401
Nintedanib	173	30	17.3	13.61	178	36	20.2	16.59	1.21	(0.74,	1.96)	0.4491	
Pirfenidone	133	25	18.8	14.89	127	25	19.7	15.57	1.24	(0.71,	2.17)	0.4490	
Region													0.6389
Europe	136	19	14.0	10.87	136	27	19.9	16.09	1.42	(0.79,	2.56)	0.2399	
Asia	72	19	26.4	21.53	79	18	22.8	18.80	1.13	(0.59,	2.17)	0.7120	
Canada and USA	75	14	18.7	14.73	56	8	14.3	10.67	0.80	(0.33,	1.90)	0.6099	
Rest of the World	23	3	13.0	9.90	34	8	23.5	20.48	1.95	(0.51,	7.40)	0.3290	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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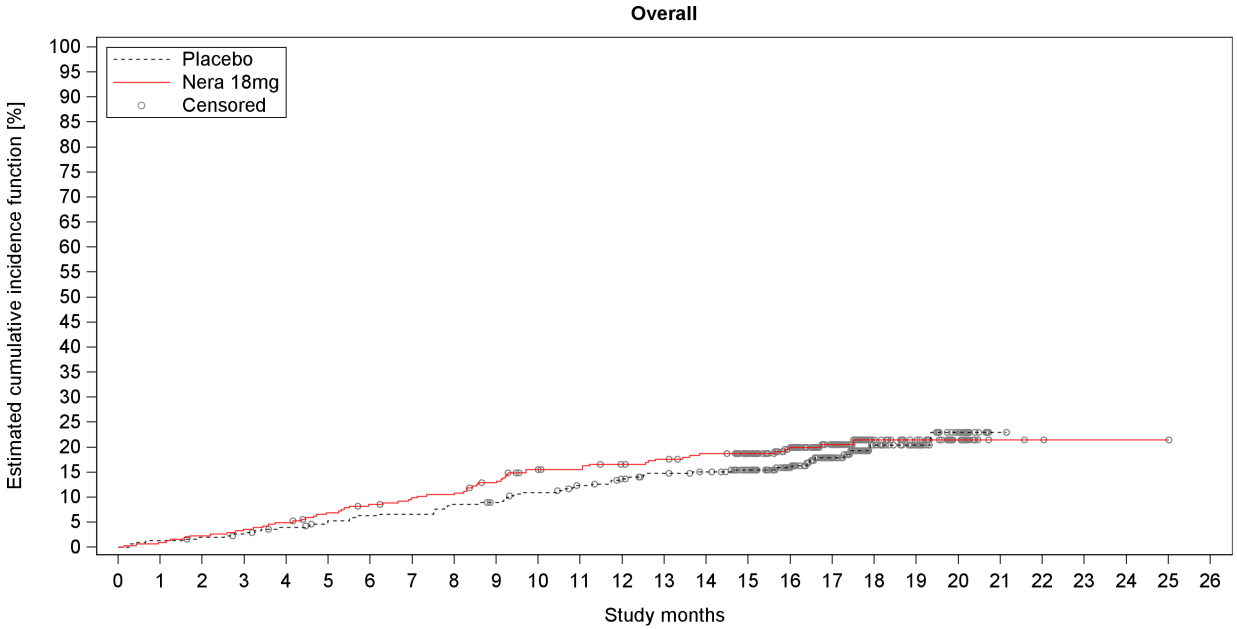

Number at risk (percentage relative to baseline)

Placebo	306	302	299	296	290	284	281	280	274	271	264	257	249	243	239	221	186	128	67	46	18	1	0	0	0	0	0
%	100.0	98.7	97.7	96.7	94.8	92.8	91.8	91.5	89.5	88.6	86.3	84.0	81.4	79.4	78.1	72.2	60.8	41.8	21.9	15.0	5.9	0.3	0.0	0.0	0.0	0.0	0.0
Nera 18mg	305	302	298	294	290	282	276	271	269	260	249	247	240	236	230	211	181	127	54	35	18	3	2	1	1	1	0
%	100.0	99.0	97.7	96.4	95.1	92.5	90.5	88.9	88.2	85.2	81.6	81.0	78.7	77.4	75.4	69.2	59.3	41.6	17.7	11.5	5.9	1.0	0.7	0.3	0.3	0.3	0.0

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

Placebo	0	0	1	2	4	6	6	6	6	8	9	12	16	19	22	39	73	127	185	206	233	250	251	251	251	251	251
%	0.0	0.0	0.3	0.7	1.3	2.0	2.0	2.0	2.0	2.6	2.9	3.9	5.2	6.2	7.2	12.7	23.9	41.5	60.5	67.3	76.1	81.7	82.0	82.0	82.0	82.0	82.0
Nera 18mg	0	0	0	0	0	2	3	4	4	6	9	11	15	16	19	38	65	118	190	209	226	241	242	243	243	243	244
%	0.0	0.0	0.0	0.0	0.0	0.7	1.0	1.3	1.3	2.0	3.0	3.6	4.9	5.2	6.2	12.5	21.3	38.7	62.3	68.5	74.1	79.0	79.3	79.7	79.7	79.7	80.0

Study: 1305-0014

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

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Figure H.1.1.1.1.2.4: 1

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

Table H.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 (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	306	86	28.1	23.99	305	90	29.5	25.32	1.08	(0.80,	1.45)	0.6240	
Age													0.3515
<65 years	69	17	24.6	20.04	63	13	20.6	16.61	0.79	(0.38,	1.64)	0.5305	
>=65 years	237	69	29.1	25.21	242	77	31.8	27.78	1.16	(0.83,	1.60)	0.3821	
Sex													0.5002
Male	269	81	30.1	26.14	255	78	30.6	26.32	1.06	(0.78,	1.45)	0.6988	
Female	37	5	13.5	10.29	50	12	24.0	20.28	1.55	(0.54,	4.41)	0.4128	
Baseline FVC percent predicted													0.1951
<=70%	109	34	31.2	27.52	112	43	38.4	36.94	1.33	(0.85,	2.09)	0.2103	
>70%	197	52	26.4	22.13	193	47	24.4	19.66	0.90	(0.60,	1.33)	0.5942	
Type of AF therapy													0.4474
Nintedanib	173	45	26.0	21.81	178	54	30.3	26.30	1.19	(0.80,	1.77)	0.3809	
Pirfenidone	133	41	30.8	26.95	127	36	28.3	23.97	0.95	(0.60,	1.48)	0.8108	
Region													0.1852
Europe	136	34	25.0	20.92	136	39	28.7	24.62	1.14	(0.72,	1.81)	0.5698	
Asia	72	23	31.9	27.26	79	29	36.7	33.82	1.35	(0.78,	2.35)	0.2895	
Canada and USA	75	25	33.3	30.13	56	12	21.4	16.41	0.57	(0.29,	1.14)	0.1108	
Rest of the World	23	4	17.4	13.98	34	10	29.4	26.20	1.88	(0.59,	6.02)	0.2892	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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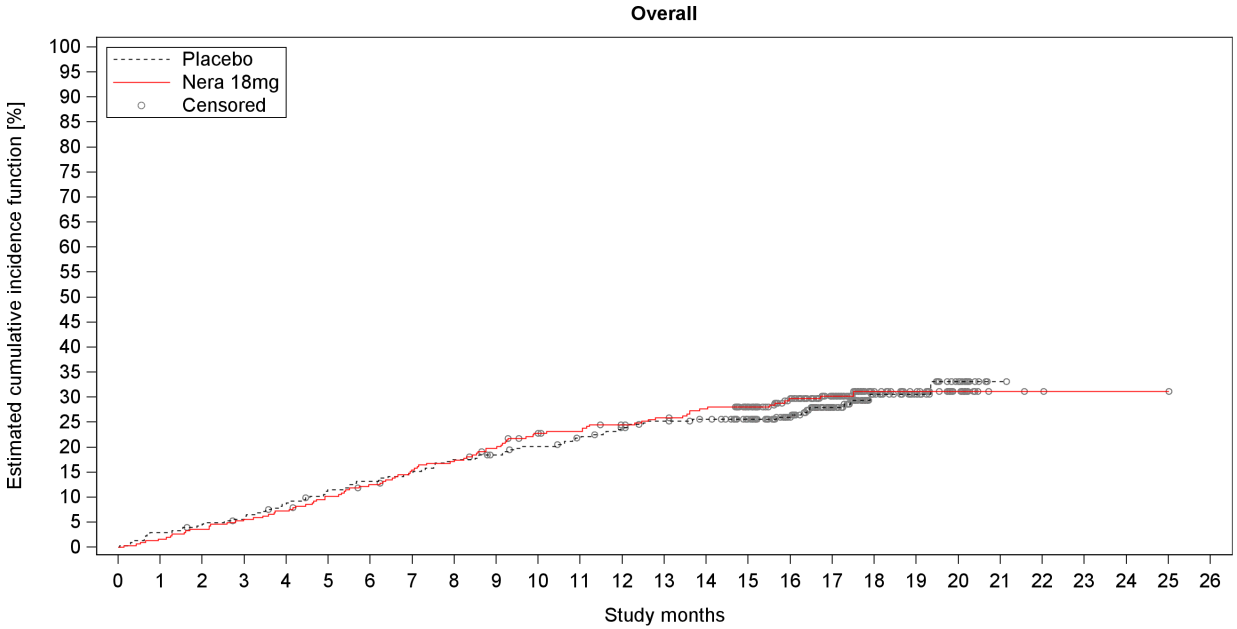

Number at risk (percentage relative to baseline)

Placebo	306	297	292	287	277	267	262	257	249	244	238	231	223	217	213	198	167	114	57	37	14	1	0	0	0	0	0
%	100.0	97.1	95.4	93.8	90.5	87.3	85.6	84.0	81.4	79.7	77.8	75.5	72.9	70.9	69.6	64.7	54.6	37.3	18.6	12.1	4.6	0.3	0.0	0.0	0.0	0.0	0.0
Nera 18mg	305	300	294	288	283	273	265	255	250	240	229	226	218	213	206	189	161	115	49	33	17	3	2	1	1	1	0
%	100.0	98.4	96.4	94.4	92.8	89.5	86.9	83.6	82.0	78.7	75.1	74.1	71.5	69.8	67.5	62.0	52.8	37.7	16.1	10.8	5.6	1.0	0.7	0.3	0.3	0.3	0.0

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

Placebo	0	0	1	2	3	4	4	4	4	6	7	9	11	13	16	31	61	110	164	184	206	219	220	220	220	220	220
%	0.0	0.0	0.3	0.7	1.0	1.3	1.3	1.3	1.3	2.0	2.3	2.9	3.6	4.2	5.2	10.1	19.9	35.9	53.6	60.1	67.3	71.6	71.9	71.9	71.9	71.9	71.9
Nera 18mg	0	0	0	0	0	1	2	3	3	5	7	9	13	14	16	32	56	101	166	182	198	212	213	214	214	214	215
%	0.0	0.0	0.0	0.0	0.0	0.3	0.7	1.0	1.0	1.6	2.3	3.0	4.3	4.6	5.2	10.5	18.4	33.1	54.4	59.7	64.9	69.5	69.8	70.2	70.2	70.2	70.5

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.1.1.1.1.2.5: 1

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H.1.1.1.1.3 Time to event analyses of quality of life

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

Table H.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 (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	306	118	38.6	37.76	305	117	38.4	39.04	1.09	(0.85,	1.42)	0.4929	
Age													0.2269
<65 years	69	30	43.5	40.33	63	22	34.9	32.96	0.81	(0.47,	1.41)	0.4631	
>=65 years	237	88	37.1	36.95	242	95	39.3	40.79	1.20	(0.89,	1.60)	0.2322	
Sex													0.6342
Male	269	106	39.4	39.10	255	99	38.8	39.38	1.07	(0.81,	1.41)	0.6170	
Female	37	12	32.4	28.95	50	18	36.0	37.30	1.30	(0.61,	2.78)	0.4906	
Baseline FVC percent predicted													0.0925
<=70%	109	54	49.5	55.02	112	44	39.3	45.30	0.83	(0.56,	1.24)	0.3596	
>70%	197	64	32.5	29.86	193	73	37.8	36.04	1.30	(0.93,	1.83)	0.1304	
Type of AF therapy													0.1709
Nintedanib	173	69	39.9	38.87	178	59	33.1	34.69	0.93	(0.66,	1.32)	0.6832	
Pirfenidone	133	49	36.8	36.30	127	58	45.7	44.75	1.33	(0.91,	1.96)	0.1395	
Region													0.2629
Europe	136	50	36.8	33.92	136	55	40.4	41.28	1.27	(0.87,	1.87)	0.2203	
Asia	72	35	48.6	52.77	79	28	35.4	35.71	0.69	(0.42,	1.14)	0.1507	
Canada and USA	75	25	33.3	31.86	56	20	35.7	34.30	1.13	(0.63,	2.04)	0.6804	
Rest of the World	23	8	34.8	39.37	34	14	41.2	47.16	1.35	(0.56,	3.22)	0.5036	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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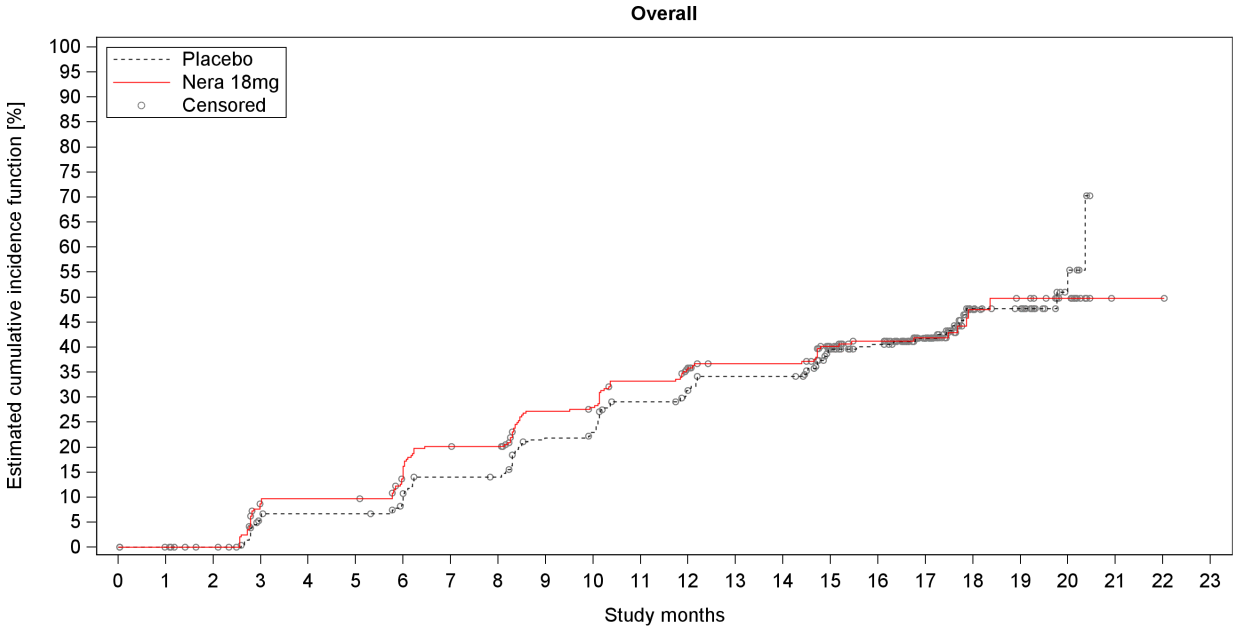

Number at risk (percentage relative to baseline)

Placebo	306	291	289	263	259	259	251	233	232	208	204	185	176	167	167	133	118	82	39	35	11	0	0	0
%	100.0	95.1	94.4	85.9	84.6	84.6	82.0	76.1	75.8	68.0	66.7	60.5	57.5	54.6	54.6	43.5	38.6	26.8	12.7	11.4	3.6	0.0	0.0	0.0
Nera 18mg	305	294	290	259	256	256	240	222	221	195	192	177	160	152	152	123	109	87	26	21	11	1	1	0
%	100.0	96.4	95.1	84.9	83.9	83.9	78.7	72.8	72.5	63.9	63.0	58.0	52.5	49.8	49.8	40.3	35.7	28.5	8.5	6.9	3.6	0.3	0.3	0.0

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

Placebo	0	15	17	27	28	28	31	34	35	38	39	42	45	47	47	68	81	115	152	156	179	188	188	188
%	0.0	4.9	5.6	8.8	9.2	9.2	10.1	11.1	11.4	12.4	12.7	13.7	14.7	15.4	15.4	22.2	26.5	37.6	49.7	51.0	58.5	61.4	61.4	61.4
Nera 18mg	0	11	15	21	21	21	26	26	27	34	35	36	47	52	52	73	85	106	163	167	177	187	187	188
%	0.0	3.6	4.9	6.9	6.9	6.9	8.5	8.5	8.9	11.1	11.5	11.8	15.4	17.0	17.0	23.9	27.9	34.8	53.4	54.8	58.0	61.3	61.3	61.6

Study: 1305-0014

Figure H.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 (AF background)

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Table H.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 (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	306	141	46.1	47.54	305	127	41.6	43.61	0.97	(0.76, 1.23)	0.7833	
Age												0.7901
<65 years	69	29	42.0	39.52	63	24	38.1	36.72	0.91	(0.53, 1.57)	0.7330	
>=65 years	237	112	47.3	50.18	242	103	42.6	45.61	0.99	(0.75, 1.30)	0.9305	
Sex												0.4894
Male	269	128	47.6	49.88	255	106	41.6	43.17	0.94	(0.72, 1.21)	0.6136	
Female	37	13	35.1	32.51	50	21	42.0	45.96	1.22	(0.61, 2.44)	0.5818	
Baseline FVC percent predicted												0.7786
<=70%	109	57	52.3	59.78	112	51	45.5	56.50	1.00	(0.69, 1.47)	0.9822	
>70%	197	84	42.6	41.74	193	76	39.4	37.82	0.94	(0.68, 1.28)	0.6794	
Type of AF therapy												0.6955
Nintedanib	173	78	45.1	45.15	178	67	37.6	41.23	0.92	(0.67, 1.28)	0.6373	
Pirfenidone	133	63	47.4	50.87	127	60	47.2	46.61	1.02	(0.71, 1.45)	0.9229	
Region												0.6570
Europe	136	62	45.6	44.74	136	58	42.6	45.06	1.04	(0.72, 1.48)	0.8493	
Asia	72	38	52.8	60.34	79	32	40.5	42.18	0.73	(0.45, 1.17)	0.1928	
Canada and USA	75	31	41.3	41.86	56	24	42.9	42.32	1.01	(0.59, 1.73)	0.9837	
Rest of the World	23	10	43.5	47.67	34	13	38.2	43.45	1.12	(0.49, 2.57)	0.7874	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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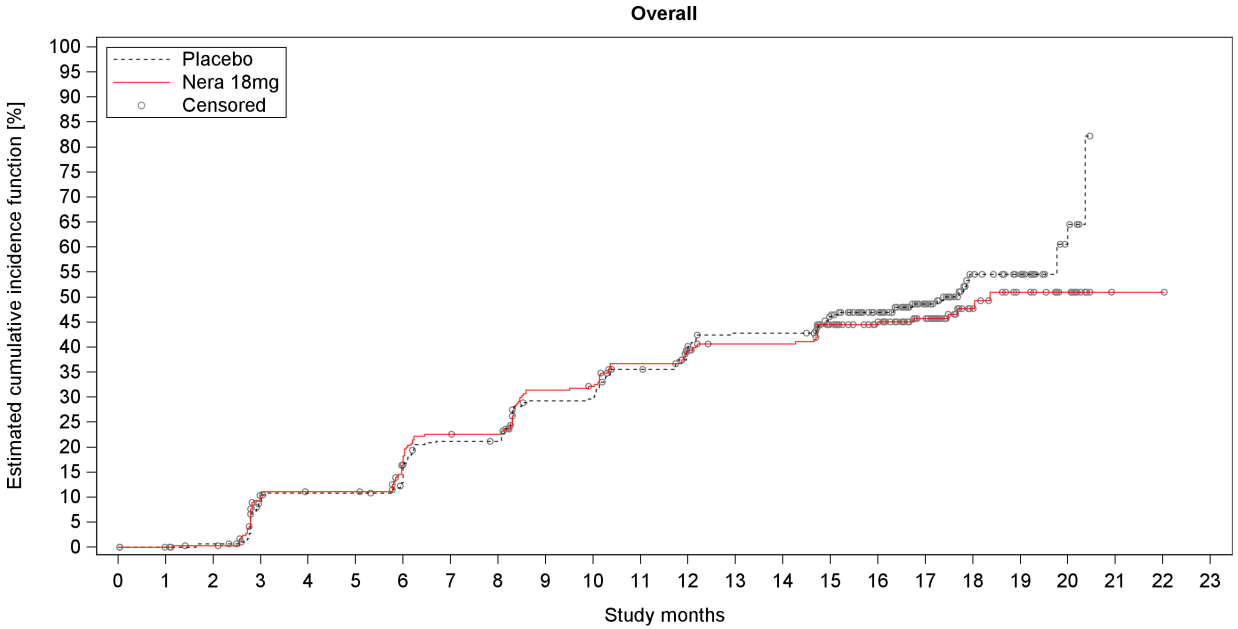

Number at risk (percentage relative to baseline)																								
Placebo	306	292	290	258	252	252	243	217	216	191	189	172	158	147	147	129	110	76	37	30	10	0	0	0
%	100.0	95.4	94.8	84.3	82.4	82.4	79.4	70.9	70.6	62.4	61.8	56.2	51.6	48.0	48.0	42.2	35.9	24.8	12.1	9.8	3.3	0.0	0.0	0.0
Nera 18mg	305	295	291	255	252	252	232	215	214	184	181	166	148	140	140	117	104	81	35	21	11	1	1	0
%	100.0	96.7	95.4	83.6	82.6	82.6	76.1	70.5	70.2	60.3	59.3	54.4	48.5	45.9	45.9	38.4	34.1	26.6	11.5	6.9	3.6	0.3	0.3	0.0
Number censored (percentage relative to number at risk at baseline)																								
Placebo	0	14	14	22	23	23	26	29	30	33	33	35	39	41	41	51	68	99	132	139	157	165	165	165
%	0.0	4.6	4.6	7.2	7.5	7.5	8.5	9.5	9.8	10.8	10.8	11.4	12.7	13.4	13.4	16.7	22.2	32.4	43.1	45.4	51.3	53.9	53.9	53.9
Nera 18mg	0	10	13	20	21	21	26	26	27	33	34	37	49	53	53	67	80	101	145	157	167	177	177	178
%	0.0	3.3	4.3	6.6	6.9	6.9	8.5	8.5	8.9	10.8	11.1	12.1	16.1	17.4	17.4	22.0	26.2	33.1	47.5	51.5	54.8	58.0	58.0	58.4

Study: 1305-0014

Figure H.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 (AF background)

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BI Trial No.: x1305p3.hta

Figure H.1.1.1.1.3.1: 2

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Table H.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 (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	306	131	42.8	41.96	305	138	45.2	47.36	1.17	(0.92,	1.49)	0.1938	
Age													0.7717
<65 years	69	32	46.4	42.17	63	29	46.0	46.40	1.10	(0.66,	1.82)	0.7218	
>=65 years	237	99	41.8	41.89	242	109	45.0	47.62	1.19	(0.91,	1.57)	0.2070	
Sex													0.4421
Male	269	117	43.5	43.14	255	115	45.1	46.86	1.13	(0.87,	1.47)	0.3493	
Female	37	14	37.8	34.17	50	23	46.0	50.00	1.51	(0.76,	3.00)	0.2398	
Baseline FVC percent predicted													0.6350
<=70%	109	52	47.7	51.55	112	53	47.3	56.70	1.08	(0.73,	1.58)	0.7035	
>70%	197	79	40.1	37.38	193	85	44.0	42.95	1.21	(0.89,	1.65)	0.2192	
Type of AF therapy													0.8090
Nintedanib	173	71	41.0	40.10	178	74	41.6	44.03	1.15	(0.83,	1.59)	0.4163	
Pirfenidone	133	60	45.1	44.41	127	64	50.4	51.89	1.22	(0.85,	1.73)	0.2809	
Region													0.7857
Europe	136	58	42.6	40.24	136	63	46.3	49.51	1.26	(0.88,	1.80)	0.2124	
Asia	72	34	47.2	49.18	79	35	44.3	45.83	0.95	(0.59,	1.53)	0.8320	
Canada and USA	75	27	36.0	33.81	56	23	41.1	39.37	1.22	(0.70,	2.12)	0.4898	
Rest of the World	23	12	52.2	62.97	34	17	50.0	57.93	0.98	(0.47,	2.06)	0.9552	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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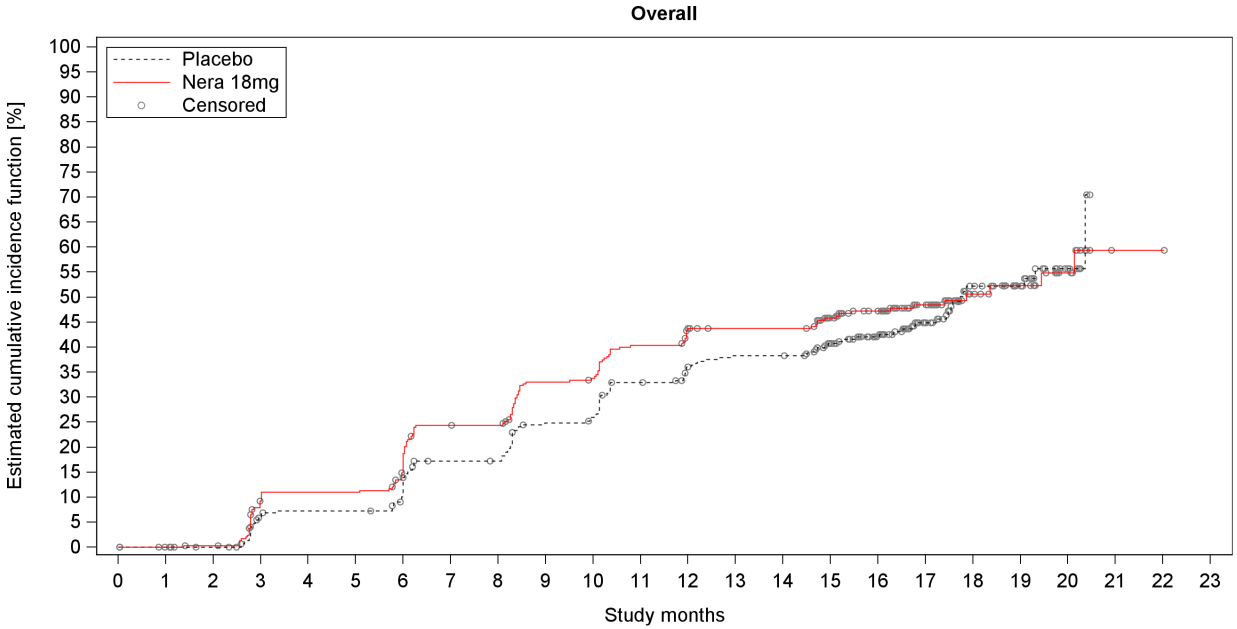

Number at risk (percentage relative to baseline)

Placebo	306	298	296	269	264	264	253	229	228	205	201	180	167	160	160	140	116	79	42	34	12	0	0	0
%	100.0	97.4	96.7	87.9	86.3	86.3	82.7	74.8	74.5	67.0	65.7	58.8	54.6	52.3	52.3	45.8	37.9	25.8	13.7	11.1	3.9	0.0	0.0	0.0
Nera 18mg	305	298	293	261	256	256	241	213	212	185	182	164	144	139	139	118	101	76	33	22	12	1	1	0
%	100.0	97.7	96.1	85.6	83.9	83.9	79.0	69.8	69.5	60.7	59.7	53.8	47.2	45.6	45.6	38.7	33.1	24.9	10.8	7.2	3.9	0.3	0.3	0.0

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

Placebo	0	8	10	20	21	21	24	28	29	31	32	34	39	40	40	54	75	107	136	144	164	175	175	175
%	0.0	2.6	3.3	6.5	6.9	6.9	7.8	9.2	9.5	10.1	10.5	11.1	12.7	13.1	13.1	17.6	24.5	35.0	44.4	47.1	53.6	57.2	57.2	57.2
Nera 18mg	0	7	11	17	17	17	21	22	23	26	27	27	39	43	43	59	73	96	137	147	156	166	166	167
%	0.0	2.3	3.6	5.6	5.6	5.6	6.9	7.2	7.5	8.5	8.9	8.9	12.8	14.1	14.1	19.3	23.9	31.5	44.9	48.2	51.1	54.4	54.4	54.8

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.1.1.1.1.3.1: 3

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

Table H.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 (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	306	168	54.9	62.61	305	172	56.4	67.04	1.11	(0.89,	1.37)	0.3561	
Age													0.4071
<65 years	69	44	63.8	69.86	63	35	55.6	64.51	0.93	(0.60,	1.45)	0.7480	
>=65 years	237	124	52.3	60.39	242	137	56.6	67.72	1.15	(0.90,	1.47)	0.2560	
Sex													0.2953
Male	269	147	54.6	63.49	255	140	54.9	64.32	1.05	(0.83,	1.33)	0.6739	
Female	37	21	56.8	57.08	50	32	64.0	82.25	1.46	(0.83,	2.58)	0.1929	
Baseline FVC percent predicted													0.3873
<=70%	109	65	59.6	74.29	112	61	54.5	72.32	0.97	(0.69,	1.38)	0.8788	
>70%	197	103	52.3	56.96	193	111	57.5	64.45	1.18	(0.90,	1.55)	0.2233	
Type of AF therapy													0.3886
Nintedanib	173	95	54.9	64.11	178	93	52.2	63.15	1.02	(0.76,	1.36)	0.9027	
Pirfenidone	133	73	54.9	60.78	127	79	62.2	72.28	1.23	(0.89,	1.69)	0.2054	
Region													0.6203
Europe	136	74	54.4	59.09	136	79	58.1	70.71	1.25	(0.91,	1.72)	0.1753	
Asia	72	36	50.0	57.71	79	41	51.9	59.07	1.00	(0.64,	1.57)	0.9943	
Canada and USA	75	44	58.7	69.26	56	30	53.6	56.77	0.88	(0.55,	1.40)	0.5851	
Rest of the World	23	14	60.9	81.57	34	22	64.7	97.38	1.24	(0.63,	2.42)	0.5336	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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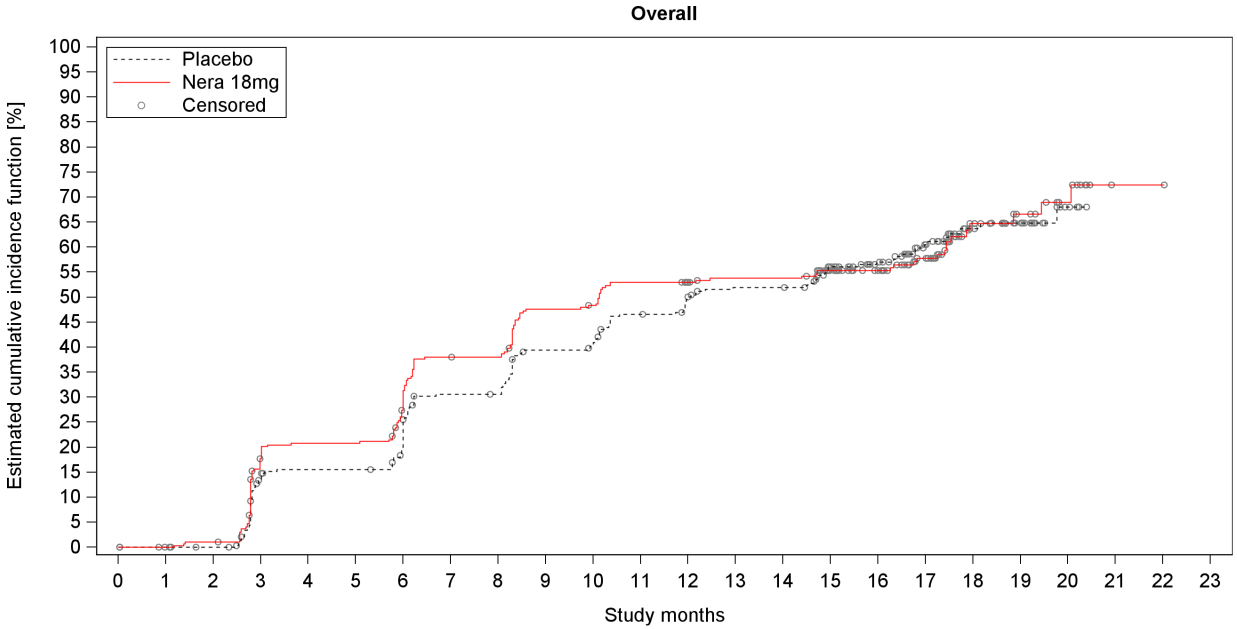

Number at risk (percentage relative to baseline)

Placebo	306	298	296	247	239	239	225	190	189	163	159	141	131	122	122	103	85	60	32	24	6	0	0	0
%	100.0	97.4	96.7	80.7	78.1	78.1	73.5	62.1	61.8	53.3	52.0	46.1	42.8	39.9	39.9	33.7	27.8	19.6	10.5	7.8	2.0	0.0	0.0	0.0
Nera 18mg	305	298	293	238	229	229	206	176	175	147	144	131	122	117	117	99	86	66	25	16	9	1	1	0
%	100.0	97.7	96.1	78.0	75.1	75.1	67.5	57.7	57.4	48.2	47.2	43.0	40.0	38.4	38.4	32.5	28.2	21.6	8.2	5.2	3.0	0.3	0.3	0.0

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

Placebo	0	8	10	20	22	22	25	29	30	32	33	35	37	40	40	49	65	84	108	115	132	138	138	138
%	0.0	2.6	3.3	6.5	7.2	7.2	8.2	9.5	9.8	10.5	10.8	11.4	12.1	13.1	13.1	16.0	21.2	27.5	35.3	37.6	43.1	45.1	45.1	45.1
Nera 18mg	0	7	9	15	15	15	19	19	20	21	22	22	31	34	34	48	61	77	111	119	125	132	132	133
%	0.0	2.3	3.0	4.9	4.9	4.9	6.2	6.2	6.6	6.9	7.2	7.2	10.2	11.1	11.1	15.7	20.0	25.2	36.4	39.0	41.0	43.3	43.3	43.6

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.1.1.1.1.3.2: 1

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Table H.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 (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	306	120	39.2	37.14	305	102	33.4	31.26	0.86	(0.66,	1.13)	0.2863	
Age													0.8774
<65 years	69	27	39.1	33.23	63	21	33.3	29.85	0.90	(0.51,	1.60)	0.7295	
>=65 years	237	93	39.2	38.45	242	81	33.5	31.64	0.86	(0.64,	1.16)	0.3222	
Sex													0.8061
Male	269	105	39.0	37.42	255	84	32.9	30.27	0.85	(0.63,	1.13)	0.2655	
Female	37	15	40.5	35.26	50	18	36.0	36.87	0.93	(0.47,	1.87)	0.8424	
Baseline FVC percent predicted													0.6758
<=70%	109	52	47.7	50.51	112	48	42.9	45.60	0.92	(0.62,	1.37)	0.6908	
>70%	197	68	34.5	30.89	193	54	28.0	24.43	0.82	(0.57,	1.18)	0.2934	
Type of AF therapy													0.3545
Nintedanib	173	68	39.3	37.10	178	51	28.7	27.63	0.77	(0.53,	1.11)	0.1604	
Pirfenidone	133	52	39.1	37.19	127	51	40.2	35.98	0.99	(0.67,	1.46)	0.9564	
Region													0.6901
Europe	136	49	36.0	32.61	136	45	33.1	30.67	0.93	(0.62,	1.39)	0.7138	
Asia	72	33	45.8	45.65	79	24	30.4	28.41	0.65	(0.38,	1.11)	0.1162	
Canada and USA	75	31	41.3	39.51	56	23	41.1	37.40	0.96	(0.56,	1.66)	0.8930	
Rest of the World	23	7	30.4	31.65	34	10	29.4	29.73	1.03	(0.39,	2.70)	0.9598	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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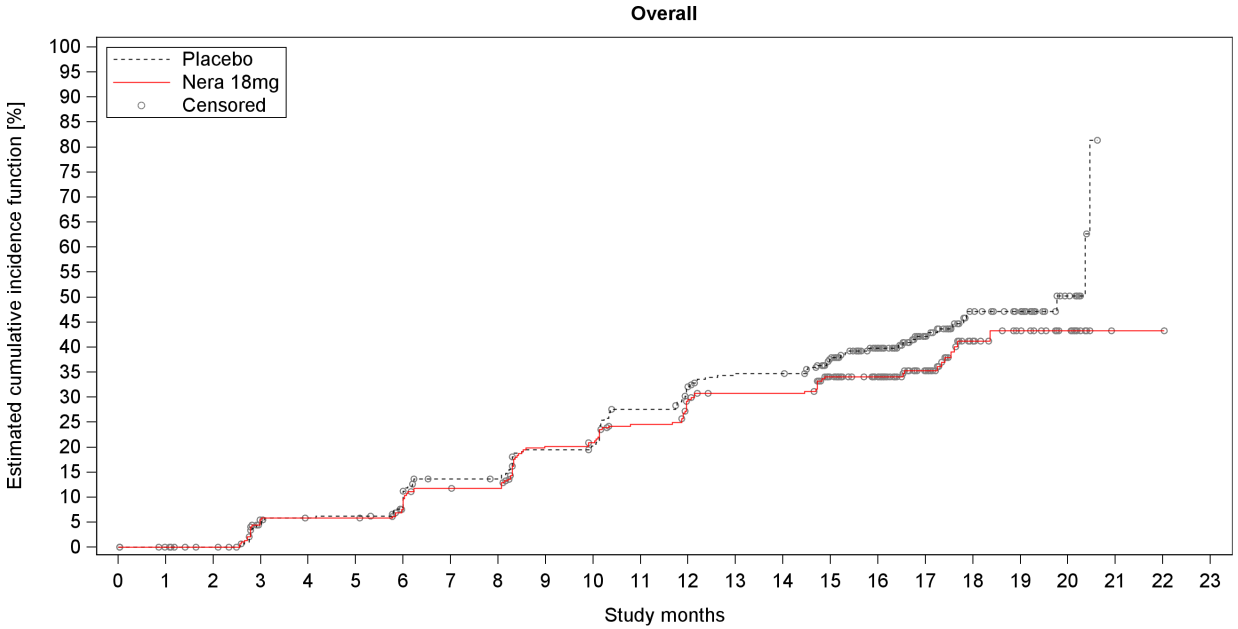

Number at risk (percentage relative to baseline)

Placebo	306	298	296	273	268	267	259	238	237	220	217	196	182	171	171	151	123	81	41	33	12	0	0	0
%	100.0	97.4	96.7	89.2	87.6	87.3	84.6	77.8	77.5	71.9	70.9	64.1	59.5	55.9	55.9	49.3	40.2	26.5	13.4	10.8	3.9	0.0	0.0	0.0
Nera 18mg	305	299	295	274	272	272	261	248	247	218	215	202	178	170	170	144	128	93	36	24	13	1	1	0
%	100.0	98.0	96.7	89.8	89.2	89.2	85.6	81.3	81.0	71.5	70.5	66.2	58.4	55.7	55.7	47.2	42.0	30.5	11.8	7.9	4.3	0.3	0.3	0.0

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

Placebo	0	8	10	20	21	21	24	29	30	31	32	33	36	39	39	52	75	113	148	156	176	186	186	186
%	0.0	2.6	3.3	6.5	6.9	6.9	7.8	9.5	9.8	10.1	10.5	10.8	11.8	12.7	12.7	17.0	24.5	36.9	48.4	51.0	57.5	60.8	60.8	60.8
Nera 18mg	0	6	10	15	16	16	22	23	24	30	31	34	46	50	50	68	84	117	168	179	190	202	202	203
%	0.0	2.0	3.3	4.9	5.2	5.2	7.2	7.5	7.9	9.8	10.2	11.1	15.1	16.4	16.4	22.3	27.5	38.4	55.1	58.7	62.3	66.2	66.2	66.6

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.1.1.1.1.3.2: 2

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Table H.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 (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	306	176	57.5	66.57	305	185	60.7	74.49	1.14	(0.93, 1.41)	0.2093	
Age												0.8863
<65 years	69	38	55.1	56.16	63	36	57.1	63.97	1.17	(0.74, 1.86)	0.4962	
>=65 years	237	138	58.2	70.15	242	149	61.6	77.58	1.13	(0.90, 1.43)	0.3036	
Sex												0.7101
Male	269	157	58.4	68.89	255	154	60.4	74.06	1.12	(0.90, 1.41)	0.3040	
Female	37	19	51.4	52.11	50	31	62.0	76.70	1.27	(0.70, 2.28)	0.4291	
Baseline FVC percent predicted												0.6016
<=70%	109	65	59.6	73.83	112	67	59.8	78.43	1.06	(0.75, 1.49)	0.7360	
>70%	197	111	56.3	62.95	193	118	61.1	72.43	1.19	(0.92, 1.55)	0.1928	
Type of AF therapy												0.0910
Nintedanib	173	93	53.8	60.26	178	107	60.1	77.77	1.34	(1.01, 1.77)	0.0406	
Pirfenidone	133	83	62.4	75.43	127	78	61.4	70.42	0.93	(0.69, 1.27)	0.6698	
Region												0.8203
Europe	136	78	57.4	65.32	136	79	58.1	69.69	1.06	(0.77, 1.45)	0.7360	
Asia	72	43	59.7	71.70	79	49	62.0	76.85	1.06	(0.70, 1.59)	0.7921	
Canada and USA	75	41	54.7	61.19	56	35	62.5	72.65	1.23	(0.79, 1.94)	0.3615	
Rest of the World	23	14	60.9	77.85	34	22	64.7	95.39	1.44	(0.73, 2.82)	0.2887	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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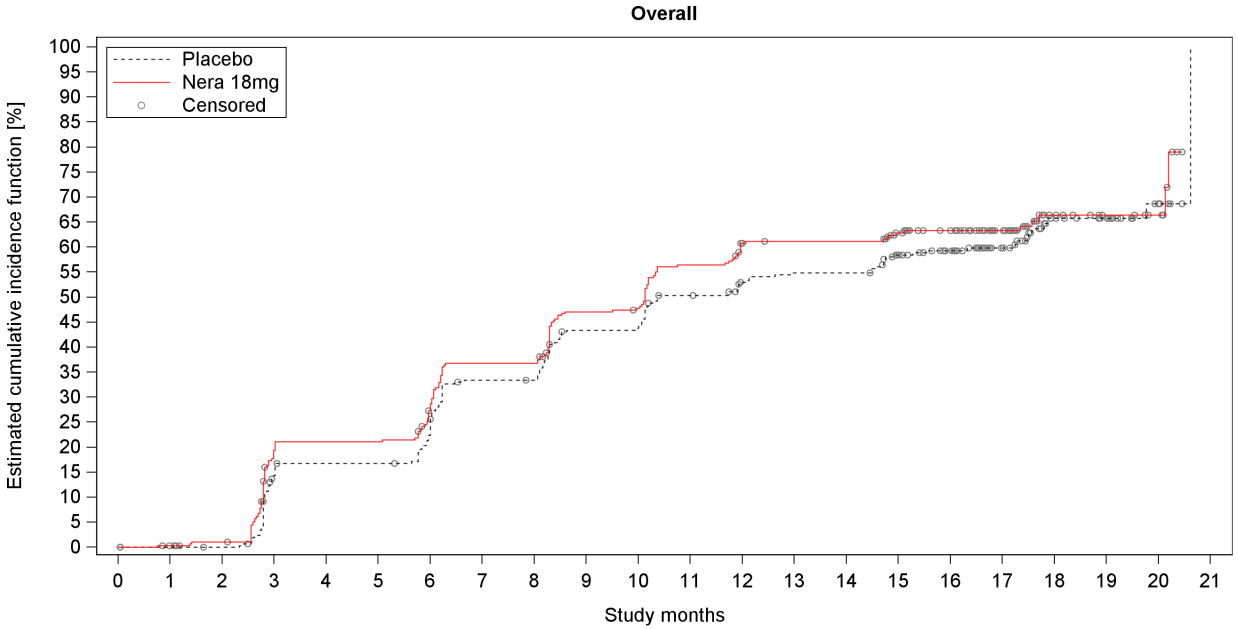

Number at risk (percentage relative to baseline)

Placebo	306	298	296	246	238	238	221	187	186	156	155	135	122	117	117	101	86	61	31	24	9	0
%	100.0	97.4	96.7	80.4	77.8	77.8	72.2	61.1	60.8	51.0	50.7	44.1	39.9	38.2	38.2	33.0	28.1	19.9	10.1	7.8	2.9	0.0
Nera 18mg	305	298	293	235	230	230	208	181	181	148	145	121	102	99	99	84	73	53	21	13	8	0
%	100.0	97.7	96.1	77.0	75.4	75.4	68.2	59.3	59.3	48.5	47.5	39.7	33.4	32.5	32.5	27.5	23.9	17.4	6.9	4.3	2.6	0.0

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

Placebo	0	8	10	18	19	19	20	23	24	26	26	28	34	34	34	41	54	78	101	108	122	130
%	0.0	2.6	3.3	5.9	6.2	6.2	6.5	7.5	7.8	8.5	8.5	9.2	11.1	11.1	11.1	13.4	17.6	25.5	33.0	35.3	39.9	42.5
Nera 18mg	0	6	9	13	13	13	17	17	17	21	22	22	29	31	31	42	52	72	101	109	114	120
%	0.0	2.0	3.0	4.3	4.3	4.3	5.6	5.6	5.6	6.9	7.2	7.2	9.5	10.2	10.2	13.8	17.0	23.6	33.1	35.7	37.4	39.3

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.1.1.1.1.3.2: 3

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

Table H.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 (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	306	195	63.7	87.24	305	187	61.3	83.78	1.05	(0.86,	1.29)	0.6373	
Age													0.5271
<65 years	69	44	63.8	78.43	63	35	55.6	69.05	0.92	(0.59,	1.44)	0.7278	
>=65 years	237	151	63.7	90.20	242	152	62.8	88.11	1.09	(0.86,	1.37)	0.4762	
Sex													0.2144
Male	269	170	63.2	87.45	255	153	60.0	79.40	0.99	(0.80,	1.24)	0.9474	
Female	37	25	67.6	85.86	50	34	68.0	111.43	1.43	(0.84,	2.42)	0.1866	
Baseline FVC percent predicted													0.2601
<=70%	109	66	60.6	84.89	112	72	64.3	100.21	1.22	(0.87,	1.71)	0.2409	
>70%	197	129	65.5	88.50	193	115	59.6	75.98	0.96	(0.74,	1.24)	0.7498	
Type of AF therapy													0.6278
Nintedanib	173	113	65.3	86.90	178	100	56.2	79.80	1.00	(0.76,	1.32)	0.9819	
Pirfenidone	133	82	61.7	87.73	127	87	68.5	88.87	1.11	(0.82,	1.50)	0.5041	
Region													0.0109
Europe	136	87	64.0	82.55	136	76	55.9	74.55	1.03	(0.76,	1.40)	0.8468	
Asia	72	48	66.7	106.58	79	44	55.7	70.70	0.62	(0.41,	0.93)	0.0218	
Canada and USA	75	47	62.7	83.65	56	43	76.8	115.92	1.54	(1.01,	2.34)	0.0449	
Rest of the World	23	13	56.5	76.92	34	24	70.6	109.48	1.62	(0.82,	3.19)	0.1615	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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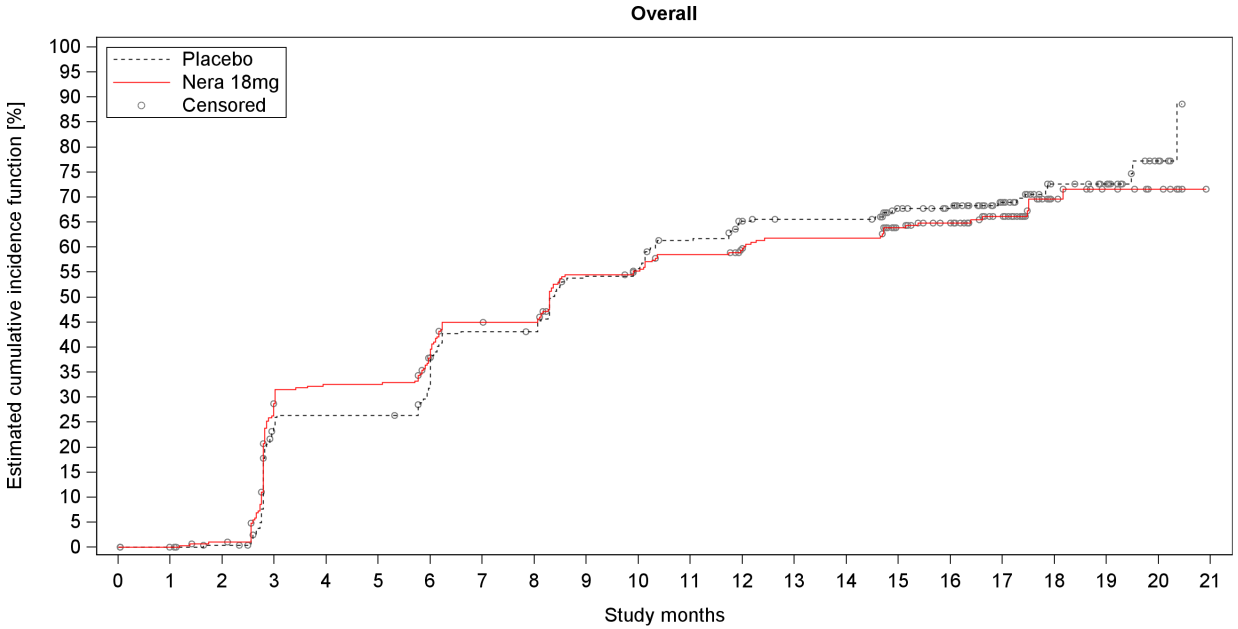

Number at risk (percentage relative to baseline)																					
Placebo	306	291	289	212	205	205	188	155	154	123	118	101	88	84	84	71	63	44	25	20	6	0
%	100.0	95.1	94.4	69.3	67.0	67.0	61.4	50.7	50.3	40.2	38.6	33.0	28.8	27.5	27.5	23.2	20.6	14.4	8.2	6.5	2.0	0.0
Nera 18mg	305	295	289	204	193	193	175	154	153	124	120	110	100	93	93	78	66	44	16	10	6	0
%	100.0	96.7	94.8	66.9	63.3	63.3	57.4	50.5	50.2	40.7	39.3	36.1	32.8	30.5	30.5	25.6	21.6	14.4	5.2	3.3	2.0	0.0
Number censored (percentage relative to number at risk at baseline)																					
Placebo	0	15	16	26	26	26	28	30	31	32	33	35	38	41	41	49	57	74	89	94	106	111
%	0.0	4.9	5.2	8.5	8.5	8.5	9.2	9.8	10.1	10.5	10.8	11.4	12.4	13.4	13.4	16.0	18.6	24.2	29.1	30.7	34.6	36.3
Nera 18mg	0	10	13	18	18	18	21	22	23	26	28	29	37	38	38	48	58	78	103	108	112	118
%	0.0	3.3	4.3	5.9	5.9	5.9	6.9	7.2	7.5	8.5	9.2	9.5	12.1	12.5	12.5	15.7	19.0	25.6	33.8	35.4	36.7	38.7

Study: 1305-0014

Figure H.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 (AF background)

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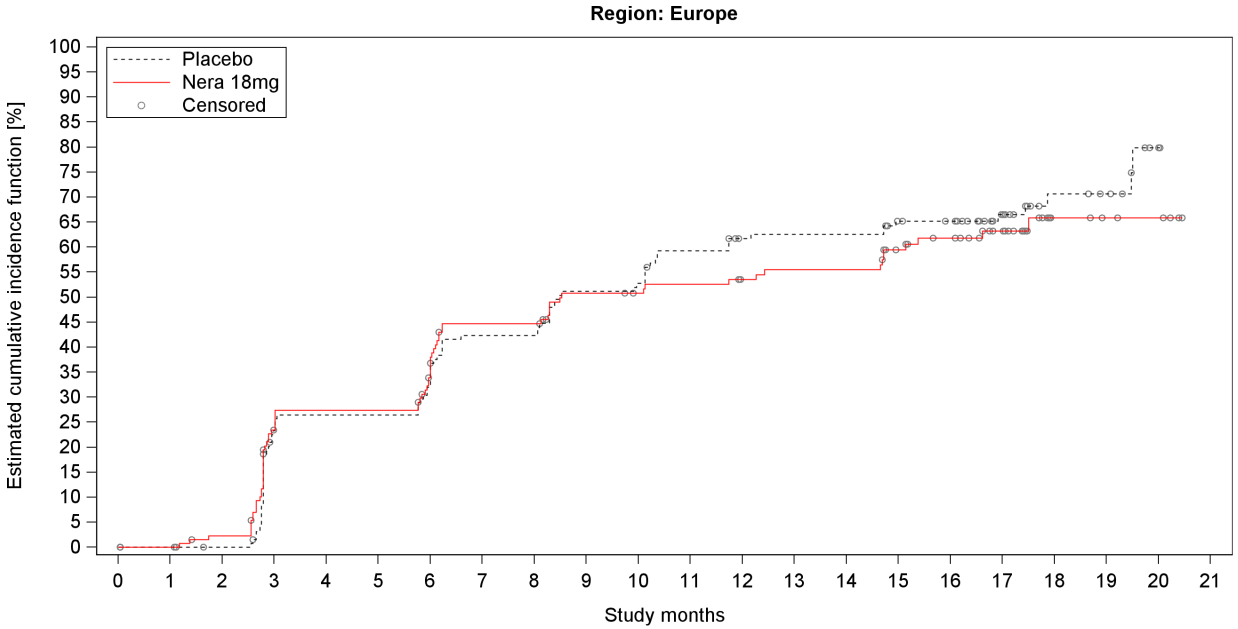

Number at risk (percentage relative to baseline)																					
Placebo	136	131	130	97	93	93	86	72	72	61	59	50	44	43	43	37	35	24	12	10	2	0
%	100.0	96.3	95.6	71.3	68.4	68.4	63.2	52.9	52.9	44.9	43.4	36.8	32.4	31.6	31.6	27.2	25.7	17.6	8.8	7.4	1.5	0.0
Nera 18mg	136	132	126	96	91	91	80	66	66	56	54	52	47	45	45	37	31	22	7	5	4	0
%	100.0	97.1	92.6	70.6	66.9	66.9	58.8	48.5	48.5	41.2	39.7	38.2	34.6	33.1	33.1	27.2	22.8	16.2	5.1	3.7	2.9	0.0
Number censored (percentage relative to number at risk at baseline)																					
Placebo	0	5	6	9	9	9	9	10	10	10	10	11	14	14	14	17	19	29	39	41	47	49
%	0.0	3.7	4.4	6.6	6.6	6.6	6.6	7.4	7.4	7.4	7.4	8.1	10.3	10.3	10.3	12.5	14.0	21.3	28.7	30.1	34.6	36.0
Nera 18mg	0	4	7	10	10	10	13	14	14	17	19	19	23	23	23	27	31	39	53	55	56	60
%	0.0	2.9	5.1	7.4	7.4	7.4	9.6	10.3	10.3	12.5	14.0	14.0	16.9	16.9	16.9	19.9	22.8	28.7	39.0	40.4	41.2	44.1

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.1.1.1.1.3.3: 1

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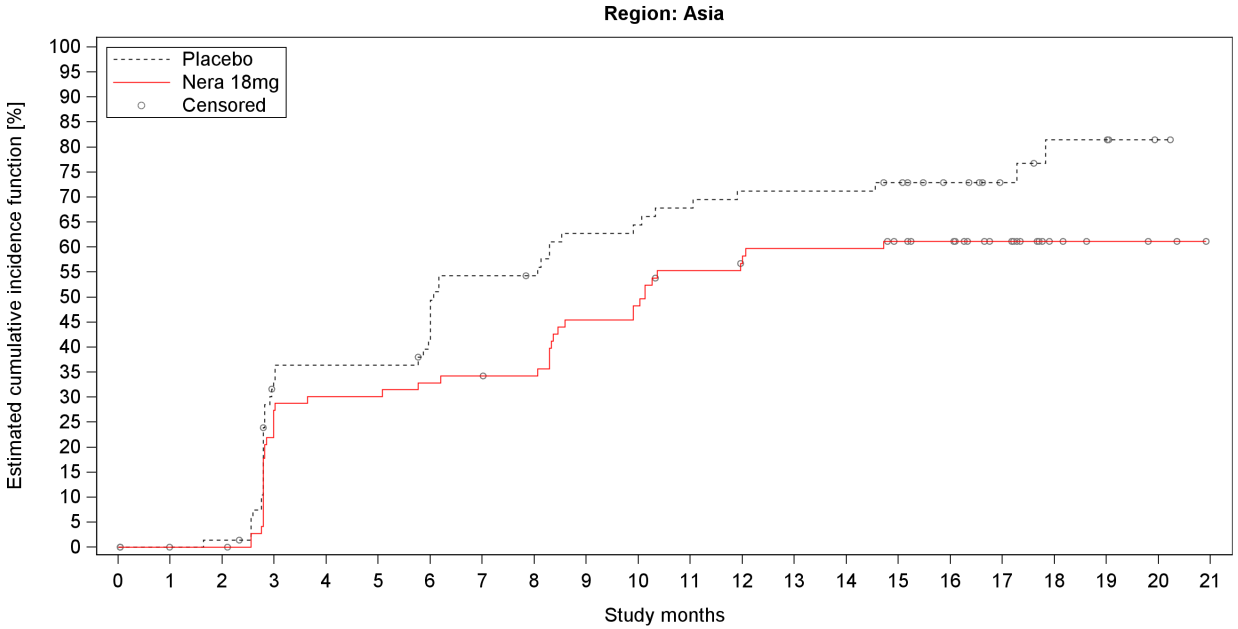

Number at risk (percentage relative to baseline)

Placebo	72	68	67	42	40	40	36	28	27	22	21	19	17	17	17	15	11	7	4	4	1	0
%	100.0	94.4	93.1	58.3	55.6	55.6	50.0	38.9	37.5	30.6	29.2	26.4	23.6	23.6	23.6	20.8	15.3	9.7	5.6	5.6	1.4	0.0
Nera 18mg	79	74	74	53	51	51	49	48	47	39	37	31	29	27	27	23	21	14	5	3	2	0
%	100.0	93.7	93.7	67.1	64.6	64.6	62.0	60.8	59.5	49.4	46.8	39.2	36.7	34.2	34.2	29.1	26.6	17.7	6.3	3.8	2.5	0.0

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

Placebo	0	4	4	8	8	8	9	9	10	10	10	10	10	10	10	11	15	19	20	20	23	24
%	0.0	5.6	5.6	11.1	11.1	11.1	12.5	12.5	13.9	13.9	13.9	13.9	13.9	13.9	13.9	15.3	20.8	26.4	27.8	27.8	31.9	33.3
Nera 18mg	0	5	5	6	6	6	6	6	7	7	7	8	9	9	9	12	14	21	30	32	33	35
%	0.0	6.3	6.3	7.6	7.6	7.6	7.6	7.6	8.9	8.9	8.9	10.1	11.4	11.4	11.4	15.2	17.7	26.6	38.0	40.5	41.8	44.3

Study: 1305-0014

Figure H.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 (AF background)

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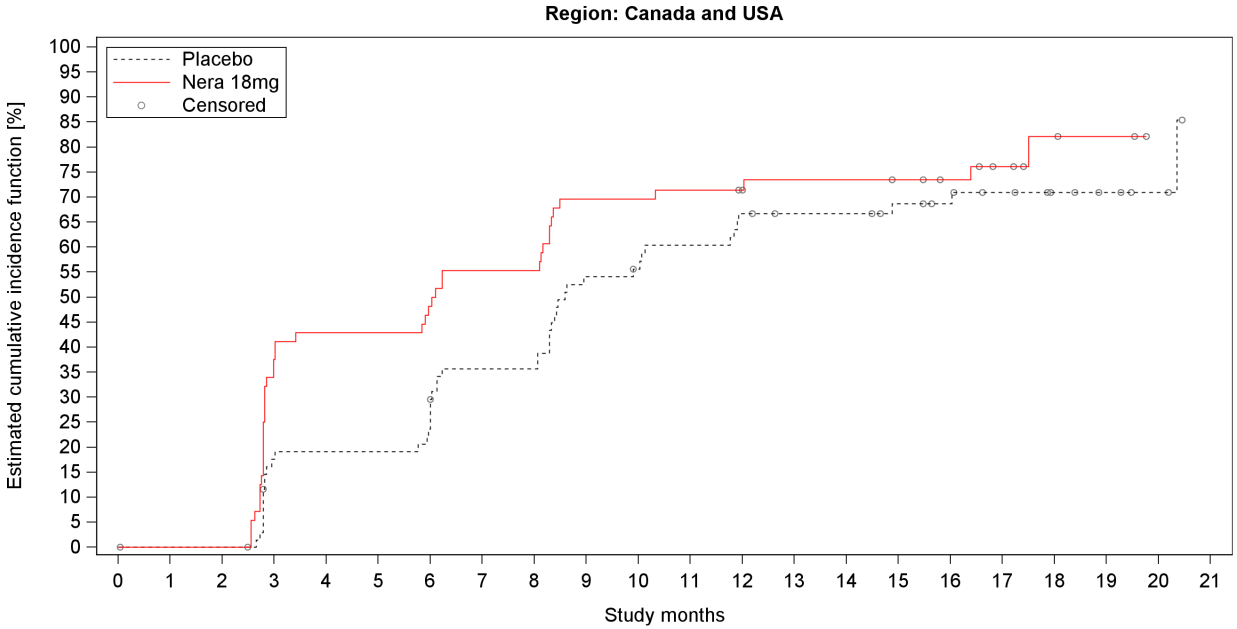

Number at risk (percentage relative to baseline)

Placebo	75	70	70	55	54	54	51	42	42	30	28	25	21	19	19	16	14	11	8	5	3	0
%	100.0	93.3	93.3	73.3	72.0	72.0	68.0	56.0	56.0	40.0	37.3	33.3	28.0	25.3	25.3	21.3	18.7	14.7	10.7	6.7	4.0	0.0
Nera 18mg	56	56	56	35	32	32	29	25	25	17	17	16	15	13	13	12	10	6	3	2	0	0
%	100.0	100.0	100.0	62.5	57.1	57.1	51.8	44.6	44.6	30.4	30.4	28.6	26.8	23.2	23.2	21.4	17.9	10.7	5.4	3.6	0.0	0.0

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

Placebo	0	5	5	8	8	8	8	9	9	9	10	10	10	12	12	14	16	18	21	24	26	28
%	0.0	6.7	6.7	10.7	10.7	10.7	10.7	12.0	12.0	12.0	13.3	13.3	13.3	16.0	16.0	18.7	21.3	24.0	28.0	32.0	34.7	37.3
Nera 18mg	0	0	0	0	0	0	0	0	0	0	0	0	1	2	2	3	5	8	10	11	13	13
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.8	3.6	3.6	5.4	8.9	14.3	17.9	19.6	23.2	23.2

Study: 1305-0014

Figure H.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 (AF background)

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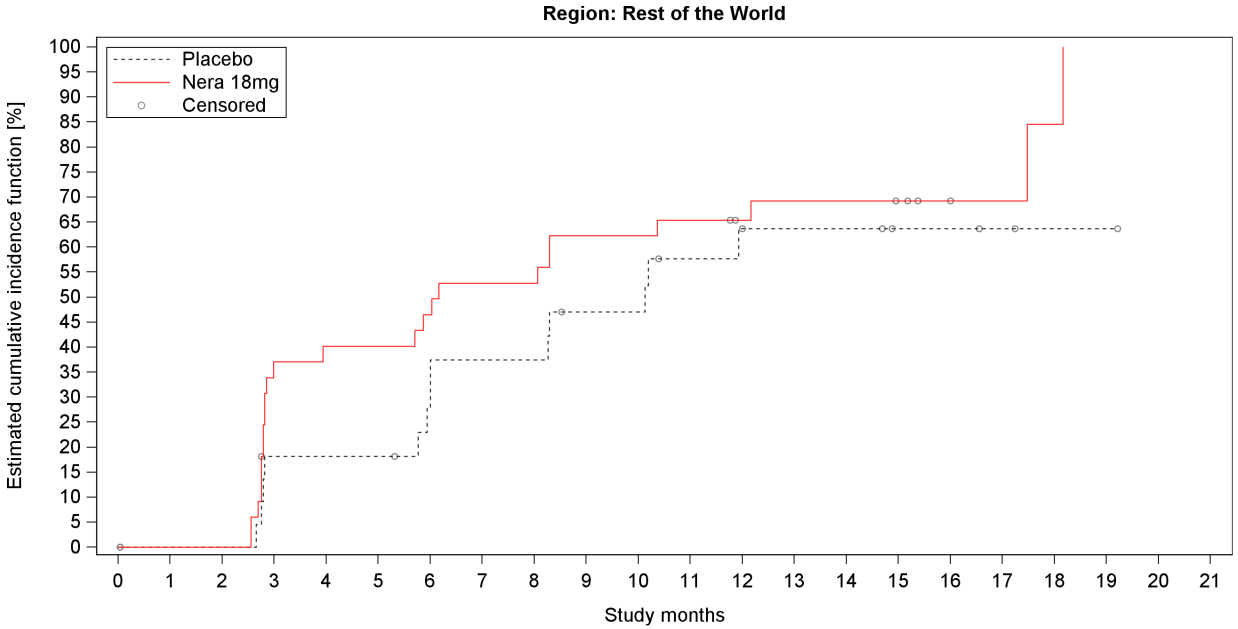

Number at risk (percentage relative to baseline)

Placebo	23	22	22	18	18	18	15	13	13	10	10	7	6	5	5	3	3	2	1	1	0	0
%	100.0	95.7	95.7	78.3	78.3	78.3	65.2	56.5	56.5	43.5	43.5	30.4	26.1	21.7	21.7	13.0	13.0	8.7	4.3	4.3	0.0	0.0
Nera 18mg	34	33	33	20	19	19	17	15	15	12	12	11	9	8	8	6	4	2	1	0	0	0
%	100.0	97.1	97.1	58.8	55.9	55.9	50.0	44.1	44.1	35.3	35.3	32.4	26.5	23.5	23.5	17.6	11.8	5.9	2.9	0.0	0.0	0.0

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

Placebo	0	1	1	1	1	1	2	2	2	3	3	4	4	5	5	7	7	8	9	9	10	10
%	0.0	4.3	4.3	4.3	4.3	4.3	8.7	8.7	8.7	13.0	13.0	17.4	17.4	21.7	21.7	30.4	30.4	34.8	39.1	39.1	43.5	43.5
Nera 18mg	0	1	1	2	2	2	2	2	2	2	2	2	4	4	4	6	8	10	10	10	10	10
%	0.0	2.9	2.9	5.9	5.9	5.9	5.9	5.9	5.9	5.9	5.9	5.9	11.8	11.8	11.8	17.6	23.5	29.4	29.4	29.4	29.4	29.4

Study: 1305-0014

Figure H.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 (AF background)

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BI Trial No.: x1305p3.hta

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Table H.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 (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	306	189	61.8	84.57	305	173	56.7	75.34	0.93	(0.76,	1.15)	0.4976	
Age													0.2953
<65 years	69	49	71.0	97.46	63	35	55.6	71.73	0.76	(0.49,	1.17)	0.2125	
>=65 years	237	140	59.1	80.82	242	138	57.0	76.31	0.99	(0.78,	1.25)	0.9168	
Sex													0.1930
Male	269	164	61.0	84.17	255	148	58.0	76.81	0.98	(0.78,	1.23)	0.8678	
Female	37	25	67.6	87.23	50	25	50.0	67.67	0.66	(0.37,	1.15)	0.1422	
Baseline FVC percent predicted													0.1636
<=70%	109	71	65.1	101.33	112	60	53.6	74.67	0.77	(0.54,	1.08)	0.1331	
>70%	197	118	59.9	76.91	193	113	58.5	75.70	1.04	(0.80,	1.35)	0.7532	
Type of AF therapy													0.5709
Nintedanib	173	102	59.0	78.15	178	95	53.4	75.51	0.98	(0.74,	1.30)	0.8989	
Pirfenidone	133	87	65.4	93.58	127	78	61.4	75.12	0.87	(0.64,	1.18)	0.3759	
Region													0.9183
Europe	136	82	60.3	79.94	136	74	54.4	74.15	0.96	(0.70,	1.31)	0.7900	
Asia	72	48	66.7	95.99	79	47	59.5	77.59	0.86	(0.57,	1.28)	0.4568	
Canada and USA	75	45	60.0	80.58	56	32	57.1	66.77	0.86	(0.54,	1.35)	0.5073	
Rest of the World	23	14	60.9	92.89	34	20	58.8	93.74	1.09	(0.55,	2.16)	0.8105	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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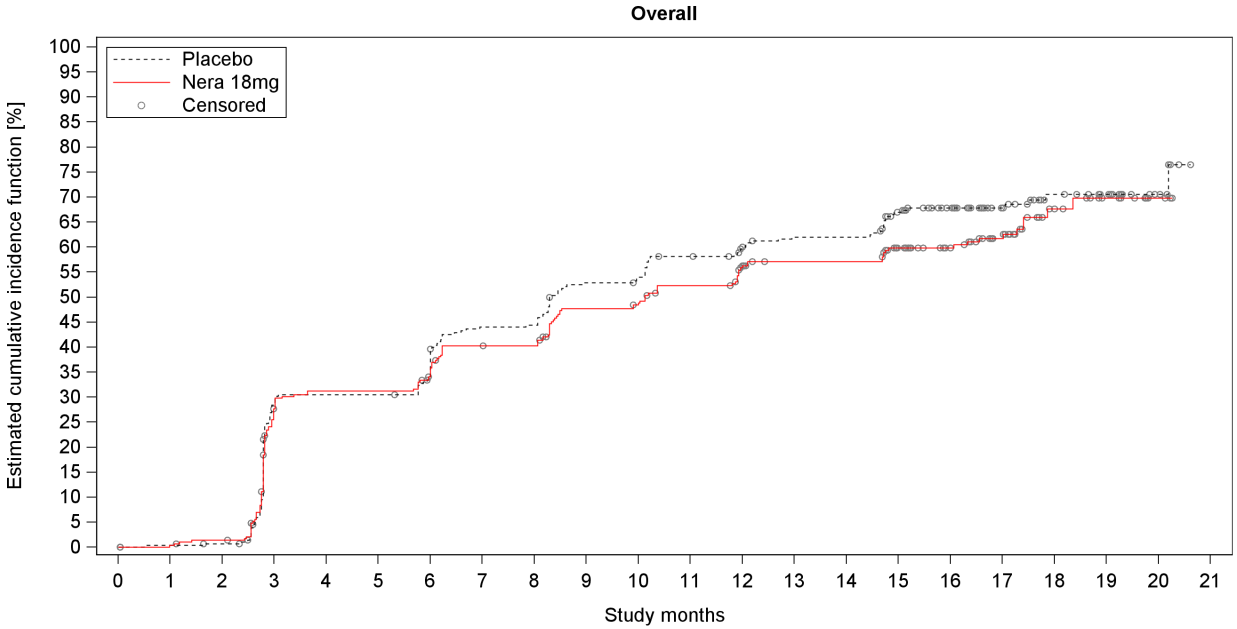

Number at risk (percentage relative to baseline)

Placebo	306	286	284	198	193	193	181	152	151	127	124	111	103	95	95	77	61	44	26	20	7	0
%	100.0	93.5	92.8	64.7	63.1	63.1	59.2	49.7	49.3	41.5	40.5	36.3	33.7	31.0	31.0	25.2	19.9	14.4	8.5	6.5	2.3	0.0
Nera 18mg	305	289	285	203	193	193	182	164	163	139	136	124	104	96	96	79	69	49	17	10	3	0
%	100.0	94.8	93.4	66.6	63.3	63.3	59.7	53.8	53.4	45.6	44.6	40.7	34.1	31.5	31.5	25.9	22.6	16.1	5.6	3.3	1.0	0.0

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

Placebo	0	19	20	27	27	27	29	31	31	32	33	34	38	40	40	46	60	77	92	98	111	117
%	0.0	6.2	6.5	8.8	8.8	8.8	9.5	10.1	10.1	10.5	10.8	11.1	12.4	13.1	13.1	15.0	19.6	25.2	30.1	32.0	36.3	38.2
Nera 18mg	0	15	16	23	23	23	26	27	28	32	33	35	46	51	51	62	72	89	116	122	129	132
%	0.0	4.9	5.2	7.5	7.5	7.5	8.5	8.9	9.2	10.5	10.8	11.5	15.1	16.7	16.7	20.3	23.6	29.2	38.0	40.0	42.3	43.3

Study: 1305-0014

Figure H.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 (AF background)

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H.1.1.1.1.4 Time to event analyses of supplemental oxygen use

Table H.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 (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	229	53	23.1	19.80	227	48	21.1	17.74	1.00	(0.67,	1.49)	0.9911	
Age													0.4599
<65 years	56	12	21.4	17.04	56	10	17.9	14.49	0.75	(0.32,	1.79)	0.5194	
>=65 years	173	41	23.7	20.79	171	38	22.2	18.86	1.09	(0.69,	1.70)	0.7180	
Sex													0.1658
Male	196	47	24.0	20.74	188	44	23.4	19.78	1.13	(0.74,	1.71)	0.5761	
Female	33	6	18.2	14.65	39	4	10.3	8.32	0.44	(0.12,	1.56)	0.2024	
Baseline FVC percent predicted													0.5464
<=70%	74	27	36.5	35.23	71	19	26.8	25.09	0.88	(0.49,	1.60)	0.6731	
>70%	155	26	16.8	13.62	156	29	18.6	14.89	1.13	(0.66,	1.93)	0.6669	
Type of AF therapy													0.1155
Nintedanib	133	32	24.1	20.88	128	22	17.2	14.49	0.75	(0.43,	1.29)	0.2975	
Pirfenidone	96	21	21.9	18.37	99	26	26.3	21.89	1.42	(0.79,	2.55)	0.2417	
Region													0.9365
Europe	102	19	18.6	15.26	97	20	20.6	17.05	1.13	(0.60,	2.13)	0.7106	
Asia	59	15	25.4	22.21	62	13	21.0	17.52	1.09	(0.51,	2.32)	0.8204	
Canada and USA	47	15	31.9	28.93	40	11	27.5	22.39	0.86	(0.40,	1.89)	0.7150	
Rest of the World	21	4	19.0	16.83	28	4	14.3	13.36	0.80	(0.20,	3.22)	0.7538	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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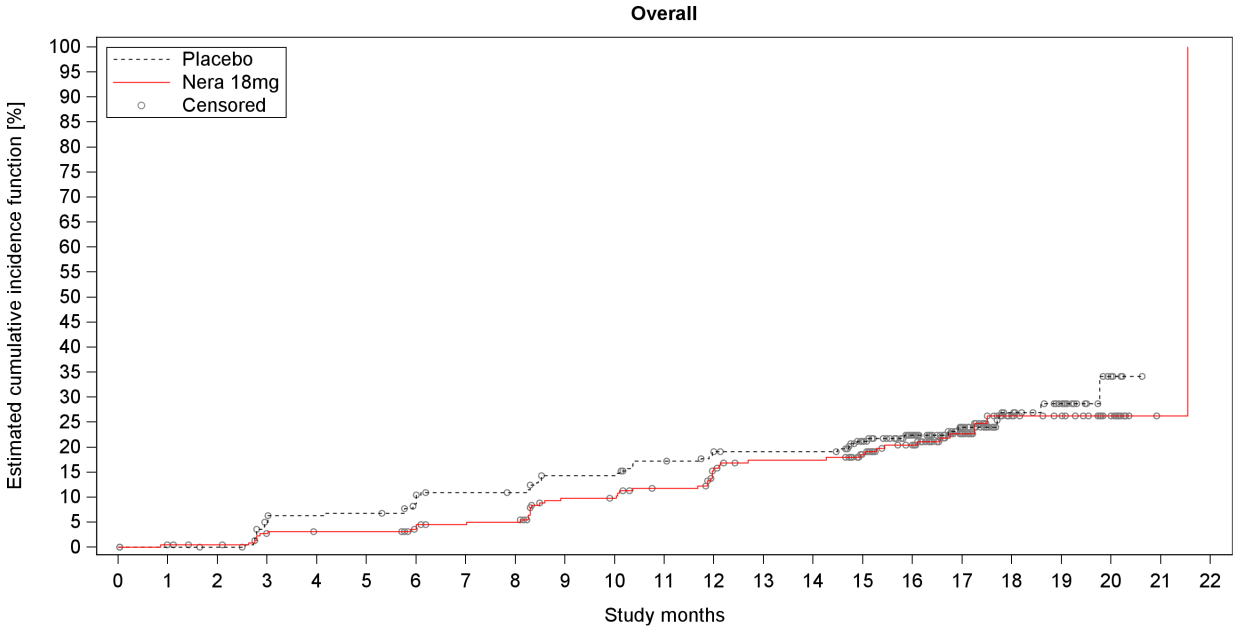

Number at risk (percentage relative to baseline)

Placebo	229	225	224	208	204	203	196	189	188	179	179	171	165	163	163	145	120	86	45	33	8	0	0
%	100.0	98.3	97.8	90.8	89.1	88.6	85.6	82.5	82.1	78.2	78.2	74.7	72.1	71.2	71.2	63.3	52.4	37.6	19.7	14.4	3.5	0.0	0.0
Nera 18mg	227	224	222	214	212	212	207	203	202	186	185	178	161	154	154	137	122	87	35	24	11	1	0
%	100.0	98.7	97.8	94.3	93.4	93.4	91.2	89.4	89.0	81.9	81.5	78.4	70.9	67.8	67.8	60.4	53.7	38.3	15.4	10.6	4.8	0.4	0.0

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

Placebo	0	4	5	10	11	11	14	16	17	19	19	21	23	25	25	39	62	94	133	144	168	176	176
%	0.0	1.7	2.2	4.4	4.8	4.8	6.1	7.0	7.4	8.3	8.3	9.2	10.0	10.9	10.9	17.0	27.1	41.0	58.1	62.9	73.4	76.9	76.9
Nera 18mg	0	2	4	7	8	8	12	14	14	20	21	24	34	37	37	52	64	96	145	156	169	179	179
%	0.0	0.9	1.8	3.1	3.5	3.5	5.3	6.2	6.2	8.8	9.3	10.6	15.0	16.3	16.3	22.9	28.2	42.3	63.9	68.7	74.4	78.9	78.9

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.1.1.1.1.4: 1

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Table H.1.1.1.1.4: 2 Cox model for time to increase of supplemental oxygen use over the whole trial - 18mg - FAS (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	306	114	37.3	36.65	305	101	33.1	31.39	0.87	(0.66,	1.14)	0.2988	
Age													0.1229
<65 years	69	24	34.8	30.53	63	13	20.6	17.66	0.54	(0.27,	1.06)	0.0722	
>=65 years	237	90	38.0	38.72	242	88	36.4	35.47	0.96	(0.71,	1.29)	0.7895	
Sex													0.1481
Male	269	105	39.0	39.23	255	93	36.5	35.11	0.95	(0.72,	1.26)	0.7458	
Female	37	9	24.3	20.73	50	8	16.0	14.07	0.46	(0.18,	1.19)	0.1090	
Baseline FVC percent predicted													0.7476
<=70%	109	54	49.5	57.82	112	46	41.1	45.89	0.83	(0.56,	1.22)	0.3402	
>70%	197	60	30.5	27.57	193	55	28.5	24.83	0.90	(0.62,	1.31)	0.5848	
Type of AF therapy													0.7323
Nintedanib	173	62	35.8	35.82	178	57	32.0	31.10	0.83	(0.58,	1.20)	0.3222	
Pirfenidone	133	52	39.1	37.69	127	44	34.6	31.78	0.92	(0.61,	1.38)	0.6734	
Region													0.2349
Europe	136	43	31.6	29.03	136	47	34.6	32.69	1.08	(0.71,	1.63)	0.7215	
Asia	72	27	37.5	37.44	79	24	30.4	28.65	0.89	(0.51,	1.55)	0.6828	
Canada and USA	75	40	53.3	59.67	56	21	37.5	34.00	0.57	(0.33,	0.97)	0.0379	
Rest of the World	23	4	17.4	16.83	34	9	26.5	27.76	1.49	(0.46,	4.87)	0.5058	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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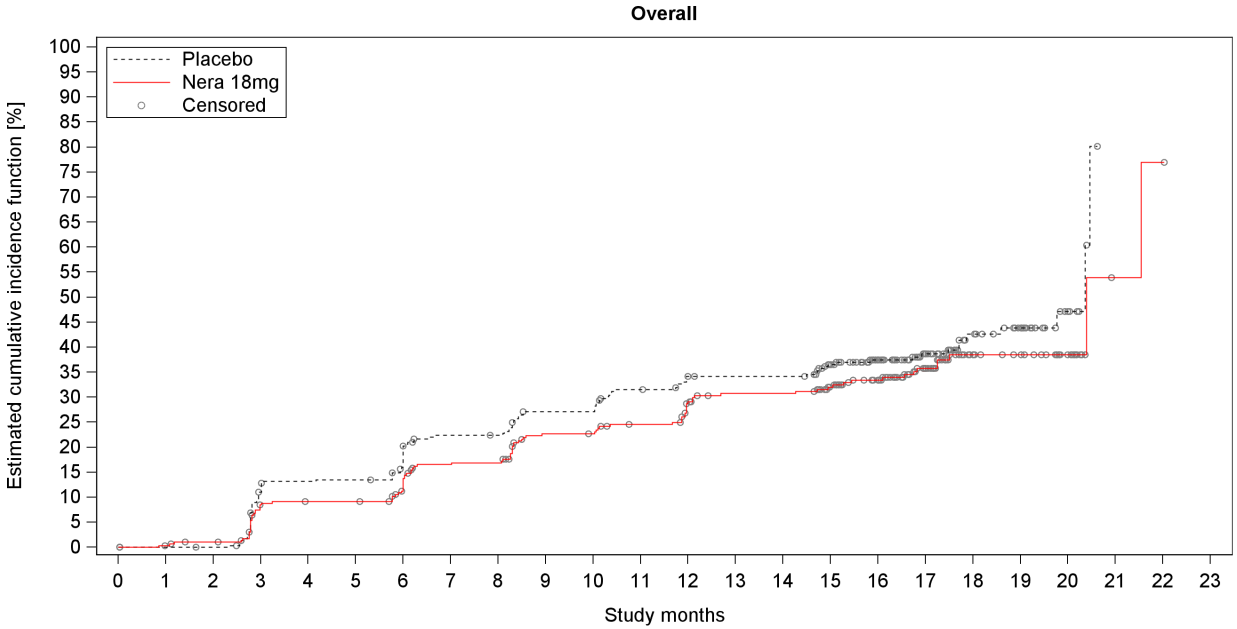

Number at risk (percentage relative to baseline)																								
Placebo	306	294	293	254	247	246	236	215	214	199	199	185	176	174	174	154	128	93	50	38	11	0	0	0
%	100.0	96.1	95.8	83.0	80.7	80.4	77.1	70.3	69.9	65.0	65.0	60.5	57.5	56.9	56.9	50.3	41.8	30.4	16.3	12.4	3.6	0.0	0.0	0.0
Nera 18mg	305	298	294	267	264	264	252	234	233	211	210	202	179	169	169	150	133	95	39	26	13	2	1	0
%	100.0	97.7	96.4	87.5	86.6	86.6	82.6	76.7	76.4	69.2	68.9	66.2	58.7	55.4	55.4	49.2	43.6	31.1	12.8	8.5	4.3	0.7	0.3	0.0
Number censored (percentage relative to number at risk at baseline)																								
Placebo	0	12	13	20	21	21	24	27	28	30	30	32	34	36	36	50	74	107	146	157	183	192	192	192
%	0.0	3.9	4.2	6.5	6.9	6.9	7.8	8.8	9.2	9.8	9.8	10.5	11.1	11.8	11.8	16.3	24.2	35.0	47.7	51.3	59.8	62.7	62.7	62.7
Nera 18mg	0	6	8	13	14	14	20	23	23	29	30	33	45	50	50	66	80	114	167	180	193	203	203	204
%	0.0	2.0	2.6	4.3	4.6	4.6	6.6	7.5	7.5	9.5	9.8	10.8	14.8	16.4	16.4	21.6	26.2	37.4	54.8	59.0	63.3	66.6	66.6	66.9

Study: 1305-0014

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

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H.1.1.1.2 Analyses of continuous variables

H.1.1.1.2.1 MMRM Analysis

Table H.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 (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	306	298	24.4	0.9	291 (100.0%)												
Nera 18mg	305	298	25.6	1.0	295 (100.0%)												
Week 12																	
Placebo		293	24.4	1.0	286 (98.3%)	0.2	0.6	-0.9	1.4								
Nera 18mg		294	27.2	1.0	288 (97.6%)	1.9	0.6	0.7	3.0	1.6	0.8	0.0	3.2	0.0492	0.16	0.00	0.33
Week 26																	
Placebo		278	25.4	1.0	272 (93.5%)	2.0	0.7	0.6	3.4								
Nera 18mg		282	28.3	1.2	277 (93.9%)	3.3	0.7	1.9	4.7	1.3	1.0	-0.6	3.3	0.1841			
Week 36																	
Placebo		268	27.5	1.1	262 (90.0%)	4.4	0.7	3.0	5.8								
Nera 18mg		270	28.9	1.2	265 (89.8%)	4.6	0.7	3.1	6.0	0.2	1.0	-1.9	2.2	0.8828			
Week 44																	
Placebo		266	28.8	1.2	259 (89.0%)	5.4	0.8	3.9	7.0								
Nera 18mg		259	29.5	1.2	254 (86.1%)	5.6	0.8	4.1	7.2	0.2	1.1	-2.0	2.4	0.8562			
Week 52																	
Placebo		258	29.0	1.3	253 (86.9%)	6.7	0.8	5.0	8.3								
Nera 18mg		260	29.5	1.2	255 (86.4%)	5.3	0.8	3.7	7.0	-1.3	1.2	-3.6	1.0	0.2566			
Week 64																	
Placebo		240	28.7	1.3	235 (80.8%)	7.6	0.9	5.8	9.4								
Nera 18mg		231	29.0	1.4	228 (77.3%)	5.6	0.9	3.7	7.4	-2.0	1.3	-4.6	0.6	0.1262			
Week 76																	
Placebo		172	27.2	1.5	167 (57.4%)												
Nera 18mg		171	29.8	1.6	168 (56.9%)												
Week 88																	
Placebo		49	24.5	2.4	48 (16.5%)												
Nera 18mg		36	28.3	3.5	35 (11.9%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	6.6	NC	1 (0.3%)												
Age																	
Test for homogeneity (H0)^																	
Week 12														0.0758			

Study: 1305-0014. 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, 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 H.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 (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 95% CI value	lower	upper
Week 26														0.9753			
Week 36														0.2197			
Week 44														0.8714			
Week 52														0.8100			
Week 64														0.7044			
<65 years																	
Baseline																	
Placebo	69	67	22.8	1.8	67 (100.0%)												
Nera 18mg	63	62	24.8	2.0	62 (100.0%)												
Week 12																	
Placebo		65	24.9	2.2	64 (95.5%)	1.6	1.2	-0.8	4.0								
Nera 18mg		62	25.1	2.0	61 (98.4%)	0.4	1.3	-2.0	2.9	-1.1	1.8	-4.6	2.3	0.5154			
Week 26																	
Placebo		66	23.4	1.7	64 (95.5%)	2.0	1.5	-0.9	4.9								
Nera 18mg		62	28.0	2.3	61 (98.4%)	3.3	1.5	0.3	6.2	1.2	2.1	-2.9	5.4	0.5518			
Week 36																	
Placebo		65	27.1	2.3	63 (94.0%)	5.2	1.5	2.3	8.2								
Nera 18mg		59	26.4	2.2	58 (93.5%)	3.0	1.6	-0.1	6.1	-2.2	2.2	-6.5	2.1	0.3103			
Week 44																	
Placebo		64	28.7	2.5	62 (92.5%)	6.2	1.6	3.1	9.4								
Nera 18mg		56	30.6	2.6	55 (88.7%)	6.8	1.7	3.5	10.1	0.6	2.3	-4.0	5.1	0.8116			
Week 52																	
Placebo		63	26.6	2.3	61 (91.0%)	5.6	1.7	2.3	9.0								
Nera 18mg		55	29.5	2.5	54 (87.1%)	4.8	1.8	1.2	8.3	-0.9	2.5	-5.7	4.0	0.7310			
Week 64																	
Placebo		60	27.7	2.5	58 (86.6%)	7.6	1.9	3.9	11.4								
Nera 18mg		49	29.8	3.1	48 (77.4%)	4.7	2.0	0.7	8.6	-3.0	2.8	-8.5	2.5	0.2846			
Week 76																	
Placebo		38	24.6	2.7	37 (55.2%)												
Nera 18mg		35	30.6	3.3	34 (54.8%)												
Week 88																	
Placebo		16	24.7	4.3	15 (22.4%)												
Nera 18mg		7	35.6	8.5	7 (11.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												

Study: 1305-0014. 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, 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 H.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 (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		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	237	231	24.9	1.0	224 (100.0%)												
Nera 18mg	242	236	25.8	1.2	233 (100.0%)												
Week 12																	
Placebo		228	24.3	1.1	222 (99.1%)	-0.1	0.7	-1.4	1.2								
Nera 18mg		232	27.8	1.2	227 (97.4%)	2.2	0.7	1.0	3.5	2.4	0.9	0.6	4.2	0.0103	0.24	0.06	0.43
Week 26																	
Placebo		212	26.0	1.2	208 (92.9%)	2.0	0.8	0.4	3.5								
Nera 18mg		220	28.3	1.3	216 (92.7%)	3.3	0.8	1.7	4.8	1.3	1.1	-0.9	3.5	0.2425			
Week 36																	
Placebo		203	27.6	1.3	199 (88.8%)	4.1	0.8	2.5	5.8								
Nera 18mg		211	29.6	1.3	207 (88.8%)	5.0	0.8	3.4	6.6	0.8	1.2	-1.5	3.1	0.4818			
Week 44																	
Placebo		202	28.8	1.4	197 (87.9%)	5.2	0.9	3.4	7.0								
Nera 18mg		203	29.1	1.4	199 (85.4%)	5.3	0.9	3.6	7.1	0.1	1.3	-2.4	2.6	0.9203			
Week 52																	
Placebo		195	29.7	1.5	192 (85.7%)	7.0	1.0	5.2	8.9								
Nera 18mg		205	29.5	1.4	201 (86.3%)	5.5	0.9	3.7	7.3	-1.5	1.3	-4.2	1.1	0.2540			
Week 64																	
Placebo		180	29.1	1.5	177 (79.0%)	7.6	1.1	5.5	9.7								
Nera 18mg		182	28.8	1.6	180 (77.3%)	5.8	1.1	3.7	7.9	-1.8	1.5	-4.7	1.2	0.2377			
Week 76																	
Placebo		134	27.9	1.7	130 (58.0%)												
Nera 18mg		136	29.6	1.8	134 (57.5%)												
Week 88																	
Placebo		33	24.5	2.9	33 (14.7%)												
Nera 18mg		29	26.6	3.8	28 (12.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	6.6	NC	1 (0.4%)												
Sex																	
Test for homogeneity (H0)^																	

Study: 1305-0014. 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, 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 H.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 (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														0.3611			
Week 26														0.6082			
Week 36														0.3197			
Week 44														0.1747			
Week 52														0.0744			
Week 64														0.3988			
Male																	
Baseline																	
Placebo	269	263	24.2	1.0	256 (100.0%)												
Nera 18mg	255	248	25.4	1.1	245 (100.0%)												
Week 12																	
Placebo		258	24.2	1.0	252 (98.4%)	0.2	0.6	-1.0	1.4								
Nera 18mg		245	26.7	1.1	239 (97.6%)	1.4	0.6	0.2	2.7	1.2	0.9	-0.5	3.0	0.1669			
Week 26																	
Placebo		242	25.1	1.1	238 (93.0%)	1.9	0.8	0.5	3.4								
Nera 18mg		235	27.9	1.2	230 (93.9%)	3.0	0.8	1.5	4.5	1.1	1.1	-1.0	3.2	0.3212			
Week 36																	
Placebo		232	27.3	1.2	228 (89.1%)	4.7	0.8	3.2	6.3								
Nera 18mg		227	28.7	1.3	222 (90.6%)	4.5	0.8	2.9	6.1	-0.3	1.1	-2.5	2.0	0.8218			
Week 44																	
Placebo		230	28.7	1.3	225 (87.9%)	5.9	0.8	4.3	7.5								
Nera 18mg		218	29.1	1.3	213 (86.9%)	5.5	0.9	3.8	7.2	-0.4	1.2	-2.8	2.0	0.7393			
Week 52																	
Placebo		223	28.9	1.4	220 (85.9%)	7.1	0.9	5.4	8.9								
Nera 18mg		219	29.0	1.3	214 (87.3%)	4.9	0.9	3.2	6.7	-2.2	1.3	-4.7	0.3	0.0855			
Week 64																	
Placebo		205	27.8	1.3	202 (78.9%)	7.3	1.0	5.3	9.3								
Nera 18mg		198	29.4	1.5	195 (79.6%)	5.7	1.0	3.7	7.7	-1.6	1.4	-4.4	1.2	0.2712			
Week 76																	
Placebo		149	26.5	1.5	145 (56.6%)												
Nera 18mg		148	29.6	1.6	145 (59.2%)												
Week 88																	
Placebo		42	25.0	2.5	42 (16.4%)												
Nera 18mg		31	29.0	3.9	30 (12.2%)												
Week 100																	

Study: 1305-0014. 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, 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 H.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 (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		0	NC	NC	0 (0.0%)												
Nera 18mg		1	6.6	NC	1 (0.4%)												
Female																	
Baseline																	
Placebo	37	35	26.4	2.8	35 (100.0%)												
Nera 18mg	50	50	26.4	2.6	50 (100.0%)												
Week 12																	
Placebo		35	26.2	3.4	34 (97.1%)	0.6	1.7	-2.7	3.9								
Nera 18mg		49	29.7	2.7	49 (98.0%)	4.0	1.4	1.3	6.8	3.4	2.2	-0.9	7.7	0.1225			
Week 26																	
Placebo		36	27.3	3.1	34 (97.1%)	2.1	2.0	-1.9	6.0								
Nera 18mg		47	30.1	3.2	47 (94.0%)	4.6	1.7	1.3	8.0	2.5	2.6	-2.6	7.7	0.3373			
Week 36																	
Placebo		36	28.5	3.0	34 (97.1%)	2.1	2.1	-2.0	6.2								
Nera 18mg		43	30.0	3.0	43 (86.0%)	4.8	1.8	1.3	8.3	2.7	2.7	-2.7	8.1	0.3255			
Week 44																	
Placebo		36	29.4	3.4	34 (97.1%)	2.4	2.2	-2.0	6.7								
Nera 18mg		41	31.2	3.4	41 (82.0%)	6.3	1.9	2.5	10.0	3.9	2.9	-1.8	9.6	0.1833			
Week 52																	
Placebo		35	29.1	3.7	33 (94.3%)	3.7	2.3	-0.9	8.2								
Nera 18mg		41	32.4	3.4	41 (82.0%)	7.5	2.0	3.4	11.5	3.8	3.1	-2.3	9.9	0.2209			
Week 64																	
Placebo		35	33.9	4.2	33 (94.3%)	9.3	2.6	4.2	14.3								
Nera 18mg		33	26.6	3.9	33 (66.0%)	4.5	2.4	-0.1	9.2	-4.8	3.5	-11.6	2.1	0.1734			
Week 76																	
Placebo		23	31.2	4.8	22 (62.9%)												
Nera 18mg		23	31.2	5.4	23 (46.0%)												
Week 88																	
Placebo		7	21.8	6.7	6 (17.1%)												
Nera 18mg		5	24.1	7.4	5 (10.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Baseline FVC percent predicted

Study: 1305-0014. 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, 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 H.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 (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
Test for homogeneity (H0)^																	
Week 12														0.7129			
Week 26														0.8979			
Week 36														0.5593			
Week 44														0.3198			
Week 52														0.6320			
Week 64														0.1648			
<=70%																	
Baseline																	
Placebo	109	107	30.0	1.6	101 (100.0%)												
Nera 18mg	112	107	30.6	1.7	104 (100.0%)												
Week 12																	
Placebo		102	30.0	1.8	100 (99.0%)	1.2	1.0	-0.8	3.1								
Nera 18mg		103	32.7	1.8	99 (95.2%)	3.2	1.0	1.2	5.1	2.0	1.4	-0.7	4.8	0.1430			
Week 26																	
Placebo		94	31.0	1.8	92 (91.1%)	4.0	1.2	1.6	6.4								
Nera 18mg		96	33.7	1.8	93 (89.4%)	5.1	1.2	2.8	7.5	1.2	1.7	-2.2	4.5	0.4952			
Week 36																	
Placebo		88	34.3	2.2	86 (85.1%)	7.4	1.3	4.9	9.9								
Nera 18mg		91	34.6	1.9	88 (84.6%)	6.7	1.3	4.2	9.2	-0.7	1.8	-4.2	2.8	0.7013			
Week 44																	
Placebo		88	36.2	2.3	86 (85.1%)	8.2	1.4	5.5	10.9								
Nera 18mg		83	33.7	1.9	80 (76.9%)	6.8	1.4	4.1	9.5	-1.4	1.9	-5.1	2.4	0.4791			
Week 52																	
Placebo		86	35.8	2.3	85 (84.2%)	9.2	1.4	6.3	12.0								
Nera 18mg		85	34.9	1.9	82 (78.8%)	7.1	1.4	4.2	9.9	-2.1	2.0	-6.1	1.9	0.2971			
Week 64																	
Placebo		78	36.6	2.5	77 (76.2%)	11.9	1.6	8.7	15.1								
Nera 18mg		71	34.9	2.2	69 (66.3%)	7.3	1.7	4.0	10.5	-4.6	2.3	-9.1	-0.1	0.0450	-0.33	-0.65	-0.00
Week 76																	
Placebo		54	34.9	2.7	53 (52.5%)												
Nera 18mg		57	36.1	2.5	54 (51.9%)												
Week 88																	
Placebo		14	28.7	3.8	14 (13.9%)												
Nera 18mg		9	38.7	7.9	8 (7.7%)												

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Model is based on fixed, categorical effects of treatment 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 H.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 (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 95% CI value	lower	upper
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	197	191	21.3	1.0	190 (100.0%)												
Nera 18mg	193	191	22.7	1.2	191 (100.0%)												
Week 12																	
Placebo		191	21.5	1.1	186 (97.9%)	-0.2	0.7	-1.7	1.2								
Nera 18mg		191	24.2	1.2	189 (99.0%)	1.2	0.7	-0.2	2.6	1.4	1.0	-0.6	3.4	0.1668			
Week 26																	
Placebo		184	22.5	1.1	180 (94.7%)	0.9	0.9	-0.8	2.6								
Nera 18mg		186	25.5	1.4	184 (96.3%)	2.3	0.9	0.6	4.0	1.4	1.2	-1.0	3.8	0.2435			
Week 36																	
Placebo		180	24.2	1.2	176 (92.6%)	2.9	0.9	1.1	4.6								
Nera 18mg		179	26.0	1.4	177 (92.7%)	3.5	0.9	1.7	5.2	0.6	1.3	-1.9	3.1	0.6396			
Week 44																	
Placebo		178	25.1	1.3	173 (91.1%)	4.0	1.0	2.1	5.9								
Nera 18mg		176	27.5	1.6	174 (91.1%)	5.0	1.0	3.1	6.9	1.0	1.4	-1.7	3.6	0.4692			
Week 52																	
Placebo		172	25.5	1.5	168 (88.4%)	5.4	1.0	3.4	7.4								
Nera 18mg		175	26.9	1.5	173 (90.6%)	4.5	1.0	2.5	6.5	-0.9	1.4	-3.7	1.9	0.5201			
Week 64																	
Placebo		162	25.0	1.4	158 (83.2%)	5.4	1.1	3.1	7.7								
Nera 18mg		160	26.4	1.7	159 (83.2%)	4.7	1.1	2.5	6.9	-0.7	1.6	-3.9	2.4	0.6556			
Week 76																	
Placebo		118	23.6	1.7	114 (60.0%)												
Nera 18mg		114	26.6	2.0	114 (59.7%)												
Week 88																	
Placebo		35	22.8	2.9	34 (17.9%)												
Nera 18mg		27	24.9	3.6	27 (14.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	6.6	NC	1 (0.5%)												

Study: 1305-0014. 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, 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 H.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 (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
Type of AF therapy																	
Test for homogeneity (H0)^																	
Week 12														0.2820			
Week 26														0.2215			
Week 36														0.2146			
Week 44														0.4687			
Week 52														0.7084			
Week 64														0.7734			
Nintedanib																	
Baseline																	
Placebo	173	169	24.2	1.2	165 (100.0%)												
Nera 18mg	178	174	25.5	1.3	172 (100.0%)												
Week 12																	
Placebo		164	23.6	1.3	161 (97.6%)	-0.2	0.8	-1.7	1.3								
Nera 18mg		169	27.3	1.4	166 (96.5%)	2.2	0.8	0.7	3.7	2.4	1.1	0.3	4.5	0.0285	0.24	0.03	0.46
Week 26																	
Placebo		156	23.7	1.3	153 (92.7%)	1.0	0.9	-0.9	2.8								
Nera 18mg		159	27.4	1.5	157 (91.3%)	3.4	0.9	1.6	5.2	2.4	1.3	-0.2	5.0	0.0711			
Week 36																	
Placebo		153	25.8	1.4	150 (90.9%)	3.2	1.0	1.3	5.1								
Nera 18mg		151	27.8	1.6	149 (86.6%)	4.5	1.0	2.6	6.4	1.3	1.4	-1.4	4.0	0.3572			
Week 44																	
Placebo		149	27.8	1.6	146 (88.5%)	4.8	1.0	2.8	6.9								
Nera 18mg		142	27.2	1.6	139 (80.8%)	4.3	1.0	2.2	6.3	-0.6	1.5	-3.4	2.3	0.7090			
Week 52																	
Placebo		147	28.3	1.6	144 (87.3%)	6.0	1.1	3.8	8.1								
Nera 18mg		147	27.7	1.6	144 (83.7%)	4.2	1.1	2.1	6.4	-1.7	1.6	-4.8	1.3	0.2679			
Week 64																	
Placebo		134	26.1	1.6	131 (79.4%)	5.8	1.2	3.3	8.2								
Nera 18mg		125	26.5	1.8	124 (72.1%)	4.0	1.2	1.6	6.5	-1.7	1.8	-5.2	1.7	0.3286			
Week 76																	
Placebo		99	25.6	1.9	97 (58.8%)												
Nera 18mg		93	28.1	2.2	91 (52.9%)												
Week 88																	
Placebo		28	28.3	3.4	27 (16.4%)												

Study: 1305-0014. 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 H.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 (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		22	30.9	4.5	21 (12.2%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Pirfenidone																	
Baseline																	
Placebo	133	129	24.8	1.4	126 (100.0%)												
Nera 18mg	127	124	25.7	1.6	123 (100.0%)												
Week 12																	
Placebo		129	25.5	1.6	125 (99.2%)	0.8	0.9	-0.9	2.6								
Nera 18mg		125	27.1	1.6	122 (99.2%)	1.4	0.9	-0.3	3.2	0.6	1.3	-1.9	3.1	0.6329			
Week 26																	
Placebo		122	27.6	1.6	119 (94.4%)	3.2	1.1	1.1	5.3								
Nera 18mg		123	29.4	1.7	120 (97.6%)	3.2	1.1	1.0	5.3	-0.1	1.5	-3.0	2.9	0.9640			
Week 36																	
Placebo		115	29.8	1.8	112 (88.9%)	6.0	1.1	3.8	8.2								
Nera 18mg		119	30.3	1.7	116 (94.3%)	4.6	1.1	2.5	6.8	-1.3	1.6	-4.4	1.8	0.3988			
Week 44																	
Placebo		117	30.1	1.9	113 (89.7%)	6.3	1.2	3.9	8.6								
Nera 18mg		117	32.2	1.9	115 (93.5%)	7.3	1.2	5.0	9.6	1.1	1.7	-2.2	4.4	0.5241			
Week 52																	
Placebo		111	29.9	2.0	109 (86.5%)	7.6	1.3	5.1	10.1								
Nera 18mg		113	31.9	1.9	111 (90.2%)	6.8	1.3	4.3	9.2	-0.8	1.8	-4.3	2.7	0.6371			
Week 64																	
Placebo		106	32.1	2.2	104 (82.5%)	9.9	1.4	7.1	12.7								
Nera 18mg		106	32.0	2.1	104 (84.6%)	7.4	1.4	4.7	10.2	-2.5	2.0	-6.4	1.4	0.2121			
Week 76																	
Placebo		73	29.3	2.4	70 (55.6%)												
Nera 18mg		78	31.8	2.2	77 (62.6%)												
Week 88																	
Placebo		21	19.4	2.9	21 (16.7%)												
Nera 18mg		14	24.3	5.4	14 (11.4%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	6.6	NC	1 (0.8%)												

Study: 1305-0014. 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 H.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 (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
Region																	
Test for homogeneity (H0)^																	
Week 12														0.4255			
Week 26														0.2942			
Week 36														0.0453			
Week 44														0.8860			
Week 52														0.8898			
Week 64														0.8309			
Europe																	
Baseline																	
Placebo	136	133	23.4	1.3	131 (100.0%)												
Nera 18mg	136	133	26.4	1.5	132 (100.0%)												
Week 12																	
Placebo		130	24.2	1.4	127 (96.9%)	0.8	0.9	-0.9	2.5								
Nera 18mg		128	27.5	1.6	126 (95.5%)	1.6	0.9	-0.1	3.3	0.8	1.2	-1.6	3.2	0.5161			
Week 26																	
Placebo		123	23.6	1.4	121 (92.4%)	1.7	1.1	-0.4	3.8								
Nera 18mg		125	29.5	1.7	123 (93.2%)	4.4	1.1	2.3	6.4	2.7	1.5	-0.2	5.6	0.0725			
Week 36																	
Placebo		120	25.0	1.6	118 (90.1%)	3.6	1.1	1.4	5.7								
Nera 18mg		118	31.1	1.7	116 (87.9%)	5.9	1.1	3.7	8.1	2.3	1.6	-0.7	5.4	0.1324			
Week 44																	
Placebo		121	28.1	1.8	118 (90.1%)	5.9	1.2	3.6	8.2								
Nera 18mg		115	31.1	2.0	112 (84.8%)	6.4	1.2	4.0	8.7	0.5	1.7	-2.8	3.7	0.7813			
Week 52																	
Placebo		118	27.2	1.7	116 (88.5%)	6.7	1.2	4.3	9.2								
Nera 18mg		116	30.6	1.8	113 (85.6%)	5.4	1.3	3.0	7.9	-1.3	1.8	-4.8	2.2	0.4628			
Week 64																	
Placebo		111	26.6	1.7	109 (83.2%)	6.7	1.4	4.0	9.4								
Nera 18mg		99	28.9	2.0	98 (74.2%)	5.0	1.4	2.2	7.8	-1.7	2.0	-5.5	2.2	0.3984			
Week 76																	
Placebo		80	24.9	2.1	78 (59.5%)												
Nera 18mg		73	31.4	2.5	72 (54.5%)												
Week 88																	
Placebo		22	24.1	3.6	22 (16.8%)												

Study: 1305-0014. 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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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 H.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 (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		18	29.8	5.7	18 (13.6%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Asia																	
Baseline																	
Placebo	72	70	25.2	1.8	68 (100.0%)												
Nera 18mg	79	78	24.1	2.0	76 (100.0%)												
Week 12																	
Placebo		69	23.8	2.0	68 (100.0%)	-0.6	1.2	-3.0	1.8								
Nera 18mg		77	25.3	1.9	76 (100.0%)	1.6	1.1	-0.6	3.8	2.2	1.7	-1.1	5.4	0.1857			
Week 26																	
Placebo		63	26.0	1.9	62 (91.2%)	2.0	1.5	-0.9	4.9								
Nera 18mg		74	25.3	2.4	73 (96.1%)	1.3	1.4	-1.4	4.0	-0.7	2.0	-4.7	3.2	0.7247			
Week 36																	
Placebo		62	29.4	2.5	61 (89.7%)	5.2	1.5	2.2	8.2								
Nera 18mg		72	25.6	2.3	71 (93.4%)	2.8	1.4	0.0	5.6	-2.4	2.1	-6.5	1.7	0.2589			
Week 44																	
Placebo		60	30.4	2.7	59 (86.8%)	6.1	1.6	2.9	9.3								
Nera 18mg		69	27.9	2.2	68 (89.5%)	5.3	1.5	2.3	8.3	-0.8	2.2	-5.2	3.6	0.7191			
Week 52																	
Placebo		57	31.1	3.0	56 (82.4%)	7.3	1.8	3.9	10.8								
Nera 18mg		66	27.8	2.4	65 (85.5%)	5.2	1.6	2.0	8.4	-2.1	2.4	-6.8	2.6	0.3787			
Week 64																	
Placebo		55	36.3	3.5	54 (79.4%)	12.2	1.9	8.4	16.0								
Nera 18mg		64	28.6	2.7	63 (82.9%)	5.9	1.8	2.3	9.4	-6.3	2.7	-11.5	-1.1	0.0176	-0.44	-0.80	-0.07
Week 76																	
Placebo		38	31.7	3.5	37 (54.4%)												
Nera 18mg		51	26.9	2.8	50 (65.8%)												
Week 88																	
Placebo		11	23.4	4.6	10 (14.7%)												
Nera 18mg		8	25.8	5.6	8 (10.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	

Study: 1305-0014. 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, 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 H.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 (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
Baseline																	
Placebo	75	74	25.8	1.8	71 (100.0%)												
Nera 18mg	56	54	25.8	2.3	54 (100.0%)												
Week 12																	
Placebo		71	25.2	2.2	70 (98.6%)	0.1	1.2	-2.2	2.4								
Nera 18mg		55	29.0	2.5	53 (98.1%)	3.0	1.4	0.3	5.6	2.9	1.8	-0.7	6.4	0.1103			
Week 26																	
Placebo		69	27.2	2.1	68 (95.8%)	2.5	1.4	-0.3	5.3								
Nera 18mg		54	30.9	2.8	52 (96.3%)	4.2	1.6	1.0	7.4	1.7	2.2	-2.6	5.9	0.4366			
Week 36																	
Placebo		64	28.4	2.2	63 (88.7%)	4.3	1.5	1.4	7.2								
Nera 18mg		53	30.4	2.8	51 (94.4%)	4.8	1.7	1.6	8.1	0.5	2.2	-3.9	4.9	0.8161			
Week 44																	
Placebo		64	28.2	2.4	63 (88.7%)	4.5	1.6	1.4	7.6								
Nera 18mg		49	29.5	3.0	48 (88.9%)	5.4	1.8	1.9	9.0	0.9	2.4	-3.8	5.6	0.7059			
Week 52																	
Placebo		64	30.0	2.7	63 (88.7%)	6.6	1.7	3.3	9.9								
Nera 18mg		52	30.5	2.9	51 (94.4%)	5.8	1.9	2.1	9.5	-0.8	2.5	-5.8	4.2	0.7521			
Week 64																	
Placebo		57	26.0	2.2	56 (78.9%)	6.0	1.9	2.3	9.7								
Nera 18mg		46	29.0	3.6	45 (83.3%)	5.4	2.1	1.2	9.5	-0.6	2.8	-6.2	5.0	0.8310			
Week 76																	
Placebo		40	27.0	2.9	39 (54.9%)												
Nera 18mg		35	28.9	3.8	34 (63.0%)												
Week 88																	
Placebo		13	28.1	5.2	13 (18.3%)												
Nera 18mg		8	20.9	5.2	7 (13.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	6.6	NC	1 (1.9%)												
Rest of the World																	
Baseline																	
Placebo	23	21	23.8	3.6	21 (100.0%)												
Nera 18mg	34	33	25.2	2.8	33 (100.0%)												
Week 12																	
Placebo		23	25.5	4.0	21 (100.0%)	-0.0	2.2	-4.3	4.2								

Study: 1305-0014. 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 H.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 (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		34	27.7	3.0	33 (100.0%)	1.5	1.7	-1.9	4.9	1.5	2.8	-3.9	6.9	0.5809			
Week 26																	
Placebo		23	27.8	4.4	21 (100.0%)	1.8	2.6	-3.3	6.8								
Nera 18mg		29	25.7	2.6	29 (87.9%)	2.2	2.2	-2.0	6.4	0.5	3.4	-6.1	7.0	0.8923			
Week 36																	
Placebo		22	32.8	4.7	20 (95.2%)	7.3	2.7	2.0	12.5								
Nera 18mg		27	25.4	2.7	27 (81.8%)	2.9	2.3	-1.6	7.4	-4.4	3.5	-11.3	2.5	0.2146			
Week 44																	
Placebo		21	29.9	4.0	19 (90.5%)	3.6	2.9	-2.1	9.3								
Nera 18mg		26	26.3	3.1	26 (78.8%)	3.9	2.5	-0.9	8.7	0.3	3.8	-7.2	7.7	0.9430			
Week 52																	
Placebo		19	29.8	5.0	18 (85.7%)	4.6	3.1	-1.5	10.7								
Nera 18mg		26	27.1	3.2	26 (78.8%)	4.7	2.6	-0.5	9.8	0.1	4.1	-7.9	8.0	0.9859			
Week 64																	
Placebo		17	27.5	5.0	16 (76.2%)	3.8	3.5	-3.1	10.6								
Nera 18mg		22	31.1	3.9	22 (66.7%)	7.5	2.9	1.7	13.3	3.7	4.6	-5.2	12.7	0.4137			
Week 76																	
Placebo		14	28.3	5.9	13 (61.9%)												
Nera 18mg		12	35.1	4.1	12 (36.4%)												
Week 88																	
Placebo		3	15.8	3.8	3 (14.3%)												
Nera 18mg		2	54.6	5.0	2 (6.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0014. 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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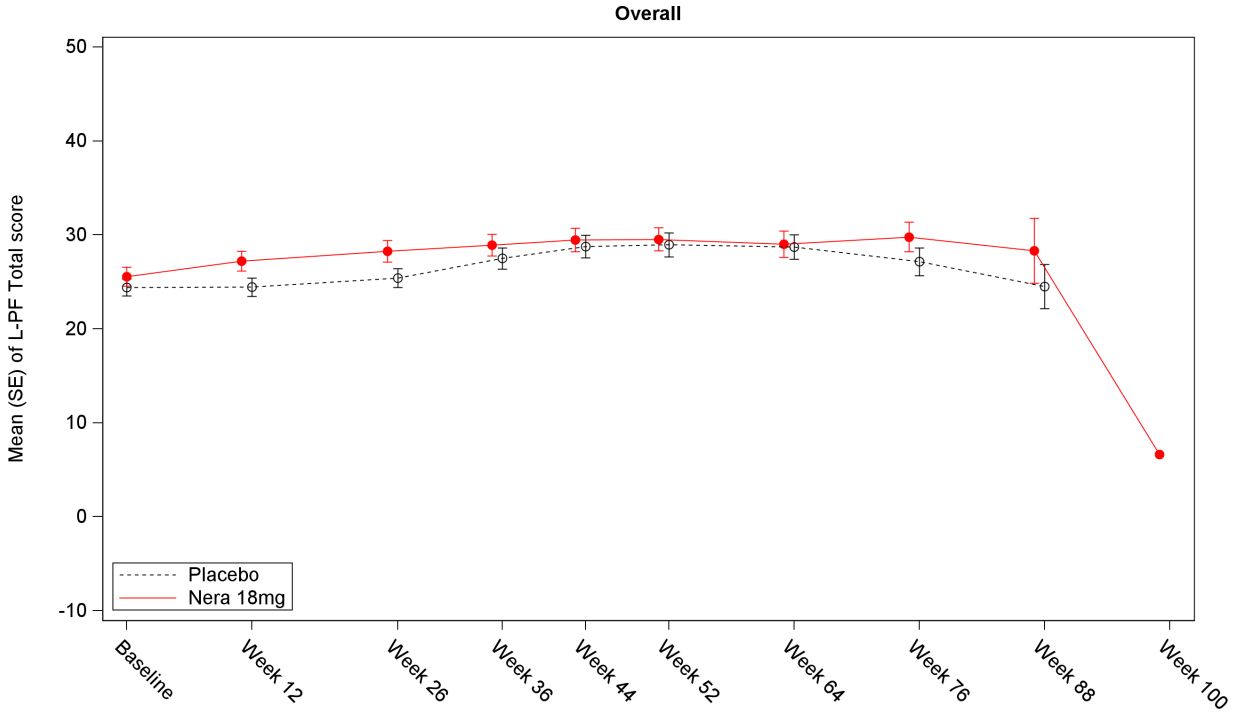

Number of patients									
Placebo	298	293	278	268	266	258	240	172	49	0
Nera 18mg	298	294	282	270	259	260	231	171	36	1

Study: 1305-0014. Number of patients refers to the number of patients with observed data at visit.

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

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Figure H.1.1.1.2.1: 1

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Table H.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 (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	306	299	27.5	1.0	292 (100.0%)												
Nera 18mg	305	299	29.0	1.2	296 (100.0%)												
Week 12																	
Placebo		295	27.2	1.1	289 (99.0%)	0.1	0.7	-1.3	1.5								
Nera 18mg		298	30.4	1.2	293 (99.0%)	1.6	0.7	0.2	2.9	1.5	1.0	-0.4	3.4	0.1293			
Week 26																	
Placebo		278	27.9	1.1	273 (93.5%)	1.6	0.8	-0.1	3.2								
Nera 18mg		282	30.9	1.3	278 (93.9%)	2.6	0.8	1.0	4.3	1.0	1.2	-1.3	3.4	0.3783			
Week 36																	
Placebo		270	30.3	1.2	265 (90.8%)	4.1	0.8	2.4	5.7								
Nera 18mg		271	31.5	1.3	267 (90.2%)	3.7	0.8	2.0	5.3	-0.4	1.2	-2.7	1.9	0.7427			
Week 44																	
Placebo		267	31.9	1.3	261 (89.4%)	5.5	0.9	3.7	7.3								
Nera 18mg		259	31.7	1.4	255 (86.1%)	4.6	0.9	2.8	6.4	-0.9	1.3	-3.4	1.6	0.4846			
Week 52																	
Placebo		258	32.2	1.4	254 (87.0%)	6.9	1.0	5.0	8.8								
Nera 18mg		260	32.3	1.4	256 (86.5%)	4.8	1.0	2.9	6.7	-2.1	1.4	-4.8	0.6	0.1249			
Week 64																	
Placebo		240	31.9	1.5	236 (80.8%)	7.7	1.1	5.6	9.8								
Nera 18mg		233	31.9	1.5	231 (78.0%)	5.2	1.1	3.1	7.3	-2.5	1.5	-5.5	0.5	0.0987			
Week 76																	
Placebo		174	30.0	1.6	170 (58.2%)												
Nera 18mg		171	32.5	1.8	168 (56.8%)												
Week 88																	
Placebo		49	26.1	2.6	48 (16.4%)												
Nera 18mg		36	30.1	3.8	35 (11.8%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	7.1	NC	1 (0.3%)												
Age																	
Test for homogeneity (H0)^																	
Week 12														0.0504			

Study: 1305-0014. 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 H.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 (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 95% CI value	lower	upper
Week 26														0.8437			
Week 36														0.4541			
Week 44														0.7739			
Week 52														0.6787			
Week 64														0.7659			
<65 years																	
Baseline																	
Placebo	69	67	25.9	2.2	67 (100.0%)												
Nera 18mg	63	62	28.3	2.3	62 (100.0%)												
Week 12																	
Placebo		65	28.4	2.5	64 (95.5%)	1.7	1.5	-1.2	4.6								
Nera 18mg		62	27.8	2.3	61 (98.4%)	-0.5	1.5	-3.5	2.5	-2.2	2.1	-6.3	2.0	0.3022			
Week 26																	
Placebo		66	25.8	2.0	64 (95.5%)	1.3	1.8	-2.1	4.8								
Nera 18mg		62	31.1	2.6	61 (98.4%)	2.8	1.8	-0.7	6.4	1.5	2.5	-3.5	6.4	0.5613			
Week 36																	
Placebo		66	29.3	2.5	64 (95.5%)	4.1	1.7	0.7	7.4								
Nera 18mg		60	29.5	2.5	59 (95.2%)	2.0	1.8	-1.5	5.5	-2.1	2.5	-6.9	2.8	0.4087			
Week 44																	
Placebo		64	31.6	2.8	62 (92.5%)	5.9	1.9	2.2	9.5								
Nera 18mg		56	33.2	2.8	55 (88.7%)	5.7	2.0	1.8	9.5	-0.2	2.7	-5.5	5.1	0.9394			
Week 52																	
Placebo		63	29.8	2.7	61 (91.0%)	5.4	2.0	1.6	9.3								
Nera 18mg		55	32.9	2.8	54 (87.1%)	4.3	2.1	0.3	8.4	-1.1	2.9	-6.7	4.5	0.7038			
Week 64																	
Placebo		60	30.6	2.7	58 (86.6%)	7.1	2.2	2.8	11.4								
Nera 18mg		49	32.7	3.5	48 (77.4%)	3.7	2.3	-0.9	8.3	-3.4	3.2	-9.7	2.9	0.2869			
Week 76																	
Placebo		38	27.9	3.1	37 (55.2%)												
Nera 18mg		35	33.1	3.4	34 (54.8%)												
Week 88																	
Placebo		16	26.8	4.8	15 (22.4%)												
Nera 18mg		7	38.9	9.9	7 (11.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												

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Table H.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 (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		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	237	232	28.0	1.2	225 (100.0%)												
Nera 18mg	242	237	29.2	1.4	234 (100.0%)												
Week 12																	
Placebo		230	26.9	1.2	225 (100.0%)	-0.4	0.8	-1.9	1.2								
Nera 18mg		236	31.1	1.4	232 (99.1%)	2.1	0.8	0.6	3.7	2.5	1.1	0.3	4.7	0.0248	0.21	0.03	0.39
Week 26																	
Placebo		212	28.6	1.4	209 (92.9%)	1.6	1.0	-0.3	3.5								
Nera 18mg		220	30.8	1.5	217 (92.7%)	2.5	0.9	0.7	4.4	0.9	1.4	-1.8	3.6	0.5063			
Week 36																	
Placebo		204	30.6	1.4	201 (89.3%)	4.1	1.0	2.2	5.9								
Nera 18mg		211	32.0	1.5	208 (88.9%)	4.1	0.9	2.3	6.0	0.1	1.3	-2.6	2.7	0.9629			
Week 44																	
Placebo		203	32.0	1.5	199 (88.4%)	5.4	1.0	3.4	7.5								
Nera 18mg		203	31.3	1.6	200 (85.5%)	4.3	1.0	2.3	6.3	-1.1	1.5	-4.0	1.8	0.4562			
Week 52																	
Placebo		195	33.0	1.7	193 (85.8%)	7.3	1.1	5.2	9.5								
Nera 18mg		205	32.1	1.5	202 (86.3%)	4.9	1.1	2.8	7.0	-2.4	1.5	-5.5	0.6	0.1149			
Week 64																	
Placebo		180	32.3	1.7	178 (79.1%)	7.9	1.2	5.5	10.3								
Nera 18mg		184	31.7	1.7	183 (78.2%)	5.6	1.2	3.2	7.9	-2.3	1.7	-5.7	1.1	0.1777			
Week 76																	
Placebo		136	30.6	1.9	133 (59.1%)												
Nera 18mg		136	32.3	2.0	134 (57.3%)												
Week 88																	
Placebo		33	25.8	3.1	33 (14.7%)												
Nera 18mg		29	28.0	4.0	28 (12.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	7.1	NC	1 (0.4%)												
Sex																	
Test for homogeneity (H0)^																	

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

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Table H.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 (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														0.1415			
Week 26														0.6744			
Week 36														0.3391			
Week 44														0.3227			
Week 52														0.1199			
Week 64														0.3453			
Male																	
Baseline																	
Placebo	269	264	27.2	1.1	257 (100.0%)												
Nera 18mg	255	249	29.0	1.3	246 (100.0%)												
Week 12																	
Placebo		259	27.0	1.2	254 (98.8%)	0.1	0.7	-1.3	1.6								
Nera 18mg		249	29.9	1.3	244 (99.2%)	0.9	0.8	-0.6	2.4	0.8	1.1	-1.3	2.9	0.4427			
Week 26																	
Placebo		242	27.5	1.2	239 (93.0%)	1.5	0.9	-0.3	3.3								
Nera 18mg		235	30.6	1.4	231 (93.9%)	2.3	0.9	0.5	4.1	0.8	1.3	-1.8	3.3	0.5441			
Week 36																	
Placebo		234	30.0	1.3	231 (89.9%)	4.3	0.9	2.5	6.1								
Nera 18mg		228	31.3	1.4	224 (91.1%)	3.4	0.9	1.6	5.2	-0.9	1.3	-3.4	1.7	0.4997			
Week 44																	
Placebo		231	31.6	1.4	227 (88.3%)	5.9	1.0	3.9	7.8								
Nera 18mg		218	31.5	1.4	214 (87.0%)	4.4	1.0	2.5	6.4	-1.4	1.4	-4.2	1.3	0.3089			
Week 52																	
Placebo		223	32.2	1.5	221 (86.0%)	7.3	1.0	5.3	9.4								
Nera 18mg		219	31.9	1.4	215 (87.4%)	4.4	1.0	2.3	6.4	-3.0	1.5	-5.8	-0.1	0.0452	-0.19	-0.38	-0.00
Week 64																	
Placebo		205	30.8	1.5	203 (79.0%)	7.2	1.1	5.0	9.5								
Nera 18mg		200	32.4	1.6	198 (80.5%)	5.3	1.2	3.0	7.6	-1.9	1.6	-5.2	1.3	0.2348			
Week 76																	
Placebo		151	29.1	1.7	148 (57.6%)												
Nera 18mg		148	32.5	1.8	145 (58.9%)												
Week 88																	
Placebo		42	26.2	2.8	42 (16.3%)												
Nera 18mg		31	30.8	4.2	30 (12.2%)												
Week 100																	

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

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Table H.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 (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 95% CI value	lower	upper
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	7.1	NC	1 (0.4%)												
Female																	
Baseline																	
Placebo	37	35	30.3	3.4	35 (100.0%)												
Nera 18mg	50	50	29.0	3.2	50 (100.0%)												
Week 12																	
Placebo		36	29.2	3.5	35 (100.0%)	-0.3	2.0	-4.3	3.7								
Nera 18mg		49	33.0	3.2	49 (98.0%)	4.7	1.7	1.4	8.0	5.0	2.6	-0.2	10.2	0.0579			
Week 26																	
Placebo		36	30.6	3.7	34 (97.1%)	2.1	2.4	-2.7	6.8								
Nera 18mg		47	32.2	3.6	47 (94.0%)	4.3	2.0	0.3	8.3	2.2	3.2	-4.0	8.4	0.4831			
Week 36																	
Placebo		36	32.6	3.5	34 (97.1%)	2.4	2.4	-2.3	7.1								
Nera 18mg		43	32.4	3.3	43 (86.0%)	4.8	2.1	0.7	8.8	2.4	3.1	-3.8	8.6	0.4486			
Week 44																	
Placebo		36	33.5	4.0	34 (97.1%)	3.2	2.6	-1.9	8.2								
Nera 18mg		41	32.6	3.9	41 (82.0%)	5.4	2.3	1.0	9.8	2.2	3.4	-4.5	8.9	0.5141			
Week 52																	
Placebo		35	32.5	4.1	33 (94.3%)	3.6	2.7	-1.7	8.9								
Nera 18mg		41	34.2	3.8	41 (82.0%)	6.7	2.4	2.1	11.4	3.1	3.6	-4.0	10.2	0.3891			
Week 64																	
Placebo		35	38.6	4.9	33 (94.3%)	10.3	3.0	4.4	16.1								
Nera 18mg		33	29.0	4.4	33 (66.0%)	4.2	2.7	-1.1	9.6	-6.0	4.0	-13.9	1.8	0.1328			
Week 76																	
Placebo		23	35.9	5.4	22 (62.9%)												
Nera 18mg		23	32.1	5.7	23 (46.0%)												
Week 88																	
Placebo		7	26.0	7.5	6 (17.1%)												
Nera 18mg		5	26.2	7.8	5 (10.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Baseline FVC percent predicted

Study: 1305-0014. 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 H.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 (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 95% CI value	lower	upper
Test for homogeneity (H0)^																	
Week 12														0.5960			
Week 26														0.9844			
Week 36														0.6478			
Week 44														0.3260			
Week 52														0.8937			
Week 64														0.2268			
<=70%																	
Baseline																	
Placebo	109	107	33.2	1.8	101 (100.0%)												
Nera 18mg	112	107	34.7	2.0	104 (100.0%)												
Week 12																	
Placebo		102	33.3	2.0	100 (99.0%)	1.5	1.2	-0.8	3.9								
Nera 18mg		105	37.2	2.0	101 (97.1%)	3.8	1.2	1.4	6.1	2.2	1.7	-1.0	5.5	0.1824			
Week 26																	
Placebo		94	33.7	2.0	92 (91.1%)	4.1	1.5	1.3	7.0								
Nera 18mg		96	37.0	2.1	93 (89.4%)	5.1	1.4	2.3	8.0	1.0	2.0	-3.0	5.0	0.6134			
Week 36																	
Placebo		89	37.3	2.3	87 (86.1%)	7.8	1.4	5.0	10.7								
Nera 18mg		91	37.8	2.1	88 (84.6%)	6.7	1.4	3.9	9.5	-1.1	2.0	-5.1	2.8	0.5761			
Week 44																	
Placebo		89	39.2	2.5	87 (86.1%)	8.8	1.6	5.7	11.9								
Nera 18mg		83	36.1	2.0	80 (76.9%)	6.0	1.6	2.9	9.2	-2.7	2.2	-7.1	1.7	0.2250			
Week 52																	
Placebo		86	39.3	2.6	85 (84.2%)	9.9	1.7	6.7	13.2								
Nera 18mg		85	38.5	2.0	82 (78.8%)	7.6	1.7	4.3	10.9	-2.3	2.3	-6.9	2.3	0.3208			
Week 64																	
Placebo		78	40.0	2.7	77 (76.2%)	12.7	1.9	9.0	16.3								
Nera 18mg		72	38.0	2.5	70 (67.3%)	7.6	1.9	3.8	11.3	-5.1	2.6	-10.3	0.1	0.0531			
Week 76																	
Placebo		54	37.9	3.1	53 (52.5%)												
Nera 18mg		57	39.2	2.8	54 (51.9%)												
Week 88																	
Placebo		14	31.1	4.5	14 (13.9%)												
Nera 18mg		9	40.2	8.8	8 (7.7%)												

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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, continuous 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 H.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 (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		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	197	192	24.3	1.2	191 (100.0%)												
Nera 18mg	193	192	25.8	1.4	192 (100.0%)												
Week 12																	
Placebo		193	24.0	1.3	189 (99.0%)	-0.7	0.9	-2.4	1.0								
Nera 18mg		193	26.7	1.4	192 (100.0%)	0.4	0.9	-1.2	2.1	1.1	1.2	-1.3	3.5	0.3515			
Week 26																	
Placebo		184	24.9	1.3	181 (94.8%)	0.2	1.0	-1.8	2.3								
Nera 18mg		186	27.7	1.6	185 (96.4%)	1.3	1.0	-0.7	3.3	1.1	1.5	-1.8	3.9	0.4611			
Week 36																	
Placebo		181	26.9	1.4	178 (93.2%)	2.1	1.0	0.1	4.1								
Nera 18mg		180	28.3	1.5	179 (93.2%)	2.1	1.0	0.1	4.1	0.0	1.4	-2.8	2.8	0.9985			
Week 44																	
Placebo		178	28.2	1.5	174 (91.1%)	3.8	1.1	1.6	6.0								
Nera 18mg		176	29.6	1.7	175 (91.1%)	3.8	1.1	1.6	6.0	-0.0	1.6	-3.1	3.1	0.9864			
Week 52																	
Placebo		172	28.7	1.6	169 (88.5%)	5.3	1.2	3.0	7.6								
Nera 18mg		175	29.3	1.7	174 (90.6%)	3.3	1.2	1.0	5.6	-1.9	1.7	-5.2	1.3	0.2411			
Week 64																	
Placebo		162	28.0	1.6	159 (83.2%)	5.2	1.3	2.6	7.7								
Nera 18mg		161	29.2	1.9	161 (83.9%)	3.9	1.3	1.4	6.5	-1.2	1.8	-4.8	2.4	0.5077			
Week 76																	
Placebo		120	26.5	1.9	117 (61.3%)												
Nera 18mg		114	29.1	2.2	114 (59.4%)												
Week 88																	
Placebo		35	24.1	3.1	34 (17.8%)												
Nera 18mg		27	26.8	4.0	27 (14.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	7.1	NC	1 (0.5%)												

Study: 1305-0014. 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, 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 H.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 (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
Type of AF therapy																	
Test for homogeneity (H0)^																	
Week 12														0.4075			
Week 26														0.1539			
Week 36														0.1653			
Week 44														0.7775			
Week 52														0.7121			
Week 64														0.7181			
Nintedanib																	
Baseline																	
Placebo	173	169	27.4	1.4	165 (100.0%)												
Nera 18mg	178	174	29.2	1.5	172 (100.0%)												
Week 12																	
Placebo		166	26.7	1.5	163 (98.8%)	-0.3	0.9	-2.1	1.5								
Nera 18mg		173	30.7	1.6	170 (98.8%)	1.9	0.9	0.1	3.7	2.2	1.3	-0.4	4.8	0.0917			
Week 26																	
Placebo		156	25.8	1.4	153 (92.7%)	-0.1	1.1	-2.3	2.1								
Nera 18mg		159	30.0	1.8	157 (91.3%)	2.5	1.1	0.3	4.7	2.5	1.6	-0.6	5.6	0.1072			
Week 36																	
Placebo		154	28.2	1.6	151 (91.5%)	2.4	1.1	0.2	4.5								
Nera 18mg		151	30.3	1.7	149 (86.6%)	3.4	1.1	1.2	5.6	1.0	1.6	-2.0	4.1	0.5060			
Week 44																	
Placebo		150	30.3	1.7	147 (89.1%)	4.3	1.2	1.9	6.6								
Nera 18mg		142	29.3	1.7	139 (80.8%)	3.0	1.2	0.6	5.4	-1.3	1.7	-4.6	2.1	0.4586			
Week 52																	
Placebo		147	31.4	1.8	144 (87.3%)	5.9	1.3	3.4	8.4								
Nera 18mg		147	30.2	1.8	144 (83.7%)	3.3	1.3	0.8	5.8	-2.5	1.8	-6.1	1.0	0.1602			
Week 64																	
Placebo		134	29.0	1.8	131 (79.4%)	5.4	1.4	2.6	8.2								
Nera 18mg		127	29.1	2.0	126 (73.3%)	3.4	1.4	0.6	6.2	-2.0	2.0	-6.0	1.9	0.3092			
Week 76																	
Placebo		101	28.5	2.1	99 (60.0%)												
Nera 18mg		93	30.6	2.5	91 (52.9%)												
Week 88																	
Placebo		28	30.3	3.7	27 (16.4%)												

Study: 1305-0014. 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 H.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 (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		22	32.6	5.0	21 (12.2%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Pirfenidone																	
Baseline																	
Placebo	133	130	27.7	1.6	127 (100.0%)												
Nera 18mg	127	125	28.7	1.9	124 (100.0%)												
Week 12																	
Placebo		129	27.9	1.7	126 (99.2%)	0.6	1.1	-1.5	2.6								
Nera 18mg		125	29.9	1.8	123 (99.2%)	1.1	1.1	-1.0	3.2	0.6	1.5	-2.4	3.5	0.7151			
Week 26																	
Placebo		122	30.6	1.8	120 (94.5%)	3.7	1.3	1.2	6.2								
Nera 18mg		123	32.0	1.9	121 (97.6%)	2.8	1.3	0.3	5.3	-0.9	1.8	-4.4	2.7	0.6288			
Week 36																	
Placebo		116	33.1	2.0	114 (89.8%)	6.2	1.3	3.7	8.7								
Nera 18mg		120	33.0	1.8	118 (95.2%)	4.0	1.3	1.5	6.4	-2.3	1.8	-5.8	1.3	0.2069			
Week 44																	
Placebo		117	33.9	2.1	114 (89.8%)	7.1	1.4	4.4	9.8								
Nera 18mg		117	34.6	2.1	116 (93.5%)	6.6	1.4	3.9	9.2	-0.5	1.9	-4.3	3.3	0.7803			
Week 52																	
Placebo		111	33.3	2.2	110 (86.6%)	8.1	1.5	5.3	11.0								
Nera 18mg		113	35.0	2.0	112 (90.3%)	6.6	1.4	3.7	9.4	-1.5	2.1	-5.6	2.5	0.4579			
Week 64																	
Placebo		106	35.6	2.3	105 (82.7%)	10.5	1.6	7.4	13.7								
Nera 18mg		106	35.3	2.3	105 (84.7%)	7.4	1.6	4.2	10.5	-3.1	2.3	-7.6	1.3	0.1662			
Week 76																	
Placebo		73	32.2	2.7	71 (55.9%)												
Nera 18mg		78	34.7	2.5	77 (62.1%)												
Week 88																	
Placebo		21	20.6	3.1	21 (16.5%)												
Nera 18mg		14	26.2	5.7	14 (11.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	7.1	NC	1 (0.8%)												

Study: 1305-0014. 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 H.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 (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
Region																	
Test for homogeneity (H0)^																	
Week 12														0.9543			
Week 26														0.1866			
Week 36														0.0085			
Week 44														0.5604			
Week 52														0.9023			
Week 64														0.8598			
Europe																	
Baseline																	
Placebo	136	133	26.5	1.6	131 (100.0%)												
Nera 18mg	136	134	29.4	1.8	133 (100.0%)												
Week 12																	
Placebo		131	26.9	1.6	128 (97.7%)	0.6	1.1	-1.5	2.6								
Nera 18mg		131	30.7	1.8	130 (97.7%)	1.9	1.0	-0.2	4.0	1.3	1.5	-1.6	4.3	0.3663			
Week 26																	
Placebo		123	25.9	1.6	121 (92.4%)	1.0	1.3	-1.5	3.5								
Nera 18mg		125	31.6	1.9	124 (93.2%)	3.7	1.3	1.3	6.2	2.8	1.8	-0.8	6.3	0.1240			
Week 36																	
Placebo		121	27.5	1.7	119 (90.8%)	2.9	1.2	0.4	5.3								
Nera 18mg		118	33.8	1.9	117 (88.0%)	5.7	1.2	3.2	8.1	2.8	1.8	-0.7	6.3	0.1113			
Week 44																	
Placebo		122	30.4	1.9	119 (90.8%)	5.2	1.4	2.5	7.9								
Nera 18mg		115	32.9	2.2	113 (85.0%)	5.3	1.4	2.6	8.0	0.2	1.9	-3.6	3.9	0.9370			
Week 52																	
Placebo		118	30.3	2.0	116 (88.5%)	6.8	1.4	4.0	9.6								
Nera 18mg		116	33.2	2.0	114 (85.7%)	5.1	1.4	2.2	7.9	-1.7	2.0	-5.7	2.3	0.3971			
Week 64																	
Placebo		111	29.5	1.9	109 (83.2%)	6.5	1.6	3.4	9.6								
Nera 18mg		100	31.1	2.2	100 (75.2%)	4.2	1.6	1.1	7.4	-2.3	2.3	-6.7	2.1	0.3098			
Week 76																	
Placebo		81	27.4	2.3	79 (60.3%)												
Nera 18mg		73	33.4	2.8	72 (54.1%)												
Week 88																	
Placebo		22	25.2	4.2	22 (16.8%)												

Study: 1305-0014. 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 H.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 (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		18	33.3	6.1	18 (13.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Asia																	
Baseline																	
Placebo	72	70	28.6	2.2	68 (100.0%)												
Nera 18mg	79	78	28.7	2.4	76 (100.0%)												
Week 12																	
Placebo		69	27.4	2.5	68 (100.0%)	-0.4	1.5	-3.2	2.5								
Nera 18mg		77	29.1	2.4	76 (100.0%)	0.8	1.4	-1.9	3.5	1.2	2.0	-2.7	5.1	0.5490			
Week 26																	
Placebo		63	30.3	2.4	62 (91.2%)	2.9	1.8	-0.6	6.3								
Nera 18mg		74	29.1	2.8	73 (96.1%)	0.7	1.6	-2.6	3.9	-2.2	2.4	-6.9	2.5	0.3617			
Week 36																	
Placebo		62	34.1	3.0	61 (89.7%)	6.3	1.7	2.9	9.7								
Nera 18mg		72	28.2	2.5	71 (93.4%)	1.0	1.6	-2.1	4.2	-5.2	2.4	-9.9	-0.6	0.0279	-0.38	-0.73	-0.04
Week 44																	
Placebo		60	36.2	3.2	59 (86.8%)	8.3	1.9	4.5	12.0								
Nera 18mg		69	31.3	2.5	68 (89.5%)	4.3	1.8	0.8	7.8	-3.9	2.6	-9.1	1.2	0.1340			
Week 52																	
Placebo		57	35.8	3.3	56 (82.4%)	8.2	2.0	4.2	12.2								
Nera 18mg		66	31.5	2.9	65 (85.5%)	4.3	1.9	0.6	8.1	-3.9	2.8	-9.4	1.6	0.1629			
Week 64																	
Placebo		55	41.4	4.0	54 (79.4%)	13.5	2.2	9.1	17.9								
Nera 18mg		64	33.2	3.1	63 (82.9%)	6.1	2.1	2.0	10.2	-7.4	3.0	-13.4	-1.4	0.0152	-0.45	-0.81	-0.08
Week 76																	
Placebo		38	35.9	4.1	37 (54.4%)												
Nera 18mg		51	30.9	3.2	50 (65.8%)												
Week 88																	
Placebo		11	25.6	5.1	10 (14.7%)												
Nera 18mg		8	27.5	6.2	8 (10.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	

Study: 1305-0014. 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 H.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 (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
Baseline																	
Placebo	75	74	28.7	2.1	71 (100.0%)												
Nera 18mg	56	54	28.9	2.7	54 (100.0%)												
Week 12																	
Placebo		72	27.7	2.2	71 (100.0%)	-0.4	1.4	-3.2	2.4								
Nera 18mg		56	31.6	2.8	54 (100.0%)	2.3	1.6	-0.9	5.5	2.7	2.2	-1.5	7.0	0.2046			
Week 26																	
Placebo		69	28.7	2.2	68 (95.8%)	1.0	1.7	-2.3	4.4								
Nera 18mg		54	33.7	3.0	52 (96.3%)	3.9	1.9	0.1	7.8	2.9	2.6	-2.2	8.0	0.2596			
Week 36																	
Placebo		65	30.3	2.2	64 (90.1%)	2.9	1.7	-0.4	6.2								
Nera 18mg		54	33.5	3.1	52 (96.3%)	4.6	1.9	0.9	8.3	1.7	2.5	-3.3	6.7	0.5022			
Week 44																	
Placebo		64	30.9	2.6	63 (88.7%)	4.2	1.9	0.6	7.9								
Nera 18mg		49	31.0	3.3	48 (88.9%)	4.1	2.1	0.0	8.3	-0.1	2.8	-5.6	5.4	0.9731			
Week 52																	
Placebo		64	32.8	2.8	63 (88.7%)	6.3	2.0	2.5	10.2								
Nera 18mg		52	33.1	3.2	51 (94.4%)	5.8	2.2	1.5	10.1	-0.6	2.9	-6.3	5.2	0.8456			
Week 64																	
Placebo		57	28.4	2.3	56 (78.9%)	5.4	2.2	1.2	9.7								
Nera 18mg		47	31.4	3.9	46 (85.2%)	5.7	2.4	0.9	10.4	0.3	3.3	-6.1	6.6	0.9354			
Week 76																	
Placebo		41	29.9	3.0	40 (56.3%)												
Nera 18mg		35	30.9	4.2	34 (63.0%)												
Week 88																	
Placebo		13	29.7	5.3	13 (18.3%)												
Nera 18mg		8	18.5	4.8	7 (13.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	7.1	NC	1 (1.9%)												
Rest of the World																	
Baseline																	
Placebo	23	22	26.5	4.1	22 (100.0%)												
Nera 18mg	34	33	28.5	3.3	33 (100.0%)												
Week 12																	
Placebo		23	27.4	4.3	22 (100.0%)	0.3	2.6	-4.8	5.3								

Study: 1305-0014. 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 H.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 (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		34	30.3	3.5	33 (100.0%)	0.7	2.1	-3.4	4.8	0.4	3.3	-6.0	6.9	0.8917			
Week 26																	
Placebo		23	29.9	4.8	22 (100.0%)	2.9	3.0	-3.0	8.9								
Nera 18mg		29	27.0	3.1	29 (87.9%)	0.5	2.6	-4.6	5.6	-2.4	4.0	-10.2	5.4	0.5397			
Week 36																	
Placebo		22	35.7	5.1	21 (95.5%)	7.8	3.0	1.9	13.6								
Nera 18mg		27	25.8	2.7	27 (81.8%)	0.0	2.6	-5.0	5.1	-7.7	3.9	-15.5	0.0	0.0505			
Week 44																	
Placebo		21	31.4	4.3	20 (90.9%)	3.2	3.3	-3.2	9.7								
Nera 18mg		26	28.8	3.5	26 (78.8%)	2.9	2.9	-2.7	8.6	-0.3	4.4	-8.9	8.3	0.9461			
Week 52																	
Placebo		19	31.5	5.5	19 (86.4%)	4.6	3.5	-2.3	11.5								
Nera 18mg		26	28.8	3.4	26 (78.8%)	2.8	3.0	-3.1	8.8	-1.8	4.6	-10.9	7.3	0.7000			
Week 64																	
Placebo		17	28.4	5.6	17 (77.3%)	3.8	3.9	-3.8	11.4								
Nera 18mg		22	32.9	4.6	22 (66.7%)	5.8	3.4	-0.9	12.4	2.0	5.2	-8.1	12.1	0.7007			
Week 76																	
Placebo		14	29.3	6.5	14 (63.6%)												
Nera 18mg		12	37.7	4.3	12 (36.4%)												
Week 88																	
Placebo		3	19.4	5.2	3 (13.6%)												
Nera 18mg		2	58.3	4.8	2 (6.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0014. 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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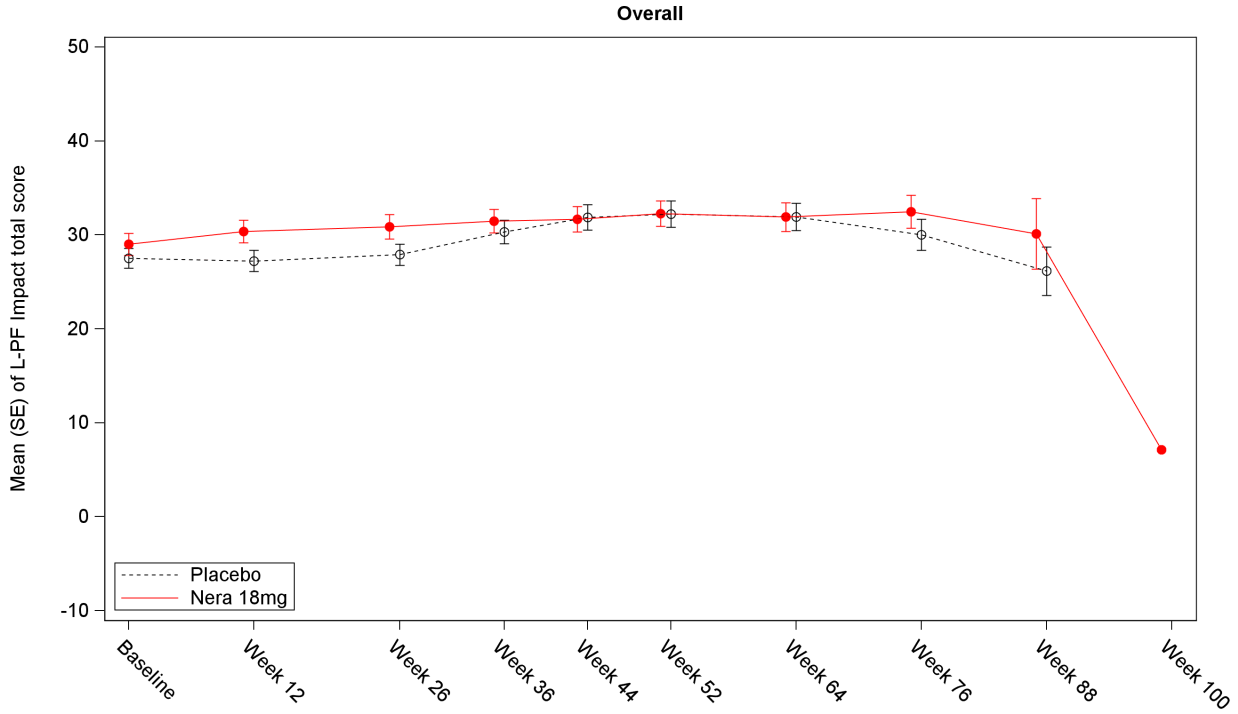

Number of patients

Placebo	299	295	278	270	267	258	240	174	49	0
Nera 18mg	299	298	282	271	259	260	233	171	36	1

Study: 1305-0014. Number of patients refers to the number of patients with observed data at visit.

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

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Table H.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 (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	306	305	21.1	0.8	298 (100.0%)												
Nera 18mg	305	303	22.3	0.9	300 (100.0%)												
Week 12																	
Placebo		297	21.4	0.9	296 (99.3%)	0.5	0.6	-0.6	1.6								
Nera 18mg		298	24.2	1.0	296 (98.7%)	2.4	0.6	1.3	3.6	1.9	0.8	0.3	3.5	0.0195	0.19	0.03	0.35
Week 26																	
Placebo		281	23.1	1.0	280 (94.0%)	2.6	0.7	1.2	3.9								
Nera 18mg		286	25.8	1.1	284 (94.7%)	4.2	0.7	2.8	5.5	1.6	1.0	-0.3	3.5	0.1032			
Week 36																	
Placebo		269	24.5	1.1	268 (89.9%)	4.8	0.7	3.4	6.3								
Nera 18mg		273	26.5	1.1	271 (90.3%)	5.5	0.7	4.0	6.9	0.6	1.0	-1.4	2.7	0.5359			
Week 44																	
Placebo		266	25.6	1.1	265 (88.9%)	5.6	0.8	4.0	7.1								
Nera 18mg		262	27.2	1.2	260 (86.7%)	6.8	0.8	5.2	8.3	1.2	1.1	-0.9	3.4	0.2656			
Week 52																	
Placebo		258	25.7	1.2	257 (86.2%)	6.5	0.8	4.9	8.1								
Nera 18mg		260	26.8	1.2	258 (86.0%)	6.0	0.8	4.5	7.6	-0.5	1.1	-2.7	1.8	0.6896			
Week 64																	
Placebo		240	25.5	1.2	239 (80.2%)	7.5	0.9	5.7	9.2								
Nera 18mg		235	26.4	1.3	233 (77.7%)	6.1	0.9	4.4	7.9	-1.3	1.3	-3.8	1.2	0.2974			
Week 76																	
Placebo		172	24.4	1.4	171 (57.4%)												
Nera 18mg		171	27.1	1.5	170 (56.7%)												
Week 88																	
Placebo		49	22.9	2.3	49 (16.4%)												
Nera 18mg		37	26.5	3.2	37 (12.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	6.1	NC	1 (0.3%)												
Age																	
Test for homogeneity (H0)^																	
Week 12														0.1954			

Study: 1305-0014. 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 H.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 (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 95% CI value	lower	upper
Week 26														0.8725			
Week 36														0.0704			
Week 44														0.7416			
Week 52														0.9935			
Week 64														0.6563			
<65 years																	
Baseline																	
Placebo	69	69	19.4	1.6	69 (100.0%)												
Nera 18mg	63	62	21.3	1.9	62 (100.0%)												
Week 12																	
Placebo		68	21.1	1.9	68 (98.6%)	1.5	1.2	-0.9	3.8								
Nera 18mg		63	22.7	1.9	62 (100.0%)	1.4	1.3	-1.1	3.9	-0.1	1.8	-3.5	3.4	0.9608			
Week 26																	
Placebo		66	21.0	1.7	66 (95.7%)	2.5	1.4	-0.3	5.3								
Nera 18mg		62	25.0	2.1	61 (98.4%)	3.8	1.5	0.9	6.7	1.3	2.1	-2.8	5.4	0.5344			
Week 36																	
Placebo		65	24.8	2.3	65 (94.2%)	6.5	1.5	3.5	9.4								
Nera 18mg		59	23.3	2.1	58 (93.5%)	3.6	1.6	0.5	6.7	-2.9	2.2	-7.2	1.5	0.1945			
Week 44																	
Placebo		64	25.9	2.4	64 (92.8%)	7.1	1.6	4.0	10.3								
Nera 18mg		57	27.6	2.5	56 (90.3%)	7.7	1.7	4.4	11.1	0.6	2.3	-4.0	5.2	0.7979			
Week 52																	
Placebo		63	23.5	2.1	63 (91.3%)	5.7	1.6	2.5	9.0								
Nera 18mg		55	26.1	2.4	54 (87.1%)	5.2	1.8	1.8	8.7	-0.5	2.4	-5.3	4.2	0.8308			
Week 64																	
Placebo		60	24.8	2.4	60 (87.0%)	7.9	1.8	4.4	11.5								
Nera 18mg		49	26.9	2.8	48 (77.4%)	5.6	1.9	1.8	9.4	-2.3	2.6	-7.5	2.9	0.3757			
Week 76																	
Placebo		38	21.3	2.4	38 (55.1%)												
Nera 18mg		35	28.1	3.4	34 (54.8%)												
Week 88																	
Placebo		16	22.5	4.0	16 (23.2%)												
Nera 18mg		7	32.2	7.1	7 (11.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												

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Table H.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 (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		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	237	236	21.6	1.0	229 (100.0%)												
Nera 18mg	242	241	22.6	1.0	238 (100.0%)												
Week 12																	
Placebo		229	21.5	1.1	228 (99.6%)	0.2	0.7	-1.1	1.5								
Nera 18mg		235	24.6	1.1	234 (98.3%)	2.7	0.7	1.4	4.0	2.5	0.9	0.7	4.3	0.0077	0.25	0.07	0.43
Week 26																	
Placebo		215	23.7	1.2	214 (93.4%)	2.6	0.8	1.1	4.2								
Nera 18mg		224	26.0	1.2	223 (93.7%)	4.3	0.8	2.7	5.8	1.7	1.1	-0.5	3.8	0.1343			
Week 36																	
Placebo		204	24.5	1.2	203 (88.6%)	4.3	0.9	2.6	6.0								
Nera 18mg		214	27.3	1.3	213 (89.5%)	6.0	0.8	4.3	7.6	1.7	1.2	-0.7	4.0	0.1594			
Week 44																	
Placebo		202	25.5	1.3	201 (87.8%)	5.1	0.9	3.3	6.8								
Nera 18mg		205	27.1	1.3	204 (85.7%)	6.5	0.9	4.8	8.3	1.5	1.3	-1.0	4.0	0.2437			
Week 52																	
Placebo		195	26.4	1.4	194 (84.7%)	6.8	0.9	4.9	8.6								
Nera 18mg		205	27.0	1.3	204 (85.7%)	6.3	0.9	4.5	8.1	-0.5	1.3	-3.1	2.1	0.7049			
Week 64																	
Placebo		180	25.8	1.4	179 (78.2%)	7.3	1.0	5.3	9.3								
Nera 18mg		186	26.3	1.5	185 (77.7%)	6.3	1.0	4.3	8.3	-1.0	1.4	-3.8	1.8	0.4809			
Week 76																	
Placebo		134	25.3	1.6	133 (58.1%)												
Nera 18mg		136	26.9	1.7	136 (57.1%)												
Week 88																	
Placebo		33	23.1	2.8	33 (14.4%)												
Nera 18mg		30	25.2	3.6	30 (12.6%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	6.1	NC	1 (0.4%)												
Sex																	
Test for homogeneity (H0)^																	

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

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Table H.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 (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														0.9746			
Week 26														0.6088			
Week 36														0.5119			
Week 44														0.3377			
Week 52														0.1188			
Week 64														0.3389			
Male																	
Baseline																	
Placebo	269	268	21.0	0.9	261 (100.0%)												
Nera 18mg	255	253	22.0	1.0	250 (100.0%)												
Week 12																	
Placebo		261	21.2	1.0	260 (99.6%)	0.4	0.6	-0.9	1.6								
Nera 18mg		248	23.7	1.1	246 (98.4%)	2.2	0.6	1.0	3.5	1.9	0.9	0.1	3.6	0.0368	0.19	0.01	0.36
Week 26																	
Placebo		245	22.9	1.0	244 (93.5%)	2.6	0.7	1.2	4.1								
Nera 18mg		239	25.3	1.1	237 (94.8%)	4.0	0.8	2.5	5.5	1.4	1.1	-0.7	3.5	0.1959			
Week 36																	
Placebo		233	24.6	1.2	232 (88.9%)	5.2	0.8	3.6	6.7								
Nera 18mg		230	26.2	1.2	228 (91.2%)	5.6	0.8	4.0	7.2	0.4	1.1	-1.8	2.6	0.7312			
Week 44																	
Placebo		230	25.7	1.2	229 (87.7%)	5.9	0.8	4.2	7.5								
Nera 18mg		221	26.7	1.3	219 (87.6%)	6.7	0.9	5.0	8.4	0.8	1.2	-1.6	3.2	0.5050			
Week 52																	
Placebo		223	25.7	1.3	222 (85.1%)	6.8	0.9	5.1	8.5								
Nera 18mg		219	26.0	1.2	217 (86.8%)	5.6	0.9	3.9	7.4	-1.2	1.2	-3.6	1.2	0.3351			
Week 64																	
Placebo		205	24.9	1.3	204 (78.2%)	7.2	1.0	5.4	9.1								
Nera 18mg		201	26.6	1.4	199 (79.6%)	6.4	1.0	4.5	8.3	-0.8	1.4	-3.5	1.9	0.5526			
Week 76																	
Placebo		149	24.1	1.5	148 (56.7%)												
Nera 18mg		148	26.6	1.5	147 (58.8%)												
Week 88																	
Placebo		42	23.8	2.5	42 (16.1%)												
Nera 18mg		32	27.2	3.6	32 (12.8%)												
Week 100																	

Study: 1305-0014. 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, 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 H.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 (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		0	NC	NC	0 (0.0%)												
Nera 18mg		1	6.1	NC	1 (0.4%)												
Female																	
Baseline																	
Placebo	37	37	21.9	2.3	37 (100.0%)												
Nera 18mg	50	50	23.8	2.3	50 (100.0%)												
Week 12																	
Placebo		36	23.0	3.3	36 (97.3%)	1.4	1.7	-1.8	4.7								
Nera 18mg		50	26.7	2.3	50 (100.0%)	3.4	1.4	0.6	6.2	1.9	2.2	-2.4	6.2	0.3756			
Week 26																	
Placebo		36	24.0	2.7	36 (97.3%)	2.3	1.9	-1.6	6.1								
Nera 18mg		47	28.0	2.9	47 (94.0%)	5.1	1.7	1.7	8.4	2.8	2.6	-2.3	7.9	0.2784			
Week 36																	
Placebo		36	24.4	2.7	36 (97.3%)	2.6	2.1	-1.5	6.6								
Nera 18mg		43	27.7	2.9	43 (86.0%)	4.9	1.8	1.3	8.5	2.3	2.8	-3.1	7.8	0.3953			
Week 44																	
Placebo		36	25.3	3.1	36 (97.3%)	3.4	2.2	-0.9	7.6								
Nera 18mg		41	29.8	3.2	41 (82.0%)	7.2	2.0	3.4	11.1	3.8	2.9	-1.9	9.6	0.1898			
Week 52																	
Placebo		35	25.7	3.4	35 (94.6%)	4.3	2.2	-0.0	8.7								
Nera 18mg		41	30.7	3.3	41 (82.0%)	8.2	2.0	4.3	12.2	3.9	3.0	-2.0	9.8	0.1974			
Week 64																	
Placebo		35	29.3	3.7	35 (94.6%)	8.6	2.4	3.9	13.3								
Nera 18mg		34	25.2	3.5	34 (68.0%)	4.4	2.3	-0.0	8.8	-4.2	3.3	-10.6	2.2	0.2008			
Week 76																	
Placebo		23	26.5	4.4	23 (62.2%)												
Nera 18mg		23	30.2	5.2	23 (46.0%)												
Week 88																	
Placebo		7	17.7	6.1	7 (18.9%)												
Nera 18mg		5	22.0	7.2	5 (10.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Baseline FVC percent predicted

Study: 1305-0014. 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, 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 H.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 (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
Test for homogeneity (H0)^																	
Week 12														0.9136			
Week 26														0.6927			
Week 36														0.5294			
Week 44														0.4280			
Week 52														0.3725			
Week 64														0.1550			
<=70%																	
Baseline																	
Placebo	109	109	26.5	1.5	103 (100.0%)												
Nera 18mg	112	111	27.1	1.6	108 (100.0%)												
Week 12																	
Placebo		103	26.5	1.7	103 (100.0%)	1.3	1.0	-0.6	3.3								
Nera 18mg		106	28.8	1.7	105 (97.2%)	3.4	1.0	1.4	5.3	2.0	1.4	-0.7	4.8	0.1412			
Week 26																	
Placebo		96	28.8	1.8	96 (93.2%)	4.5	1.2	2.2	6.9								
Nera 18mg		99	30.8	1.7	98 (90.7%)	5.6	1.2	3.3	7.9	1.1	1.7	-2.2	4.3	0.5204			
Week 36																	
Placebo		88	31.2	2.2	88 (85.4%)	7.6	1.3	5.1	10.2								
Nera 18mg		93	31.5	1.9	92 (85.2%)	7.4	1.3	4.9	9.8	-0.3	1.8	-3.8	3.2	0.8816			
Week 44																	
Placebo		88	32.9	2.2	88 (85.4%)	8.3	1.4	5.6	10.9								
Nera 18mg		85	31.3	1.8	84 (77.8%)	8.3	1.4	5.6	10.9	0.0	1.9	-3.7	3.8	0.9965			
Week 52																	
Placebo		86	32.3	2.2	86 (83.5%)	9.0	1.4	6.2	11.7								
Nera 18mg		85	31.2	1.9	84 (77.8%)	7.1	1.4	4.3	9.8	-1.9	2.0	-5.8	2.0	0.3376			
Week 64																	
Placebo		78	33.1	2.4	78 (75.7%)	11.6	1.5	8.6	14.6								
Nera 18mg		73	32.0	2.1	72 (66.7%)	7.8	1.6	4.8	10.9	-3.8	2.2	-8.0	0.5	0.0803			
Week 76																	
Placebo		54	31.9	2.5	54 (52.4%)												
Nera 18mg		57	33.0	2.3	56 (51.9%)												
Week 88																	
Placebo		14	26.4	3.4	14 (13.6%)												
Nera 18mg		9	37.1	7.4	9 (8.3%)												

Study: 1305-0014. 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, 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 H.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 (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 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	197	196	18.1	0.9	195 (100.0%)												
Nera 18mg	193	192	19.6	1.1	192 (100.0%)												
Week 12																	
Placebo		194	18.8	1.0	193 (99.0%)	0.1	0.7	-1.4	1.5								
Nera 18mg		192	21.7	1.1	191 (99.5%)	1.9	0.7	0.5	3.3	1.9	1.0	-0.2	3.9	0.0699			
Week 26																	
Placebo		185	20.1	1.1	184 (94.4%)	1.6	0.9	-0.1	3.2								
Nera 18mg		187	23.1	1.3	186 (96.9%)	3.4	0.9	1.8	5.1	1.9	1.2	-0.5	4.2	0.1209			
Week 36																	
Placebo		181	21.3	1.2	180 (92.3%)	3.4	0.9	1.6	5.2								
Nera 18mg		180	23.9	1.3	179 (93.2%)	4.5	0.9	2.7	6.3	1.1	1.3	-1.4	3.6	0.3842			
Week 44																	
Placebo		178	22.0	1.2	177 (90.8%)	4.2	1.0	2.3	6.1								
Nera 18mg		177	25.2	1.5	176 (91.7%)	6.0	1.0	4.1	7.9	1.9	1.4	-0.8	4.5	0.1697			
Week 52																	
Placebo		172	22.4	1.3	171 (87.7%)	5.2	1.0	3.3	7.2								
Nera 18mg		175	24.6	1.4	174 (90.6%)	5.5	1.0	3.5	7.4	0.3	1.4	-2.5	3.0	0.8488			
Week 64																	
Placebo		162	21.9	1.3	161 (82.6%)	5.3	1.1	3.2	7.4								
Nera 18mg		162	23.9	1.6	161 (83.9%)	5.3	1.1	3.2	7.4	-0.0	1.5	-3.0	3.0	0.9863			
Week 76																	
Placebo		118	21.0	1.6	117 (60.0%)												
Nera 18mg		114	24.2	1.9	114 (59.4%)												
Week 88																	
Placebo		35	21.5	2.9	35 (17.9%)												
Nera 18mg		28	23.1	3.4	28 (14.6%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	6.1	NC	1 (0.5%)												

Study: 1305-0014. 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, 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 H.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 (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
Type of AF therapy																	
Test for homogeneity (H0)^																	
Week 12														0.3368			
Week 26														0.4709			
Week 36														0.3936			
Week 44														0.1618			
Week 52														0.6627			
Week 64														0.8081			
Nintedanib																	
Baseline																	
Placebo	173	173	20.6	1.1	169 (100.0%)												
Nera 18mg	178	178	22.2	1.2	176 (100.0%)												
Week 12																	
Placebo		167	20.2	1.2	167 (98.8%)	-0.1	0.8	-1.6	1.4								
Nera 18mg		172	24.0	1.2	172 (97.7%)	2.5	0.8	1.0	4.0	2.6	1.1	0.5	4.8	0.0161	0.26	0.05	0.47
Week 26																	
Placebo		158	22.0	1.2	158 (93.5%)	2.1	0.9	0.3	3.9								
Nera 18mg		163	25.0	1.4	163 (92.6%)	4.3	0.9	2.5	6.1	2.2	1.3	-0.3	4.8	0.0886			
Week 36																	
Placebo		153	23.4	1.3	153 (90.5%)	4.1	1.0	2.2	6.0								
Nera 18mg		153	25.7	1.5	153 (86.9%)	5.5	1.0	3.6	7.4	1.4	1.4	-1.3	4.2	0.3054			
Week 44																	
Placebo		149	25.1	1.5	149 (88.2%)	5.6	1.0	3.5	7.6								
Nera 18mg		144	24.9	1.5	144 (81.8%)	5.4	1.0	3.4	7.5	-0.2	1.5	-3.1	2.7	0.9161			
Week 52																	
Placebo		147	25.1	1.5	147 (87.0%)	6.0	1.1	3.9	8.1								
Nera 18mg		147	25.2	1.5	147 (83.5%)	5.1	1.1	3.0	7.2	-0.9	1.5	-3.9	2.1	0.5557			
Week 64																	
Placebo		134	23.1	1.4	134 (79.3%)	6.0	1.2	3.7	8.3								
Nera 18mg		128	24.3	1.7	128 (72.7%)	4.9	1.2	2.6	7.2	-1.0	1.7	-4.3	2.2	0.5306			
Week 76																	
Placebo		99	22.9	1.7	99 (58.6%)												
Nera 18mg		93	25.7	2.1	93 (52.8%)												
Week 88																	
Placebo		28	26.4	3.2	28 (16.6%)												

Study: 1305-0014. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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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 H.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 (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		22	29.1	4.3	22 (12.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Pirfenidone																	
Baseline																	
Placebo	133	132	21.7	1.3	129 (100.0%)												
Nera 18mg	127	125	22.6	1.4	124 (100.0%)												
Week 12																	
Placebo		130	23.0	1.5	129 (100.0%)	1.3	0.9	-0.4	3.0								
Nera 18mg		126	24.5	1.5	124 (100.0%)	2.3	0.9	0.6	4.1	1.0	1.3	-1.5	3.5	0.4174			
Week 26																	
Placebo		123	24.4	1.6	122 (94.6%)	3.2	1.1	1.2	5.3								
Nera 18mg		123	26.8	1.7	121 (97.6%)	4.0	1.1	1.9	6.1	0.8	1.5	-2.1	3.7	0.5997			
Week 36																	
Placebo		116	26.1	1.8	115 (89.1%)	5.8	1.1	3.6	8.0								
Nera 18mg		120	27.4	1.7	118 (95.2%)	5.4	1.1	3.2	7.6	-0.4	1.6	-3.5	2.8	0.8118			
Week 44																	
Placebo		117	26.3	1.8	116 (89.9%)	5.5	1.2	3.2	7.9								
Nera 18mg		118	29.9	1.8	116 (93.5%)	8.5	1.2	6.2	10.9	3.0	1.7	-0.3	6.3	0.0769			
Week 52																	
Placebo		111	26.4	1.9	110 (85.3%)	7.2	1.2	4.7	9.6								
Nera 18mg		113	28.8	1.8	111 (89.5%)	7.3	1.2	4.9	9.7	0.1	1.7	-3.3	3.5	0.9477			
Week 64																	
Placebo		106	28.6	2.1	105 (81.4%)	9.3	1.3	6.7	12.0								
Nera 18mg		107	29.0	2.0	105 (84.7%)	7.7	1.3	5.0	10.3	-1.7	1.9	-5.4	2.1	0.3817			
Week 76																	
Placebo		73	26.4	2.3	72 (55.8%)												
Nera 18mg		78	28.8	2.1	77 (62.1%)												
Week 88																	
Placebo		21	18.3	2.9	21 (16.3%)												
Nera 18mg		15	22.6	4.9	15 (12.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	6.1	NC	1 (0.8%)												

Study: 1305-0014. 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, 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 H.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 (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
Region																	
Test for homogeneity (H0)^																	
Week 12														0.2513			
Week 26														0.2758			
Week 36														0.2061			
Week 44														0.9513			
Week 52														0.9601			
Week 64														0.9260			
Europe																	
Baseline																	
Placebo	136	136	20.0	1.2	134 (100.0%)												
Nera 18mg	136	135	23.6	1.4	134 (100.0%)												
Week 12																	
Placebo		133	21.0	1.3	133 (99.3%)	1.0	0.9	-0.7	2.8								
Nera 18mg		132	24.5	1.5	131 (97.8%)	1.8	0.9	0.0	3.5	0.7	1.2	-1.7	3.2	0.5560			
Week 26																	
Placebo		125	21.4	1.4	125 (93.3%)	2.3	1.0	0.2	4.3								
Nera 18mg		128	27.8	1.6	127 (94.8%)	5.2	1.0	3.2	7.3	3.0	1.5	0.1	5.8	0.0433	0.25	0.01	0.50
Week 36																	
Placebo		121	22.5	1.6	121 (90.3%)	4.1	1.1	1.9	6.3								
Nera 18mg		121	28.5	1.7	120 (89.6%)	6.1	1.1	3.9	8.3	2.0	1.6	-1.1	5.0	0.2135			
Week 44																	
Placebo		121	25.7	1.7	121 (90.3%)	6.5	1.2	4.2	8.8								
Nera 18mg		116	29.4	1.9	115 (85.8%)	7.5	1.2	5.2	9.8	1.0	1.7	-2.3	4.2	0.5576			
Week 52																	
Placebo		118	24.2	1.6	118 (88.1%)	6.3	1.2	3.9	8.6								
Nera 18mg		116	28.1	1.8	115 (85.8%)	5.9	1.2	3.5	8.3	-0.4	1.7	-3.8	3.0	0.8114			
Week 64																	
Placebo		111	23.6	1.6	111 (82.8%)	6.4	1.3	3.8	8.9								
Nera 18mg		102	27.3	1.9	101 (75.4%)	5.9	1.3	3.3	8.5	-0.5	1.9	-4.2	3.2	0.7900			
Week 76																	
Placebo		80	22.6	2.0	80 (59.7%)												
Nera 18mg		73	29.3	2.4	73 (54.5%)												
Week 88																	
Placebo		22	23.0	3.2	22 (16.4%)												

Study: 1305-0014. 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, 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 H.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 (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		18	26.4	5.4	18 (13.4%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Asia																	
Baseline																	
Placebo	72	72	21.4	1.7	70 (100.0%)												
Nera 18mg	79	78	19.5	1.8	76 (100.0%)												
Week 12																	
Placebo		70	20.1	1.8	70 (100.0%)	-0.8	1.2	-3.2	1.5								
Nera 18mg		77	21.6	1.7	76 (100.0%)	2.3	1.2	0.1	4.6	3.2	1.7	-0.1	6.4	0.0581			
Week 26																	
Placebo		63	21.8	1.7	63 (90.0%)	1.1	1.5	-1.7	4.0								
Nera 18mg		74	21.6	2.0	73 (96.1%)	1.9	1.4	-0.7	4.6	0.8	2.0	-3.1	4.7	0.6877			
Week 36																	
Placebo		62	24.7	2.3	62 (88.6%)	4.2	1.6	1.2	7.3								
Nera 18mg		72	23.0	2.1	71 (93.4%)	4.6	1.5	1.7	7.5	0.3	2.1	-3.8	4.5	0.8700			
Week 44																	
Placebo		60	24.6	2.3	60 (85.7%)	4.3	1.6	1.1	7.5								
Nera 18mg		70	24.2	2.0	69 (90.8%)	6.2	1.5	3.1	9.2	1.9	2.3	-2.6	6.3	0.4100			
Week 52																	
Placebo		57	26.5	2.7	57 (81.4%)	6.6	1.7	3.2	10.0								
Nera 18mg		66	24.1	2.2	65 (85.5%)	6.0	1.6	2.9	9.2	-0.6	2.4	-5.2	4.0	0.8082			
Week 64																	
Placebo		55	31.3	3.2	55 (78.6%)	11.1	1.8	7.5	14.7								
Nera 18mg		64	24.0	2.4	63 (82.9%)	5.7	1.7	2.3	9.1	-5.4	2.5	-10.4	-0.5	0.0323	-0.39	-0.76	-0.03
Week 76																	
Placebo		38	27.5	3.1	38 (54.3%)												
Nera 18mg		51	22.8	2.5	50 (65.8%)												
Week 88																	
Placebo		11	21.2	4.4	11 (15.7%)												
Nera 18mg		8	24.0	5.3	8 (10.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	

Study: 1305-0014. 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 H.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 (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
Baseline																	
Placebo	75	75	22.7	1.8	72 (100.0%)												
Nera 18mg	56	56	23.0	2.0	56 (100.0%)												
Week 12																	
Placebo		71	22.9	2.2	71 (98.6%)	0.7	1.2	-1.7	3.0								
Nera 18mg		55	26.6	2.4	55 (98.2%)	4.0	1.4	1.4	6.7	3.4	1.8	-0.2	6.9	0.0630			
Week 26																	
Placebo		70	26.3	2.3	70 (97.2%)	4.2	1.4	1.5	7.0								
Nera 18mg		55	27.5	2.6	55 (98.2%)	4.9	1.6	1.8	7.9	0.6	2.1	-3.5	4.7	0.7681			
Week 36																	
Placebo		64	26.5	2.2	64 (88.9%)	5.5	1.5	2.6	8.5								
Nera 18mg		53	27.3	2.7	53 (94.6%)	5.1	1.7	1.8	8.4	-0.4	2.3	-4.8	4.0	0.8581			
Week 44																	
Placebo		64	25.4	2.3	64 (88.9%)	4.9	1.6	1.8	8.0								
Nera 18mg		50	28.0	2.8	50 (89.3%)	7.1	1.8	3.5	10.6	2.2	2.4	-2.5	6.9	0.3672			
Week 52																	
Placebo		64	27.1	2.6	64 (88.9%)	6.9	1.6	3.7	10.1								
Nera 18mg		52	27.9	2.7	52 (92.9%)	6.3	1.8	2.7	9.9	-0.6	2.5	-5.4	4.2	0.8135			
Week 64																	
Placebo		57	23.5	2.1	57 (79.2%)	6.5	1.8	3.0	10.0								
Nera 18mg		47	26.5	3.4	47 (83.9%)	6.0	2.0	2.0	9.9	-0.6	2.7	-5.8	4.7	0.8336			
Week 76																	
Placebo		40	24.0	2.9	40 (55.6%)												
Nera 18mg		35	27.0	3.6	35 (62.5%)												
Week 88																	
Placebo		13	26.6	5.5	13 (18.1%)												
Nera 18mg		8	23.4	6.2	8 (14.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	6.1	NC	1 (1.8%)												
Rest of the World																	
Baseline																	
Placebo	23	22	21.3	3.1	22 (100.0%)												
Nera 18mg	34	34	22.9	2.7	34 (100.0%)												
Week 12																	
Placebo		23	23.6	3.9	22 (100.0%)	0.8	2.1	-3.4	5.0								

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

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Table H.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 (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		34	25.0	2.9	34 (100.0%)	2.5	1.7	-0.9	5.9	1.7	2.7	-3.7	7.1	0.5418			
Week 26																	
Placebo		23	25.7	4.1	22 (100.0%)	3.3	2.5	-1.6	8.2								
Nera 18mg		29	24.4	2.3	29 (85.3%)	4.0	2.1	-0.2	8.2	0.7	3.3	-5.7	7.1	0.8280			
Week 36																	
Placebo		22	29.9	4.5	21 (95.5%)	8.4	2.7	3.1	13.7								
Nera 18mg		27	24.9	2.9	27 (79.4%)	5.9	2.3	1.3	10.4	-2.5	3.5	-9.5	4.4	0.4791			
Week 44																	
Placebo		21	28.4	3.8	20 (90.9%)	5.6	2.9	-0.0	11.2								
Nera 18mg		26	23.8	2.9	26 (76.5%)	4.9	2.5	0.1	9.8	-0.7	3.8	-8.1	6.7	0.8606			
Week 52																	
Placebo		19	28.1	4.5	18 (81.8%)	6.2	3.0	0.3	12.2								
Nera 18mg		26	25.5	3.4	26 (76.5%)	6.5	2.5	1.5	11.5	0.3	3.9	-7.5	8.0	0.9421			
Week 64																	
Placebo		17	26.5	4.4	16 (72.7%)	5.5	3.3	-1.0	12.0								
Nera 18mg		22	29.3	3.4	22 (64.7%)	9.3	2.8	3.7	14.8	3.7	4.3	-4.8	12.3	0.3880			
Week 76																	
Placebo		14	27.3	5.4	13 (59.1%)												
Nera 18mg		12	32.5	4.3	12 (35.3%)												
Week 88																	
Placebo		3	12.3	3.5	3 (13.6%)												
Nera 18mg		3	42.2	9.1	3 (8.8%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0014. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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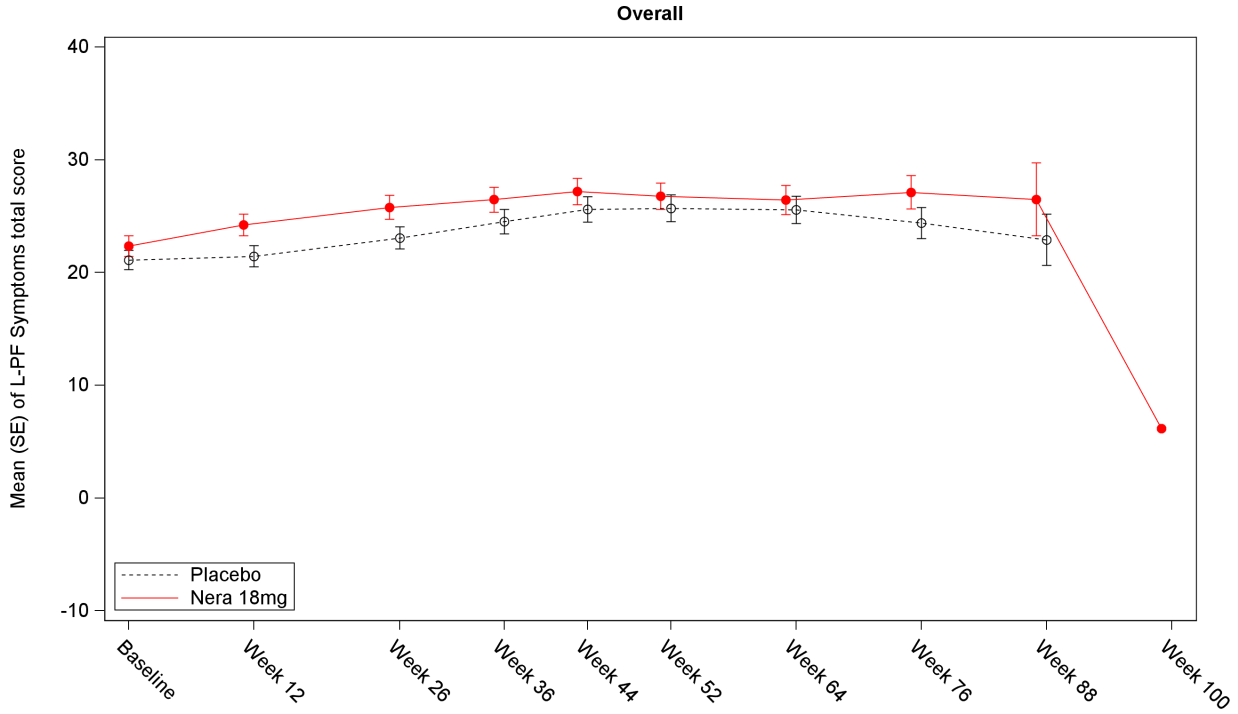

Number of patients

Placebo	305	297	281	269	266	258	240	172	49	0
Nera 18mg	303	298	286	273	262	260	235	171	37	1

Study: 1305-0014. Number of patients refers to the number of patients with observed data at visit.

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

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Figure H.1.1.1.2.1: 3

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Table H.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 (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
Overall																	
Baseline																	
Placebo	306	305	24.8	1.3	298 (100.0%)												
Nera 18mg	305	303	26.5	1.4	300 (100.0%)												
Week 12																	
Placebo		298	25.0	1.3	297 (99.7%)	0.3	0.9	-1.5	2.1								
Nera 18mg		299	28.8	1.4	297 (99.0%)	3.0	0.9	1.2	4.8	2.7	1.3	0.1	5.2	0.0414	0.17	0.01	0.33
Week 26																	
Placebo		281	26.6	1.4	280 (94.0%)	2.3	1.1	0.1	4.5								
Nera 18mg		286	31.3	1.6	284 (94.7%)	5.9	1.1	3.8	8.1	3.6	1.6	0.6	6.7	0.0189	0.20	0.03	0.36
Week 36																	
Placebo		269	28.1	1.5	268 (89.9%)	4.8	1.1	2.6	7.0								
Nera 18mg		274	30.9	1.5	272 (90.7%)	5.8	1.1	3.6	8.1	1.0	1.6	-2.1	4.2	0.5158			
Week 44																	
Placebo		266	28.4	1.5	265 (88.9%)	4.5	1.2	2.2	6.8								
Nera 18mg		262	32.1	1.7	260 (86.7%)	7.6	1.2	5.3	9.9	3.0	1.7	-0.2	6.3	0.0674			
Week 52																	
Placebo		258	28.5	1.6	257 (86.2%)	5.2	1.1	2.9	7.4								
Nera 18mg		260	29.4	1.6	258 (86.0%)	4.7	1.1	2.5	7.0	-0.4	1.6	-3.6	2.7	0.7840			
Week 64																	
Placebo		240	28.2	1.5	239 (80.2%)	5.7	1.2	3.4	8.0								
Nera 18mg		235	28.8	1.7	233 (77.7%)	4.4	1.2	2.1	6.7	-1.3	1.7	-4.6	2.0	0.4451			
Week 76																	
Placebo		172	26.9	1.8	171 (57.4%)												
Nera 18mg		171	30.9	2.0	170 (56.7%)												
Week 88																	
Placebo		49	25.0	2.9	49 (16.4%)												
Nera 18mg		37	30.4	4.3	37 (12.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (0.3%)												
Age																	
Test for homogeneity (H0)^																	
Week 12														0.4497			

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

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Table H.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 (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 26														0.6833			
Week 36														0.3473			
Week 44														0.5372			
Week 52														0.8540			
Week 64														0.6628			
<65 years																	
Baseline																	
Placebo	69	69	23.7	2.3	69 (100.0%)												
Nera 18mg	63	62	28.2	3.1	62 (100.0%)												
Week 12																	
Placebo		68	25.7	2.5	68 (98.6%)	1.9	1.9	-1.9	5.7								
Nera 18mg		63	30.4	3.0	62 (100.0%)	2.8	2.0	-1.2	6.7	0.8	2.8	-4.7	6.3	0.7687			
Week 26																	
Placebo		66	25.4	2.6	66 (95.7%)	2.3	2.3	-2.1	6.8								
Nera 18mg		62	33.9	3.2	61 (98.4%)	7.2	2.4	2.5	11.8	4.8	3.3	-1.6	11.3	0.1413			
Week 36																	
Placebo		65	30.4	3.0	65 (94.2%)	7.6	2.3	3.0	12.1								
Nera 18mg		60	31.7	3.1	59 (95.2%)	5.9	2.4	1.2	10.7	-1.7	3.3	-8.2	4.9	0.6181			
Week 44																	
Placebo		64	31.8	2.9	64 (92.8%)	8.3	2.4	3.6	13.0								
Nera 18mg		57	35.4	3.9	56 (90.3%)	9.5	2.5	4.5	14.5	1.2	3.5	-5.6	8.1	0.7216			
Week 52																	
Placebo		63	26.9	2.7	63 (91.3%)	4.2	2.3	-0.3	8.8								
Nera 18mg		55	30.8	3.3	54 (87.1%)	4.3	2.5	-0.6	9.2	0.1	3.4	-6.6	6.7	0.9854			
Week 64																	
Placebo		60	29.8	3.1	60 (87.0%)	7.6	2.4	2.9	12.2								
Nera 18mg		49	32.8	3.8	48 (77.4%)	5.0	2.6	-0.1	10.1	-2.6	3.5	-9.5	4.4	0.4672			
Week 76																	
Placebo		38	23.9	3.2	38 (55.1%)												
Nera 18mg		35	34.3	4.8	34 (54.8%)												
Week 88																	
Placebo		16	25.5	5.0	16 (23.2%)												
Nera 18mg		7	41.1	9.7	7 (11.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												

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Table H.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 (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		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	237	236	25.1	1.5	229 (100.0%)												
Nera 18mg	242	241	26.0	1.5	238 (100.0%)												
Week 12																	
Placebo		230	24.9	1.5	229 (100.0%)	-0.2	1.1	-2.3	1.9								
Nera 18mg		236	28.4	1.5	235 (98.7%)	3.0	1.0	1.0	5.1	3.2	1.5	0.3	6.1	0.0300	0.20	0.02	0.38
Week 26																	
Placebo		215	26.9	1.6	214 (93.4%)	2.3	1.3	-0.2	4.8								
Nera 18mg		224	30.6	1.8	223 (93.7%)	5.6	1.2	3.2	8.0	3.3	1.8	-0.1	6.8	0.0598			
Week 36																	
Placebo		204	27.4	1.7	203 (88.6%)	3.9	1.3	1.4	6.5								
Nera 18mg		214	30.7	1.8	213 (89.5%)	5.8	1.3	3.4	8.3	1.9	1.8	-1.6	5.5	0.2927			
Week 44																	
Placebo		202	27.2	1.7	201 (87.8%)	3.4	1.3	0.7	6.0								
Nera 18mg		205	31.1	1.8	204 (85.7%)	7.0	1.3	4.4	9.6	3.7	1.9	-0.0	7.4	0.0505			
Week 52																	
Placebo		195	29.0	1.9	194 (84.7%)	5.5	1.3	2.9	8.1								
Nera 18mg		205	29.0	1.8	204 (85.7%)	4.9	1.3	2.3	7.4	-0.6	1.8	-4.2	2.9	0.7235			
Week 64																	
Placebo		180	27.6	1.8	179 (78.2%)	5.1	1.4	2.4	7.8								
Nera 18mg		186	27.7	1.9	185 (77.7%)	4.3	1.3	1.7	6.9	-0.8	1.9	-4.5	2.9	0.6662			
Week 76																	
Placebo		134	27.7	2.2	133 (58.1%)												
Nera 18mg		136	30.0	2.2	136 (57.1%)												
Week 88																	
Placebo		33	24.7	3.7	33 (14.4%)												
Nera 18mg		30	27.9	4.8	30 (12.6%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (0.4%)												
Sex																	
Test for homogeneity (H0)^																	

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

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Table H.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 (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														0.9103			
Week 26														0.6325			
Week 36														0.4997			
Week 44														0.1247			
Week 52														0.0867			
Week 64														0.1476			
Male																	
Baseline																	
Placebo	269	268	24.8	1.4	261 (100.0%)												
Nera 18mg	255	253	26.3	1.5	250 (100.0%)												
Week 12																	
Placebo		261	24.9	1.3	260 (99.6%)	0.1	1.0	-1.8	2.1								
Nera 18mg		249	28.3	1.5	247 (98.8%)	2.7	1.0	0.7	4.7	2.6	1.4	-0.2	5.3	0.0724			
Week 26																	
Placebo		245	26.4	1.5	244 (93.5%)	2.2	1.2	-0.1	4.5								
Nera 18mg		239	30.6	1.7	237 (94.8%)	5.5	1.2	3.1	7.8	3.3	1.7	-0.0	6.6	0.0517			
Week 36																	
Placebo		233	28.3	1.6	232 (88.9%)	5.2	1.2	2.8	7.6								
Nera 18mg		231	30.6	1.7	229 (91.6%)	5.8	1.2	3.4	8.2	0.6	1.7	-2.8	4.0	0.7287			
Week 44																	
Placebo		230	28.5	1.6	229 (87.7%)	4.9	1.3	2.4	7.4								
Nera 18mg		221	30.8	1.8	219 (87.6%)	6.8	1.3	4.3	9.4	1.9	1.8	-1.6	5.5	0.2807			
Week 52																	
Placebo		223	28.8	1.7	222 (85.1%)	5.8	1.2	3.4	8.1								
Nera 18mg		219	28.5	1.7	217 (86.8%)	4.2	1.2	1.7	6.6	-1.6	1.7	-5.0	1.8	0.3609			
Week 64																	
Placebo		205	27.2	1.6	204 (78.2%)	4.9	1.3	2.4	7.4								
Nera 18mg		201	29.2	1.8	199 (79.6%)	4.6	1.3	2.1	7.1	-0.3	1.8	-3.8	3.2	0.8663			
Week 76																	
Placebo		149	26.8	1.9	148 (56.7%)												
Nera 18mg		148	30.5	2.1	147 (58.8%)												
Week 88																	
Placebo		42	26.7	3.2	42 (16.1%)												
Nera 18mg		32	32.8	4.7	32 (12.8%)												
Week 100																	

Study: 1305-0014. 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, 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 H.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 (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
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (0.4%)												
Female																	
Baseline																	
Placebo	37	37	24.8	4.1	37 (100.0%)												
Nera 18mg	50	50	27.5	3.4	50 (100.0%)												
Week 12																	
Placebo		37	26.1	4.4	37 (100.0%)	1.4	2.6	-3.7	6.6								
Nera 18mg		50	31.1	3.6	50 (100.0%)	4.4	2.3	-0.1	8.8	3.0	3.5	-3.8	9.8	0.3910			
Week 26																	
Placebo		36	27.8	4.2	36 (97.3%)	2.8	3.1	-3.2	8.9								
Nera 18mg		47	34.9	4.1	47 (94.0%)	8.2	2.7	2.9	13.5	5.4	4.1	-2.6	13.4	0.1882			
Week 36																	
Placebo		36	27.3	4.1	36 (97.3%)	2.3	3.1	-3.8	8.5								
Nera 18mg		43	32.8	4.0	43 (86.0%)	6.0	2.8	0.5	11.5	3.7	4.2	-4.6	11.9	0.3831			
Week 44																	
Placebo		36	27.2	4.5	36 (97.3%)	2.2	3.2	-4.1	8.5								
Nera 18mg		41	38.6	4.8	41 (82.0%)	11.4	2.9	5.6	17.1	9.2	4.3	0.6	17.7	0.0355	0.48	0.03	0.93
Week 52																	
Placebo		35	26.2	4.5	35 (94.6%)	1.5	3.1	-4.6	7.6								
Nera 18mg		41	33.7	4.2	41 (82.0%)	7.7	2.8	2.2	13.3	6.2	4.2	-2.0	14.5	0.1399			
Week 64																	
Placebo		35	33.6	4.9	35 (94.6%)	10.1	3.2	3.9	16.3								
Nera 18mg		34	26.6	4.7	34 (68.0%)	3.0	3.0	-3.0	8.9	-7.2	4.4	-15.7	1.4	0.1020			
Week 76																	
Placebo		23	27.5	5.8	23 (62.2%)												
Nera 18mg		23	33.2	6.5	23 (46.0%)												
Week 88																	
Placebo		7	14.9	6.5	7 (18.9%)												
Nera 18mg		5	15.0	8.6	5 (10.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Baseline FVC percent predicted

Study: 1305-0014. 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, 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 H.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 (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
Test for homogeneity (H0)^																	
Week 12														0.8999			
Week 26														0.7026			
Week 36														0.3146			
Week 44														0.2547			
Week 52														0.0475			
Week 64														0.0367			
<=70%																	
Baseline																	
Placebo	109	109	31.5	2.3	103 (100.0%)												
Nera 18mg	112	111	31.5	2.4	108 (100.0%)												
Week 12																	
Placebo		103	31.5	2.4	103 (100.0%)	2.2	1.6	-0.9	5.3								
Nera 18mg		107	34.4	2.4	106 (98.1%)	5.1	1.6	2.1	8.2	2.9	2.2	-1.4	7.2	0.1905			
Week 26																	
Placebo		96	33.5	2.6	96 (93.2%)	4.7	1.9	1.0	8.4								
Nera 18mg		99	36.5	2.6	98 (90.7%)	7.6	1.9	3.9	11.2	2.8	2.6	-2.3	8.0	0.2832			
Week 36																	
Placebo		88	35.8	2.8	88 (85.4%)	8.3	2.0	4.5	12.2								
Nera 18mg		93	35.1	2.6	92 (85.2%)	7.1	1.9	3.4	10.9	-1.2	2.7	-6.6	4.1	0.6566			
Week 44																	
Placebo		88	36.9	2.8	88 (85.4%)	7.8	2.0	3.8	11.8								
Nera 18mg		85	35.1	2.8	84 (77.8%)	8.2	2.0	4.2	12.2	0.4	2.9	-5.3	6.0	0.9009			
Week 52																	
Placebo		86	36.3	2.7	86 (83.5%)	8.5	2.0	4.7	12.4								
Nera 18mg		85	31.3	2.6	84 (77.8%)	3.6	2.0	-0.3	7.4	-5.0	2.8	-10.4	0.5	0.0732			
Week 64																	
Placebo		78	37.2	2.9	78 (75.7%)	10.9	2.0	6.9	14.9								
Nera 18mg		73	33.3	3.0	72 (66.7%)	4.7	2.1	0.6	8.7	-6.2	2.9	-11.9	-0.6	0.0315	-0.35	-0.67	-0.03
Week 76																	
Placebo		54	35.6	3.3	54 (52.4%)												
Nera 18mg		57	37.3	3.7	56 (51.9%)												
Week 88																	
Placebo		14	31.0	4.9	14 (13.6%)												
Nera 18mg		9	44.4	8.5	9 (8.3%)												

Study: 1305-0014. 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, 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 H.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 (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		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	197	196	21.1	1.5	195 (100.0%)												
Nera 18mg	193	192	23.5	1.6	192 (100.0%)												
Week 12																	
Placebo		195	21.6	1.5	194 (99.5%)	-0.7	1.1	-3.0	1.5								
Nera 18mg		192	25.7	1.6	191 (99.5%)	1.8	1.2	-0.4	4.1	2.5	1.6	-0.6	5.7	0.1184			
Week 26																	
Placebo		185	23.0	1.6	184 (94.4%)	1.0	1.4	-1.7	3.7								
Nera 18mg		187	28.6	1.9	186 (96.9%)	5.1	1.4	2.4	7.7	4.1	1.9	0.3	7.8	0.0343	0.22	0.02	0.42
Week 36																	
Placebo		181	24.4	1.7	180 (92.3%)	3.0	1.4	0.3	5.7								
Nera 18mg		181	28.8	1.9	180 (93.8%)	5.2	1.4	2.5	7.9	2.2	2.0	-1.7	6.0	0.2685			
Week 44																	
Placebo		178	24.1	1.7	177 (90.8%)	2.9	1.4	0.0	5.7								
Nera 18mg		177	30.6	2.1	176 (91.7%)	7.2	1.4	4.4	10.0	4.4	2.0	0.4	8.3	0.0325	0.23	0.02	0.44
Week 52																	
Placebo		172	24.6	1.8	171 (87.7%)	3.5	1.4	0.7	6.2								
Nera 18mg		175	28.4	1.9	174 (90.6%)	5.2	1.4	2.5	7.9	1.8	2.0	-2.1	5.6	0.3674			
Week 64																	
Placebo		162	23.8	1.7	161 (82.6%)	3.1	1.4	0.2	5.9								
Nera 18mg		162	26.8	2.1	161 (83.9%)	4.2	1.4	1.4	7.0	1.2	2.0	-2.8	5.1	0.5665			
Week 76																	
Placebo		118	22.9	2.1	117 (60.0%)												
Nera 18mg		114	27.7	2.4	114 (59.4%)												
Week 88																	
Placebo		35	22.6	3.6	35 (17.9%)												
Nera 18mg		28	25.9	4.8	28 (14.6%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (0.5%)												

Study: 1305-0014. 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 H.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 (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
Type of AF therapy																	
Test for homogeneity (H0)^																	
Week 12														0.5824			
Week 26														0.9493			
Week 36														0.6227			
Week 44														0.1122			
Week 52														0.7593			
Week 64														0.6550			
Nintedanib																	
Baseline																	
Placebo	173	173	25.0	1.7	169 (100.0%)												
Nera 18mg	178	178	25.7	1.7	176 (100.0%)												
Week 12																	
Placebo		168	24.0	1.7	168 (99.4%)	-0.5	1.2	-2.9	1.9								
Nera 18mg		173	27.8	1.7	173 (98.3%)	2.8	1.2	0.4	5.2	3.3	1.7	-0.1	6.7	0.0549			
Week 26																	
Placebo		158	26.0	1.8	158 (93.5%)	1.9	1.5	-1.0	4.8								
Nera 18mg		163	29.8	2.0	163 (92.6%)	5.7	1.4	2.8	8.5	3.7	2.1	-0.3	7.8	0.0693			
Week 36																	
Placebo		153	27.6	1.9	153 (90.5%)	4.2	1.5	1.3	7.2								
Nera 18mg		153	29.7	2.0	153 (86.9%)	6.0	1.5	3.0	8.9	1.7	2.1	-2.4	5.9	0.4152			
Week 44																	
Placebo		149	28.9	2.0	149 (88.2%)	5.1	1.6	2.1	8.2								
Nera 18mg		144	29.3	2.2	144 (81.8%)	5.8	1.6	2.7	8.9	0.7	2.2	-3.6	5.0	0.7531			
Week 52																	
Placebo		147	28.3	2.0	147 (87.0%)	4.5	1.5	1.6	7.5								
Nera 18mg		147	27.6	1.9	147 (83.5%)	3.7	1.5	0.7	6.6	-0.9	2.1	-5.0	3.3	0.6833			
Week 64																	
Placebo		134	25.7	1.9	134 (79.3%)	3.7	1.6	0.6	6.8								
Nera 18mg		128	26.1	2.2	128 (72.7%)	3.1	1.6	-0.0	6.2	-0.6	2.2	-5.0	3.7	0.7774			
Week 76																	
Placebo		99	25.3	2.3	99 (58.6%)												
Nera 18mg		93	28.3	2.7	93 (52.8%)												
Week 88																	
Placebo		28	27.5	4.2	28 (16.6%)												

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

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Table H.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 (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		22	32.8	5.5	22 (12.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Pirfenidone																	
Baseline																	
Placebo	133	132	24.6	2.0	129 (100.0%)												
Nera 18mg	127	125	27.6	2.2	124 (100.0%)												
Week 12																	
Placebo		130	26.4	2.1	129 (100.0%)	1.4	1.4	-1.4	4.1								
Nera 18mg		126	30.1	2.2	124 (100.0%)	3.2	1.4	0.4	6.1	1.9	2.0	-2.1	5.8	0.3542			
Week 26																	
Placebo		123	27.3	2.1	122 (94.6%)	2.8	1.7	-0.5	6.1								
Nera 18mg		123	33.3	2.5	121 (97.6%)	6.3	1.7	3.0	9.6	3.5	2.4	-1.1	8.2	0.1360			
Week 36																	
Placebo		116	28.8	2.3	115 (89.1%)	5.6	1.7	2.2	9.0								
Nera 18mg		121	32.4	2.3	119 (96.0%)	5.7	1.7	2.4	9.1	0.1	2.4	-4.6	4.9	0.9544			
Week 44																	
Placebo		117	27.7	2.3	116 (89.9%)	3.8	1.8	0.3	7.3								
Nera 18mg		118	35.5	2.6	116 (93.5%)	9.8	1.8	6.3	13.3	6.0	2.5	1.1	10.9	0.0170	0.31	0.06	0.57
Week 52																	
Placebo		111	28.7	2.5	110 (85.3%)	6.0	1.7	2.6	9.4								
Nera 18mg		113	31.7	2.5	111 (89.5%)	6.2	1.7	2.7	9.6	0.1	2.5	-4.7	5.0	0.9585			
Week 64																	
Placebo		106	31.3	2.5	105 (81.4%)	8.3	1.8	4.8	11.7								
Nera 18mg		107	32.0	2.6	105 (84.7%)	6.1	1.8	2.6	9.6	-2.1	2.5	-7.1	2.8	0.3992			
Week 76																	
Placebo		73	29.0	3.0	72 (55.8%)												
Nera 18mg		78	34.0	3.1	77 (62.1%)												
Week 88																	
Placebo		21	21.6	4.1	21 (16.3%)												
Nera 18mg		15	26.9	7.1	15 (12.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (0.8%)												

Study: 1305-0014. 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, 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 H.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 (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
Region																	
Test for homogeneity (H0)^																	
Week 12														0.5627			
Week 26														0.3156			
Week 36														0.1479			
Week 44														0.6845			
Week 52														0.6048			
Week 64														0.7429			
Europe																	
Baseline																	
Placebo	136	136	23.2	2.0	134 (100.0%)												
Nera 18mg	136	135	29.3	2.1	134 (100.0%)												
Week 12																	
Placebo		133	24.1	1.9	133 (99.3%)	0.8	1.4	-1.9	3.5								
Nera 18mg		132	30.1	2.2	131 (97.8%)	2.4	1.4	-0.3	5.1	1.6	2.0	-2.3	5.4	0.4228			
Week 26																	
Placebo		125	24.3	2.0	125 (93.3%)	1.8	1.6	-1.4	5.0								
Nera 18mg		128	35.1	2.5	127 (94.8%)	7.8	1.6	4.5	11.0	6.0	2.3	1.4	10.5	0.0105	0.32	0.08	0.57
Week 36																	
Placebo		121	24.8	2.1	121 (90.3%)	3.2	1.7	-0.1	6.5								
Nera 18mg		121	34.4	2.4	120 (89.6%)	6.8	1.7	3.5	10.2	3.7	2.4	-1.1	8.4	0.1279			
Week 44																	
Placebo		121	28.1	2.3	121 (90.3%)	5.5	1.7	2.1	8.9								
Nera 18mg		116	36.6	2.6	115 (85.8%)	9.0	1.8	5.5	12.5	3.5	2.5	-1.4	8.4	0.1607			
Week 52																	
Placebo		118	25.6	2.1	118 (88.1%)	4.4	1.7	1.0	7.7								
Nera 18mg		116	32.3	2.4	115 (85.8%)	4.8	1.7	1.4	8.2	0.4	2.4	-4.3	5.2	0.8536			
Week 64																	
Placebo		111	25.1	2.1	111 (82.8%)	4.2	1.7	0.8	7.7								
Nera 18mg		102	30.9	2.6	101 (75.4%)	4.1	1.8	0.6	7.6	-0.2	2.5	-5.1	4.7	0.9440			
Week 76																	
Placebo		80	25.2	2.5	80 (59.7%)												
Nera 18mg		73	35.1	3.2	73 (54.5%)												
Week 88																	
Placebo		22	26.3	4.5	22 (16.4%)												

Study: 1305-0014. 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 H.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 (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		18	31.3	6.7	18 (13.4%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Asia																	
Baseline																	
Placebo	72	72	27.3	2.8	70 (100.0%)												
Nera 18mg	79	78	21.0	2.6	76 (100.0%)												
Week 12																	
Placebo		70	23.3	2.6	70 (100.0%)	-2.8	1.9	-6.6	0.9								
Nera 18mg		77	23.9	2.4	76 (100.0%)	1.8	1.8	-1.8	5.4	4.7	2.6	-0.5	9.9	0.0779			
Week 26																	
Placebo		63	26.1	2.9	63 (90.0%)	-0.1	2.3	-4.6	4.4								
Nera 18mg		74	24.0	2.9	73 (96.1%)	2.1	2.2	-2.1	6.3	2.2	3.2	-4.0	8.4	0.4901			
Week 36																	
Placebo		62	29.3	3.2	62 (88.6%)	3.3	2.4	-1.3	8.0								
Nera 18mg		72	24.8	2.8	71 (93.4%)	3.9	2.2	-0.5	8.2	0.5	3.2	-5.8	6.9	0.8663			
Week 44																	
Placebo		60	28.1	3.1	60 (85.7%)	2.1	2.5	-2.7	6.9								
Nera 18mg		70	26.8	3.0	69 (90.8%)	6.3	2.3	1.8	10.9	4.2	3.4	-2.4	10.8	0.2105			
Week 52																	
Placebo		57	30.2	3.6	57 (81.4%)	3.8	2.4	-0.9	8.6								
Nera 18mg		66	24.1	2.9	65 (85.5%)	3.7	2.3	-0.7	8.2	-0.1	3.3	-6.6	6.4	0.9828			
Week 64																	
Placebo		55	35.4	4.1	55 (78.6%)	8.4	2.5	3.6	13.3								
Nera 18mg		64	24.5	3.1	63 (82.9%)	3.7	2.3	-0.8	8.3	-4.7	3.4	-11.3	1.9	0.1625			
Week 76																	
Placebo		38	29.6	4.3	38 (54.3%)												
Nera 18mg		51	24.4	3.3	50 (65.8%)												
Week 88																	
Placebo		11	21.6	5.5	11 (15.7%)												
Nera 18mg		8	20.3	7.1	8 (10.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	

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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 H.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 (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
Baseline																	
Placebo	75	75	25.0	2.5	72 (100.0%)												
Nera 18mg	56	56	27.2	2.7	56 (100.0%)												
Week 12																	
Placebo		72	26.1	2.7	72 (100.0%)	1.3	1.9	-2.4	5.0								
Nera 18mg		56	30.4	3.0	56 (100.0%)	3.9	2.1	-0.3	8.1	2.6	2.8	-3.0	8.2	0.3607			
Week 26																	
Placebo		70	30.1	2.9	70 (97.2%)	5.6	2.2	1.3	10.0								
Nera 18mg		55	32.7	3.4	55 (98.2%)	6.4	2.5	1.5	11.3	0.8	3.3	-5.8	7.3	0.8168			
Week 36																	
Placebo		64	31.2	2.9	64 (88.9%)	8.1	2.3	3.6	12.6								
Nera 18mg		54	32.2	3.3	54 (96.4%)	5.8	2.5	0.9	10.8	-2.2	3.4	-9.0	4.5	0.5138			
Week 44																	
Placebo		64	27.5	2.9	64 (88.9%)	4.8	2.4	0.1	9.4								
Nera 18mg		50	31.7	3.8	50 (89.3%)	7.3	2.7	2.0	12.5	2.5	3.6	-4.6	9.5	0.4895			
Week 52																	
Placebo		64	30.1	3.3	64 (88.9%)	7.2	2.3	2.7	11.7								
Nera 18mg		52	30.3	3.5	52 (92.9%)	5.2	2.6	0.2	10.2	-2.0	3.4	-8.7	4.8	0.5663			
Week 64																	
Placebo		57	24.9	2.7	57 (79.2%)	5.1	2.4	0.4	9.8								
Nera 18mg		47	27.0	4.1	47 (83.9%)	2.9	2.7	-2.3	8.1	-2.1	3.6	-9.2	4.9	0.5485			
Week 76																	
Placebo		40	23.3	3.4	40 (55.6%)												
Nera 18mg		35	28.1	4.7	35 (62.5%)												
Week 88																	
Placebo		13	27.2	6.7	13 (18.1%)												
Nera 18mg		8	31.8	10.4	8 (14.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (1.8%)												
Rest of the World																	
Baseline																	
Placebo	23	22	26.3	4.4	22 (100.0%)												
Nera 18mg	34	34	26.5	3.9	34 (100.0%)												
Week 12																	
Placebo		23	32.2	5.9	22 (100.0%)	3.9	3.4	-2.8	10.6								

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Table H.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 (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		34	32.1	4.1	34 (100.0%)	6.2	2.7	0.8	11.5	2.3	4.4	-6.3	10.8	0.6033			
Week 26																	
Placebo		23	29.3	5.6	22 (100.0%)	1.6	3.9	-6.1	9.4								
Nera 18mg		29	30.7	4.5	29 (85.3%)	6.7	3.4	0.0	13.3	5.0	5.2	-5.1	15.2	0.3315			
Week 36																	
Placebo		22	34.1	6.8	21 (95.5%)	8.5	4.1	0.5	16.4								
Nera 18mg		27	28.9	4.7	27 (79.4%)	6.4	3.5	-0.5	13.3	-2.1	5.4	-12.6	8.5	0.7015			
Week 44																	
Placebo		21	33.5	5.5	20 (90.9%)	5.5	4.3	-2.9	13.9								
Nera 18mg		26	26.8	4.6	26 (76.5%)	5.0	3.7	-2.2	12.2	-0.5	5.6	-11.6	10.5	0.9264			
Week 52																	
Placebo		19	35.7	5.9	18 (81.8%)	7.9	4.2	-0.4	16.3								
Nera 18mg		26	27.9	4.6	26 (76.5%)	6.0	3.6	-1.0	13.0	-2.0	5.5	-12.9	8.9	0.7238			
Week 64																	
Placebo		17	35.8	4.8	16 (72.7%)	8.0	4.4	-0.6	16.7								
Nera 18mg		22	35.4	5.6	22 (64.7%)	10.9	3.7	3.5	18.2	2.8	5.8	-8.6	14.2	0.6259			
Week 76																	
Placebo		14	39.6	7.4	13 (59.1%)												
Nera 18mg		12	41.0	7.0	12 (35.3%)												
Week 88																	
Placebo		3	18.1	5.0	3 (13.6%)												
Nera 18mg		3	48.6	9.7	3 (8.8%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0014. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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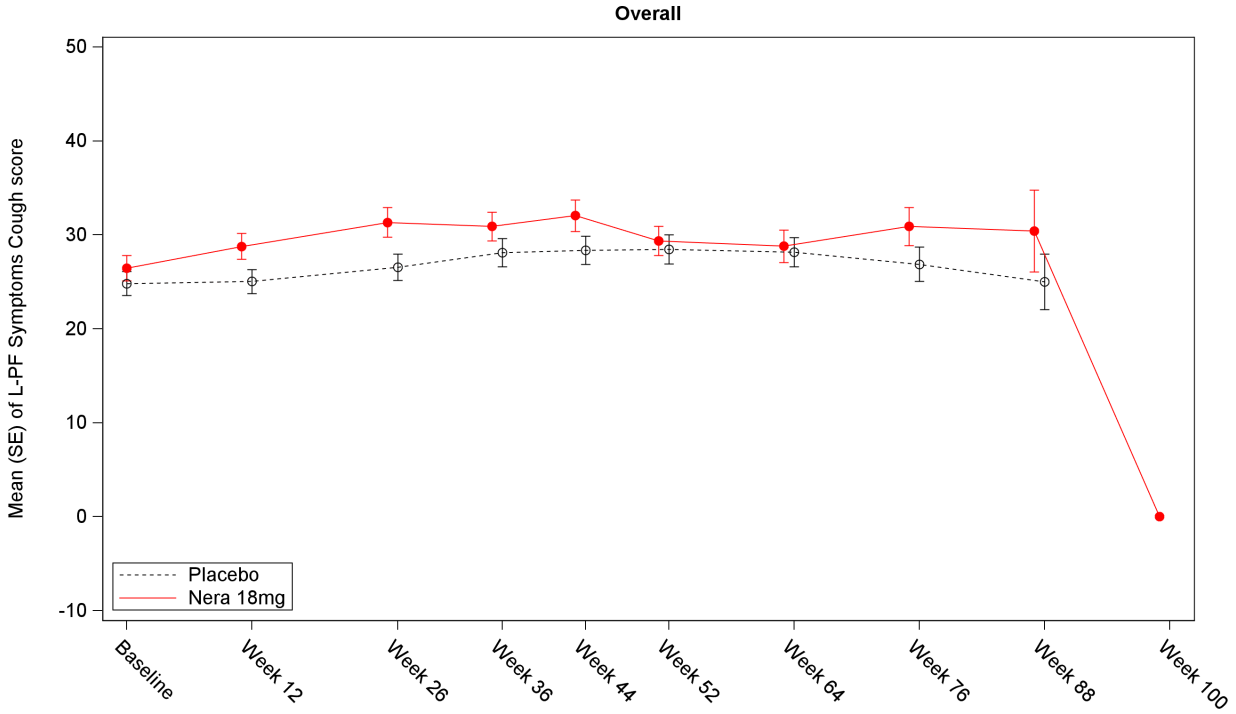

Number of patients

Placebo	305	298	281	269	266	258	240	172	49	0
Nera 18mg	303	299	286	274	262	260	235	171	37	1

Study: 1305-0014. Number of patients refers to the number of patients with observed data at visit.

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

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Table H.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 (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	306	305	12.1	0.8	298 (100.0%)												
Nera 18mg	305	304	13.1	0.9	301 (100.0%)												
Week 12																	
Placebo		298	12.3	0.9	297 (99.7%)	0.5	0.5	-0.6	1.5								
Nera 18mg		300	13.8	0.9	299 (99.3%)	1.2	0.5	0.2	2.2	0.7	0.7	-0.7	2.2	0.3376			
Week 26																	
Placebo		281	13.6	0.9	280 (94.0%)	2.0	0.6	0.8	3.2								
Nera 18mg		286	14.8	1.0	285 (94.7%)	2.3	0.6	1.1	3.6	0.3	0.9	-1.4	2.0	0.7210			
Week 36																	
Placebo		269	15.4	1.0	268 (89.9%)	4.4	0.8	3.0	5.9								
Nera 18mg		274	16.9	1.1	273 (90.7%)	4.9	0.7	3.4	6.3	0.4	1.1	-1.7	2.5	0.7040			
Week 44																	
Placebo		266	17.1	1.1	265 (88.9%)	6.0	0.8	4.5	7.5								
Nera 18mg		262	16.5	1.0	261 (86.7%)	5.2	0.8	3.7	6.7	-0.8	1.1	-2.9	1.4	0.4909			
Week 52																	
Placebo		258	17.8	1.2	257 (86.2%)	8.0	0.9	6.2	9.7								
Nera 18mg		260	18.7	1.2	259 (86.0%)	6.9	0.9	5.1	8.6	-1.1	1.3	-3.6	1.4	0.3867			
Week 64																	
Placebo		240	16.8	1.2	239 (80.2%)	8.4	1.0	6.4	10.3								
Nera 18mg		235	18.3	1.3	234 (77.7%)	7.1	1.0	5.2	9.1	-1.2	1.4	-4.0	1.5	0.3876			
Week 76																	
Placebo		172	16.6	1.4	171 (57.4%)												
Nera 18mg		171	18.1	1.4	170 (56.5%)												
Week 88																	
Placebo		49	13.8	2.1	49 (16.4%)												
Nera 18mg		37	16.6	2.6	37 (12.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	3.4	NC	1 (0.3%)												
Age																	
Test for homogeneity (H0)^																	
Week 12														0.5039			

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

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Table H.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 (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 26														0.6363			
Week 36														0.1137			
Week 44														0.5449			
Week 52														0.9869			
Week 64														0.9554			
<65 years																	
Baseline																	
Placebo	69	69	10.4	1.4	69 (100.0%)												
Nera 18mg	63	62	11.1	1.5	62 (100.0%)												
Week 12																	
Placebo		68	11.5	1.8	68 (98.6%)	0.9	1.1	-1.3	3.0								
Nera 18mg		63	11.8	1.6	62 (100.0%)	0.6	1.2	-1.6	2.9	-0.2	1.6	-3.4	2.9	0.8836			
Week 26																	
Placebo		66	10.8	1.6	66 (95.7%)	1.4	1.3	-1.1	3.9								
Nera 18mg		62	12.5	1.7	61 (98.4%)	0.9	1.3	-1.7	3.6	-0.5	1.9	-4.2	3.2	0.7915			
Week 36																	
Placebo		65	14.2	2.2	65 (94.2%)	4.9	1.5	1.9	7.9								
Nera 18mg		60	12.6	1.6	59 (95.2%)	2.2	1.6	-1.0	5.3	-2.7	2.2	-7.1	1.7	0.2219			
Week 44																	
Placebo		64	16.8	2.5	64 (92.8%)	6.7	1.6	3.6	9.8								
Nera 18mg		57	14.7	1.8	56 (90.3%)	4.8	1.7	1.5	8.0	-2.0	2.3	-6.5	2.6	0.3923			
Week 52																	
Placebo		63	15.0	2.2	63 (91.3%)	6.5	1.8	3.0	10.1								
Nera 18mg		55	16.6	2.3	54 (87.1%)	5.4	1.9	1.6	9.1	-1.2	2.6	-6.4	4.0	0.6548			
Week 64																	
Placebo		60	15.6	2.3	60 (87.0%)	8.4	2.0	4.4	12.4								
Nera 18mg		49	18.3	2.6	48 (77.4%)	7.0	2.2	2.8	11.3	-1.3	3.0	-7.2	4.5	0.6519			
Week 76																	
Placebo		38	12.3	2.4	38 (55.1%)												
Nera 18mg		35	17.0	2.9	34 (54.8%)												
Week 88																	
Placebo		16	14.6	3.6	16 (23.2%)												
Nera 18mg		7	12.6	3.3	7 (11.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												

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

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Table H.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 (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%)												
>=65 years																	
Baseline																	
Placebo	237	236	12.6	0.9	229 (100.0%)												
Nera 18mg	242	242	13.6	1.0	239 (100.0%)												
Week 12																	
Placebo		230	12.6	1.0	229 (100.0%)	0.4	0.6	-0.8	1.5								
Nera 18mg		237	14.3	1.0	237 (99.2%)	1.3	0.6	0.2	2.5	1.0	0.8	-0.7	2.6	0.2487			
Week 26																	
Placebo		215	14.4	1.1	214 (93.4%)	2.2	0.7	0.8	3.6								
Nera 18mg		224	15.4	1.1	224 (93.7%)	2.7	0.7	1.3	4.1	0.5	1.0	-1.5	2.5	0.6112			
Week 36																	
Placebo		204	15.8	1.2	203 (88.6%)	4.3	0.9	2.6	6.0								
Nera 18mg		214	18.1	1.3	214 (89.5%)	5.6	0.8	3.9	7.2	1.3	1.2	-1.1	3.6	0.2855			
Week 44																	
Placebo		202	17.2	1.3	201 (87.8%)	5.7	0.9	4.0	7.5								
Nera 18mg		205	17.0	1.2	205 (85.8%)	5.4	0.9	3.6	7.1	-0.4	1.2	-2.8	2.1	0.7567			
Week 52																	
Placebo		195	18.7	1.4	194 (84.7%)	8.4	1.0	6.4	10.4								
Nera 18mg		205	19.2	1.4	205 (85.8%)	7.3	1.0	5.3	9.2	-1.1	1.4	-3.9	1.7	0.4269			
Week 64																	
Placebo		180	17.2	1.4	179 (78.2%)	8.3	1.1	6.1	10.6								
Nera 18mg		186	18.3	1.5	186 (77.8%)	7.2	1.1	5.0	9.4	-1.2	1.6	-4.3	2.0	0.4724			
Week 76																	
Placebo		134	17.8	1.6	133 (58.1%)												
Nera 18mg		136	18.4	1.7	136 (56.9%)												
Week 88																	
Placebo		33	13.3	2.6	33 (14.4%)												
Nera 18mg		30	17.5	3.2	30 (12.6%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	3.4	NC	1 (0.4%)												
Sex																	
Test for homogeneity (H0)^																	

Study: 1305-0014. 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 H.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 (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														0.6913			
Week 26														0.4263			
Week 36														0.2129			
Week 44														0.6337			
Week 52														0.1544			
Week 64														0.9308			
Male																	
Baseline																	
Placebo	269	268	12.1	0.8	261 (100.0%)												
Nera 18mg	255	254	12.8	0.9	251 (100.0%)												
Week 12																	
Placebo		261	12.1	0.9	260 (99.6%)	0.2	0.6	-0.9	1.3								
Nera 18mg		250	13.0	0.9	249 (99.2%)	0.7	0.6	-0.4	1.8	0.5	0.8	-1.1	2.1	0.5419			
Week 26																	
Placebo		245	13.5	1.0	244 (93.5%)	2.1	0.7	0.8	3.4								
Nera 18mg		239	14.3	1.0	238 (94.8%)	2.1	0.7	0.8	3.5	0.0	1.0	-1.9	1.9	0.9973			
Week 36																	
Placebo		233	15.5	1.1	232 (88.9%)	4.8	0.8	3.2	6.4								
Nera 18mg		231	16.5	1.2	230 (91.6%)	4.6	0.8	3.0	6.2	-0.1	1.1	-2.4	2.1	0.8975			
Week 44																	
Placebo		230	17.3	1.2	229 (87.7%)	6.3	0.8	4.7	8.0								
Nera 18mg		221	16.4	1.1	220 (87.6%)	5.4	0.8	3.7	7.0	-0.9	1.2	-3.3	1.4	0.4263			
Week 52																	
Placebo		223	17.9	1.3	222 (85.1%)	8.3	1.0	6.5	10.2								
Nera 18mg		219	18.0	1.3	218 (86.9%)	6.5	1.0	4.6	8.4	-1.8	1.4	-4.5	0.8	0.1803			
Week 64																	
Placebo		205	16.6	1.3	204 (78.2%)	8.6	1.1	6.5	10.7								
Nera 18mg		201	18.4	1.4	200 (79.7%)	7.3	1.1	5.2	9.4	-1.3	1.5	-4.3	1.7	0.4083			
Week 76																	
Placebo		149	16.1	1.5	148 (56.7%)												
Nera 18mg		148	17.8	1.5	147 (58.6%)												
Week 88																	
Placebo		42	14.2	2.3	42 (16.1%)												
Nera 18mg		32	16.7	3.0	32 (12.7%)												
Week 100																	

Study: 1305-0014. 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, 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 H.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 (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		0	NC	NC	0 (0.0%)												
Nera 18mg		1	3.4	NC	1 (0.4%)												
Female																	
Baseline																	
Placebo	37	37	12.1	2.1	37 (100.0%)												
Nera 18mg	50	50	14.5	2.0	50 (100.0%)												
Week 12																	
Placebo		37	14.3	2.8	37 (100.0%)	2.3	1.5	-0.7	5.2								
Nera 18mg		50	17.7	2.3	50 (100.0%)	3.6	1.3	1.1	6.1	1.3	2.0	-2.5	5.2	0.4979			
Week 26																	
Placebo		36	13.7	2.4	36 (97.3%)	1.4	1.8	-2.1	4.8								
Nera 18mg		47	17.3	2.5	47 (94.0%)	3.4	1.5	0.4	6.4	2.0	2.3	-2.6	6.6	0.3893			
Week 36																	
Placebo		36	14.5	2.2	36 (97.3%)	2.2	2.1	-1.9	6.3								
Nera 18mg		43	19.1	3.0	43 (86.0%)	5.9	1.9	2.2	9.5	3.6	2.8	-1.9	9.1	0.1959			
Week 44																	
Placebo		36	16.1	2.5	36 (97.3%)	3.8	2.1	-0.4	8.0								
Nera 18mg		41	17.0	2.8	41 (82.0%)	4.3	1.9	0.5	8.1	0.5	2.9	-5.1	6.2	0.8512			
Week 52																	
Placebo		35	17.0	3.0	35 (94.6%)	5.5	2.4	0.7	10.3								
Nera 18mg		41	22.4	3.5	41 (82.0%)	8.8	2.2	4.4	13.1	3.3	3.3	-3.2	9.7	0.3233			
Week 64																	
Placebo		35	18.1	3.0	35 (94.6%)	7.0	2.7	1.6	12.3								
Nera 18mg		34	17.7	3.3	34 (68.0%)	6.0	2.5	1.1	11.0	-0.9	3.7	-8.2	6.3	0.8048			
Week 76																	
Placebo		23	19.9	3.9	23 (62.2%)												
Nera 18mg		23	20.5	4.9	23 (46.0%)												
Week 88																	
Placebo		7	11.3	5.0	7 (18.9%)												
Nera 18mg		5	15.4	4.4	5 (10.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Baseline FVC percent predicted

Study: 1305-0014. 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, 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 H.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 (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
Test for homogeneity (H0)^																	
Week 12														0.5876			
Week 26														0.6401			
Week 36														0.9103			
Week 44														0.3329			
Week 52														0.9295			
Week 64														0.9111			
<=70%																	
Baseline																	
Placebo	109	109	17.0	1.4	103 (100.0%)												
Nera 18mg	112	111	17.2	1.5	108 (100.0%)												
Week 12																	
Placebo		103	16.9	1.7	103 (100.0%)	1.2	0.9	-0.6	3.0								
Nera 18mg		108	18.1	1.5	107 (99.1%)	2.5	0.9	0.7	4.2	1.3	1.3	-1.2	3.7	0.3171			
Week 26																	
Placebo		96	18.5	1.9	96 (93.2%)	3.6	1.1	1.5	5.7								
Nera 18mg		99	20.0	1.6	98 (90.7%)	4.4	1.1	2.4	6.5	0.9	1.5	-2.1	3.8	0.5592			
Week 36																	
Placebo		88	21.3	2.2	88 (85.4%)	6.9	1.3	4.3	9.4								
Nera 18mg		93	21.9	1.9	92 (85.2%)	7.1	1.3	4.6	9.6	0.2	1.8	-3.3	3.8	0.9036			
Week 44																	
Placebo		88	24.4	2.3	88 (85.4%)	9.3	1.3	6.7	11.9								
Nera 18mg		85	20.7	1.8	84 (77.8%)	7.1	1.3	4.4	9.7	-2.2	1.9	-5.9	1.4	0.2297			
Week 52																	
Placebo		86	24.5	2.4	86 (83.5%)	11.1	1.5	8.1	14.1								
Nera 18mg		85	24.7	2.1	84 (77.8%)	9.8	1.5	6.8	12.8	-1.2	2.1	-5.4	3.0	0.5666			
Week 64																	
Placebo		78	23.7	2.5	78 (75.7%)	12.9	1.7	9.6	16.3								
Nera 18mg		73	25.6	2.1	72 (66.7%)	11.6	1.7	8.2	14.9	-1.3	2.4	-6.1	3.4	0.5754			
Week 76																	
Placebo		54	23.5	2.8	54 (52.4%)												
Nera 18mg		57	24.8	2.3	56 (51.9%)												
Week 88																	
Placebo		14	14.2	3.4	14 (13.6%)												
Nera 18mg		9	29.7	6.3	9 (8.3%)												

Study: 1305-0014. 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, 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 H.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 (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 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	197	196	9.3	0.8	195 (100.0%)												
Nera 18mg	193	193	10.7	1.0	193 (100.0%)												
Week 12																	
Placebo		195	9.9	0.9	194 (99.5%)	0.1	0.7	-1.2	1.4								
Nera 18mg		192	11.4	1.0	192 (99.5%)	0.5	0.7	-0.8	1.8	0.4	0.9	-1.4	2.2	0.6579			
Week 26																	
Placebo		185	11.0	0.9	184 (94.4%)	1.2	0.8	-0.3	2.7								
Nera 18mg		187	12.0	1.1	187 (96.9%)	1.2	0.8	-0.3	2.7	0.0	1.1	-2.1	2.1	0.9940			
Week 36																	
Placebo		181	12.5	1.0	180 (92.3%)	3.2	0.9	1.4	5.0								
Nera 18mg		181	14.4	1.3	181 (93.8%)	3.7	0.9	1.9	5.5	0.5	1.3	-2.1	3.0	0.7179			
Week 44																	
Placebo		178	13.5	1.1	177 (90.8%)	4.3	0.9	2.4	6.1								
Nera 18mg		177	14.5	1.3	177 (91.7%)	4.3	0.9	2.4	6.1	-0.0	1.3	-2.6	2.6	0.9857			
Week 52																	
Placebo		172	14.4	1.3	171 (87.7%)	6.3	1.1	4.2	8.5								
Nera 18mg		175	15.7	1.4	175 (90.7%)	5.3	1.1	3.2	7.5	-1.0	1.5	-4.0	2.0	0.5148			
Week 64																	
Placebo		162	13.4	1.2	161 (82.6%)	6.0	1.2	3.6	8.4								
Nera 18mg		162	15.1	1.5	162 (83.9%)	5.0	1.2	2.6	7.3	-1.0	1.7	-4.4	2.3	0.5483			
Week 76																	
Placebo		118	13.5	1.5	117 (60.0%)												
Nera 18mg		114	14.8	1.8	114 (59.1%)												
Week 88																	
Placebo		35	13.6	2.6	35 (17.9%)												
Nera 18mg		28	12.3	2.4	28 (14.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	3.4	NC	1 (0.5%)												

Study: 1305-0014. 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, 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 H.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 (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
Type of AF therapy																	
Test for homogeneity (H0)^																	
Week 12														0.9191			
Week 26														0.3943			
Week 36														0.7267			
Week 44														0.3748			
Week 52														0.4314			
Week 64														0.5807			
Nintedanib																	
Baseline																	
Placebo	173	173	11.3	1.0	169 (100.0%)												
Nera 18mg	178	178	13.5	1.2	176 (100.0%)												
Week 12																	
Placebo		168	11.3	1.0	168 (99.4%)	0.1	0.7	-1.2	1.5								
Nera 18mg		174	13.9	1.2	174 (98.9%)	0.9	0.7	-0.4	2.3	0.8	1.0	-1.1	2.7	0.4215			
Week 26																	
Placebo		158	11.8	1.1	158 (93.5%)	1.0	0.8	-0.7	2.6								
Nera 18mg		163	14.1	1.3	163 (92.6%)	1.9	0.8	0.3	3.5	1.0	1.2	-1.3	3.3	0.3980			
Week 36																	
Placebo		153	13.5	1.2	153 (90.5%)	3.2	1.0	1.2	5.2								
Nera 18mg		153	15.8	1.5	153 (86.9%)	3.9	1.0	2.0	5.9	0.7	1.4	-2.0	3.5	0.6012			
Week 44																	
Placebo		149	16.1	1.4	149 (88.2%)	5.6	1.0	3.6	7.6								
Nera 18mg		144	14.9	1.4	144 (81.8%)	4.0	1.0	2.0	6.0	-1.6	1.5	-4.5	1.3	0.2699			
Week 52																	
Placebo		147	16.8	1.5	147 (87.0%)	7.1	1.2	4.8	9.4								
Nera 18mg		147	16.8	1.5	147 (83.5%)	5.2	1.2	2.9	7.5	-1.9	1.7	-5.2	1.3	0.2443			
Week 64																	
Placebo		134	14.2	1.3	134 (79.3%)	6.8	1.3	4.2	9.4								
Nera 18mg		128	16.2	1.7	128 (72.7%)	4.9	1.3	2.3	7.5	-1.9	1.9	-5.6	1.8	0.3103			
Week 76																	
Placebo		99	15.3	1.8	99 (58.6%)												
Nera 18mg		93	16.8	2.0	93 (52.8%)												
Week 88																	
Placebo		28	16.3	2.9	28 (16.6%)												

Study: 1305-0014. 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, 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 H.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 (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		22	19.3	3.8	22 (12.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Pirfenidone																	
Baseline																	
Placebo	133	132	13.1	1.2	129 (100.0%)												
Nera 18mg	127	126	12.5	1.3	125 (100.0%)												
Week 12																	
Placebo		130	13.7	1.4	129 (100.0%)	0.9	0.8	-0.7	2.5								
Nera 18mg		126	13.7	1.3	125 (100.0%)	1.5	0.8	-0.1	3.1	0.6	1.1	-1.6	2.9	0.5763			
Week 26																	
Placebo		123	15.8	1.6	122 (94.6%)	3.4	0.9	1.5	5.3								
Nera 18mg		123	15.6	1.5	122 (97.6%)	2.9	0.9	1.0	4.7	-0.5	1.3	-3.2	2.1	0.6934			
Week 36																	
Placebo		116	17.9	1.8	115 (89.1%)	6.1	1.1	3.8	8.3								
Nera 18mg		121	18.4	1.7	120 (96.0%)	6.1	1.1	3.8	8.3	-0.0	1.6	-3.2	3.1	0.9940			
Week 44																	
Placebo		117	18.5	1.9	116 (89.9%)	6.5	1.2	4.2	8.8								
Nera 18mg		118	18.5	1.6	117 (93.6%)	6.8	1.2	4.5	9.1	0.3	1.7	-2.9	3.6	0.8329			
Week 52																	
Placebo		111	19.2	2.0	110 (85.3%)	9.0	1.3	6.4	11.7								
Nera 18mg		113	21.0	1.9	112 (89.6%)	9.1	1.3	6.4	11.7	0.1	1.9	-3.7	3.8	0.9777			
Week 64																	
Placebo		106	20.0	2.1	105 (81.4%)	10.3	1.5	7.4	13.2								
Nera 18mg		107	20.9	2.0	106 (84.8%)	10.0	1.5	7.0	12.9	-0.3	2.1	-4.5	3.8	0.8737			
Week 76																	
Placebo		73	18.4	2.2	72 (55.8%)												
Nera 18mg		78	19.7	2.1	77 (61.6%)												
Week 88																	
Placebo		21	10.4	2.8	21 (16.3%)												
Nera 18mg		15	12.5	3.4	15 (12.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	3.4	NC	1 (0.8%)												

Study: 1305-0014. 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, 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 H.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 (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
Region																	
Test for homogeneity (H0)^																	
Week 12														0.9921			
Week 26														0.2465			
Week 36														0.7827			
Week 44														0.4280			
Week 52														0.6117			
Week 64														0.7643			
Europe																	
Baseline																	
Placebo	136	136	12.8	1.1	134 (100.0%)												
Nera 18mg	136	136	14.3	1.4	135 (100.0%)												
Week 12																	
Placebo		133	12.3	1.2	133 (99.3%)	-0.0	0.8	-1.6	1.5								
Nera 18mg		133	14.4	1.4	133 (98.5%)	0.6	0.8	-1.0	2.1	0.6	1.1	-1.6	2.8	0.5869			
Week 26																	
Placebo		125	12.7	1.2	125 (93.3%)	1.1	0.9	-0.7	2.9								
Nera 18mg		128	16.0	1.5	128 (94.8%)	2.5	0.9	0.7	4.3	1.4	1.3	-1.2	4.0	0.2917			
Week 36																	
Placebo		121	14.7	1.5	121 (90.3%)	3.6	1.1	1.4	5.8								
Nera 18mg		121	18.1	1.8	121 (89.6%)	4.5	1.1	2.3	6.7	0.8	1.6	-2.3	4.0	0.5964			
Week 44																	
Placebo		121	18.1	1.7	121 (90.3%)	6.1	1.1	3.9	8.4								
Nera 18mg		116	17.2	1.6	116 (85.9%)	4.5	1.2	2.2	6.8	-1.6	1.6	-4.8	1.6	0.3203			
Week 52																	
Placebo		118	17.7	1.7	118 (88.1%)	7.2	1.3	4.6	9.8								
Nera 18mg		116	19.7	1.8	116 (85.9%)	6.2	1.3	3.5	8.8	-1.1	1.9	-4.7	2.6	0.5724			
Week 64																	
Placebo		111	16.3	1.7	111 (82.8%)	6.7	1.5	3.9	9.6								
Nera 18mg		102	18.2	1.9	102 (75.6%)	5.7	1.5	2.8	8.6	-1.1	2.1	-5.1	3.0	0.6118			
Week 76																	
Placebo		80	15.4	1.8	80 (59.7%)												
Nera 18mg		73	19.4	2.2	73 (54.1%)												
Week 88																	
Placebo		22	13.1	3.0	22 (16.4%)												

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

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Table H.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 (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		18	16.3	4.4	18 (13.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Asia																	
Baseline																	
Placebo	72	72	9.4	1.4	70 (100.0%)												
Nera 18mg	79	78	11.0	1.5	76 (100.0%)												
Week 12																	
Placebo		70	10.4	1.3	70 (100.0%)	1.1	1.1	-1.0	3.3								
Nera 18mg		77	11.3	1.4	76 (100.0%)	1.1	1.0	-1.0	3.1	-0.0	1.5	-3.0	2.9	0.9792			
Week 26																	
Placebo		63	9.8	1.2	63 (90.0%)	0.7	1.3	-1.8	3.3								
Nera 18mg		74	12.6	1.8	73 (96.1%)	1.7	1.2	-0.7	4.1	1.0	1.8	-2.6	4.5	0.5934			
Week 36																	
Placebo		62	14.8	1.9	62 (88.6%)	6.0	1.6	2.9	9.1								
Nera 18mg		72	13.8	2.1	71 (93.4%)	4.1	1.5	1.2	7.0	-1.8	2.2	-6.1	2.4	0.3930			
Week 44																	
Placebo		60	15.3	2.0	60 (85.7%)	6.5	1.6	3.3	9.7								
Nera 18mg		70	14.6	2.0	69 (90.8%)	5.4	1.5	2.4	8.4	-1.1	2.2	-5.5	3.3	0.6272			
Week 52																	
Placebo		57	18.1	2.5	57 (81.4%)	10.5	1.9	6.8	14.2								
Nera 18mg		66	15.7	2.2	65 (85.5%)	6.4	1.8	3.0	9.9	-4.1	2.6	-9.2	0.9	0.1080			
Week 64																	
Placebo		55	21.1	2.9	55 (78.6%)	12.9	2.1	8.9	17.0								
Nera 18mg		64	16.9	2.5	63 (82.9%)	7.0	1.9	3.2	10.8	-6.0	2.8	-11.5	-0.4	0.0348	-0.39	-0.75	-0.02
Week 76																	
Placebo		38	18.5	2.8	38 (54.3%)												
Nera 18mg		51	15.2	2.4	50 (65.8%)												
Week 88																	
Placebo		11	13.3	3.7	11 (15.7%)												
Nera 18mg		8	17.3	4.4	8 (10.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	

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

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Table H.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 (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
Baseline																	
Placebo	75	75	13.4	1.7	72 (100.0%)												
Nera 18mg	56	56	13.0	1.9	56 (100.0%)												
Week 12																	
Placebo		72	13.7	2.1	72 (100.0%)	0.5	1.1	-1.6	2.6								
Nera 18mg		56	15.8	2.1	56 (100.0%)	3.0	1.2	0.6	5.4	2.5	1.6	-0.7	5.7	0.1230			
Week 26																	
Placebo		70	17.3	2.4	70 (97.2%)	4.1	1.3	1.7	6.6								
Nera 18mg		55	16.1	2.3	55 (98.2%)	3.1	1.4	0.3	5.9	-1.0	1.9	-4.8	2.7	0.5795			
Week 36																	
Placebo		64	16.1	2.2	64 (88.9%)	4.1	1.5	1.1	7.2								
Nera 18mg		54	19.3	2.6	54 (96.4%)	6.3	1.7	2.9	9.6	2.1	2.3	-2.4	6.6	0.3575			
Week 44																	
Placebo		64	17.1	2.4	64 (88.9%)	5.7	1.6	2.6	8.8								
Nera 18mg		50	18.7	2.6	50 (89.3%)	6.9	1.8	3.4	10.4	1.2	2.4	-3.4	5.8	0.6125			
Week 52																	
Placebo		64	18.7	2.6	64 (88.9%)	8.1	1.8	4.5	11.6								
Nera 18mg		52	20.3	2.8	52 (92.9%)	8.1	2.0	4.2	12.0	0.0	2.7	-5.2	5.3	0.9882			
Week 64																	
Placebo		57	14.8	2.2	57 (79.2%)	8.1	2.0	4.2	12.0								
Nera 18mg		47	21.7	3.3	47 (83.9%)	10.4	2.2	6.1	14.8	2.3	3.0	-3.6	8.2	0.4376			
Week 76																	
Placebo		40	17.5	3.2	40 (55.6%)												
Nera 18mg		35	20.1	3.9	35 (62.5%)												
Week 88																	
Placebo		13	18.2	4.9	13 (18.1%)												
Nera 18mg		8	12.7	4.4	8 (14.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	3.4	NC	1 (1.8%)												
Rest of the World																	
Baseline																	
Placebo	23	22	12.1	2.6	22 (100.0%)												
Nera 18mg	34	34	13.1	2.4	34 (100.0%)												
Week 12																	
Placebo		23	14.3	3.4	22 (100.0%)	1.4	1.9	-2.4	5.2								

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Table H.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 (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		34	13.7	2.9	34 (100.0%)	0.8	1.6	-2.3	3.9	-0.6	2.5	-5.5	4.3	0.8096			
Week 26																	
Placebo		23	17.2	4.0	22 (100.0%)	4.2	2.2	-0.2	8.6								
Nera 18mg		29	12.3	2.1	29 (85.3%)	2.0	1.9	-1.7	5.8	-2.2	3.0	-8.0	3.6	0.4541			
Week 36																	
Placebo		22	18.5	4.1	21 (95.5%)	5.4	2.7	0.1	10.8								
Nera 18mg		27	15.4	2.6	27 (79.4%)	5.8	2.3	1.2	10.4	0.4	3.6	-6.6	7.5	0.9104			
Week 44																	
Placebo		21	16.8	4.0	20 (90.9%)	4.2	2.8	-1.3	9.8								
Nera 18mg		26	14.4	2.4	26 (76.5%)	4.8	2.4	-0.0	9.6	0.5	3.7	-6.8	7.9	0.8867			
Week 52																	
Placebo		19	14.8	4.4	18 (81.8%)	3.9	3.3	-2.5	10.4								
Nera 18mg		26	18.2	4.4	26 (76.5%)	8.9	2.8	3.5	14.4	5.0	4.3	-3.5	13.4	0.2473			
Week 64																	
Placebo		17	12.7	4.3	16 (72.7%)	4.1	3.7	-3.1	11.3								
Nera 18mg		22	15.9	3.6	22 (64.7%)	7.2	3.1	1.1	13.4	3.2	4.8	-6.3	12.6	0.5125			
Week 76																	
Placebo		14	16.1	5.8	13 (59.1%)												
Nera 18mg		12	16.8	4.1	12 (35.3%)												
Week 88																	
Placebo		3	1.2	0.6	3 (13.6%)												
Nera 18mg		3	26.5	11.4	3 (8.8%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0014. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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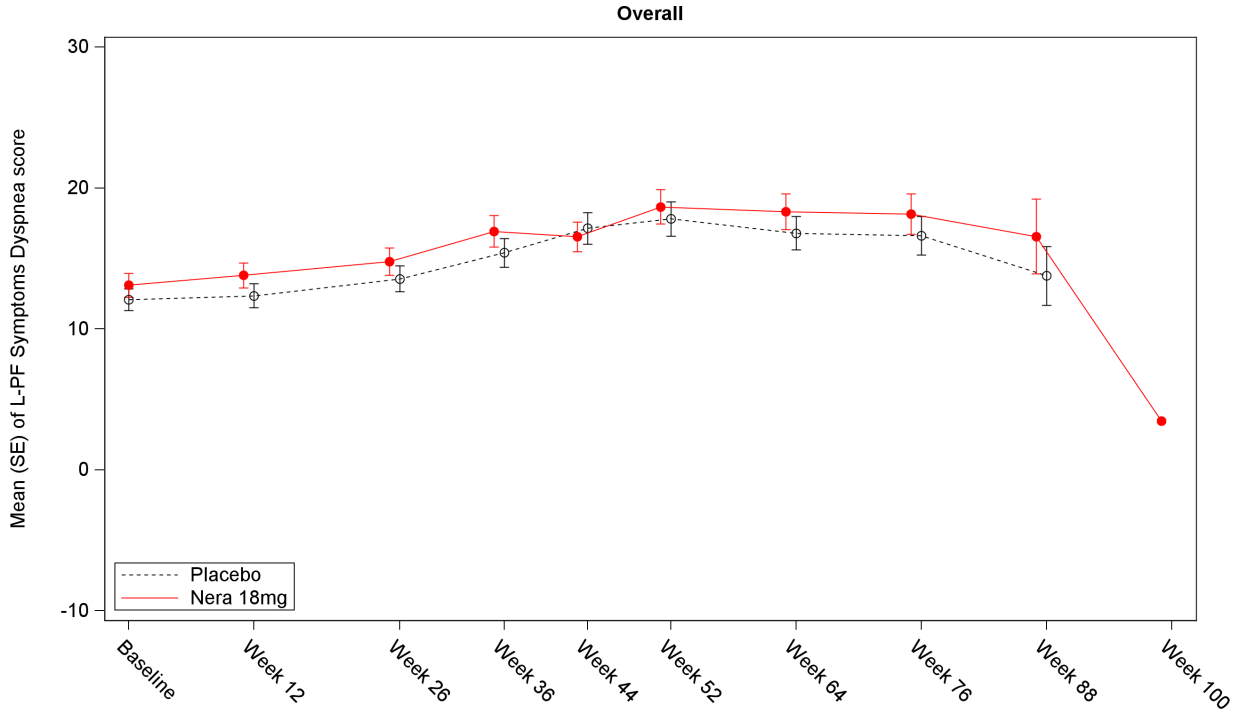

Number of patients

Placebo	305	298	281	269	266	258	240	172	49	0
Nera 18mg	304	300	286	274	262	260	235	171	37	1

Study: 1305-0014. Number of patients refers to the number of patients with observed data at visit.

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

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BI Trial No.: x1305p3.hta

Figure H.1.1.1.2.1: 5

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Table H.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 (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	306	305	26.4	1.0	298 (100.0%)												
Nera 18mg	305	304	27.4	1.0	301 (100.0%)												
Week 12																	
Placebo		297	26.9	1.1	296 (99.3%)	0.7	0.8	-0.8	2.3								
Nera 18mg		299	30.1	1.1	298 (99.0%)	3.3	0.8	1.7	4.8	2.5	1.1	0.3	4.7	0.0243	0.18	0.02	0.35
Week 26																	
Placebo		281	29.1	1.1	280 (94.0%)	3.5	0.9	1.7	5.2								
Nera 18mg		286	31.2	1.2	285 (94.7%)	4.9	0.9	3.1	6.6	1.4	1.3	-1.1	3.9	0.2677			
Week 36																	
Placebo		269	30.1	1.2	268 (89.9%)	5.1	0.9	3.2	6.9								
Nera 18mg		273	31.6	1.2	272 (90.4%)	5.8	0.9	4.0	7.6	0.7	1.3	-1.8	3.3	0.5769			
Week 44																	
Placebo		266	31.3	1.3	265 (88.9%)	6.0	1.0	4.1	8.0								
Nera 18mg		262	32.9	1.3	261 (86.7%)	7.8	1.0	5.8	9.7	1.8	1.4	-1.0	4.5	0.2128			
Week 52																	
Placebo		258	30.8	1.3	257 (86.2%)	6.3	1.0	4.4	8.2								
Nera 18mg		260	32.3	1.2	259 (86.0%)	6.7	1.0	4.8	8.6	0.4	1.4	-2.3	3.1	0.7674			
Week 64																	
Placebo		240	31.7	1.3	239 (80.2%)	8.0	1.1	5.9	10.1								
Nera 18mg		235	32.2	1.4	234 (77.7%)	7.1	1.1	5.0	9.2	-1.0	1.5	-3.9	2.0	0.5141			
Week 76																	
Placebo		172	29.7	1.5	171 (57.4%)												
Nera 18mg		171	32.3	1.6	170 (56.5%)												
Week 88																	
Placebo		49	29.9	2.7	49 (16.4%)												
Nera 18mg		37	32.5	3.6	37 (12.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	15.0	NC	1 (0.3%)												
Age																	
Test for homogeneity (H0)^																	
Week 12														0.1904			

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Table H.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 (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 26														0.6131			
Week 36														0.0505			
Week 44														0.5594			
Week 52														0.9053			
Week 64														0.6223			
<65 years																	
Baseline																	
Placebo	69	69	24.1	2.0	69 (100.0%)												
Nera 18mg	63	62	24.5	2.2	62 (100.0%)												
Week 12																	
Placebo		68	26.1	2.4	68 (98.6%)	1.3	1.7	-1.9	4.6								
Nera 18mg		63	26.1	2.1	62 (100.0%)	1.0	1.7	-2.4	4.4	-0.3	2.4	-5.0	4.4	0.9106			
Week 26																	
Placebo		66	26.9	2.0	66 (95.7%)	3.3	1.8	-0.3	6.9								
Nera 18mg		62	28.5	2.3	61 (98.4%)	3.5	1.9	-0.3	7.3	0.2	2.7	-5.1	5.4	0.9466			
Week 36																	
Placebo		65	29.7	2.6	65 (94.2%)	6.5	1.9	2.8	10.3								
Nera 18mg		59	25.8	2.4	58 (93.5%)	2.5	2.0	-1.4	6.4	-4.0	2.8	-9.5	1.4	0.1422			
Week 44																	
Placebo		64	29.0	2.7	64 (92.8%)	5.7	2.0	1.7	9.7								
Nera 18mg		57	32.7	2.7	56 (90.3%)	9.0	2.2	4.8	13.3	3.3	3.0	-2.5	9.1	0.2679			
Week 52																	
Placebo		63	28.6	2.6	63 (91.3%)	5.9	2.0	2.0	9.8								
Nera 18mg		55	30.8	2.6	54 (87.1%)	6.0	2.1	1.9	10.1	0.1	2.9	-5.6	5.7	0.9790			
Week 64																	
Placebo		60	29.1	2.7	60 (87.0%)	7.0	2.2	2.8	11.2								
Nera 18mg		49	29.6	3.0	48 (77.4%)	4.5	2.3	-0.1	9.1	-2.5	3.2	-8.7	3.8	0.4396			
Week 76																	
Placebo		38	27.7	3.1	38 (55.1%)												
Nera 18mg		35	33.1	3.6	34 (54.8%)												
Week 88																	
Placebo		16	27.4	4.7	16 (23.2%)												
Nera 18mg		7	42.9	9.9	7 (11.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												

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

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Table H.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 (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		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	237	236	27.1	1.2	229 (100.0%)												
Nera 18mg	242	242	28.1	1.2	239 (100.0%)												
Week 12																	
Placebo		229	27.2	1.2	228 (99.6%)	0.6	0.9	-1.2	2.3								
Nera 18mg		236	31.1	1.3	236 (98.7%)	3.9	0.9	2.1	5.6	3.3	1.3	0.8	5.8	0.0098	0.24	0.06	0.42
Week 26																	
Placebo		215	29.8	1.3	214 (93.4%)	3.5	1.0	1.5	5.5								
Nera 18mg		224	32.0	1.3	224 (93.7%)	5.2	1.0	3.3	7.2	1.7	1.4	-1.1	4.5	0.2327			
Week 36																	
Placebo		204	30.2	1.4	203 (88.6%)	4.6	1.1	2.5	6.7								
Nera 18mg		214	33.2	1.4	214 (89.5%)	6.7	1.0	4.6	8.7	2.1	1.5	-0.8	5.0	0.1614			
Week 44																	
Placebo		202	32.1	1.5	201 (87.8%)	6.1	1.1	3.9	8.4								
Nera 18mg		205	33.0	1.4	205 (85.8%)	7.4	1.1	5.2	9.6	1.3	1.6	-1.8	4.5	0.4110			
Week 52																	
Placebo		195	31.5	1.5	194 (84.7%)	6.4	1.1	4.3	8.6								
Nera 18mg		205	32.7	1.4	205 (85.8%)	6.9	1.1	4.8	9.0	0.5	1.6	-2.6	3.5	0.7646			
Week 64																	
Placebo		180	32.5	1.6	179 (78.2%)	8.4	1.2	6.0	10.8								
Nera 18mg		186	32.8	1.6	186 (77.8%)	7.7	1.2	5.3	10.1	-0.7	1.7	-4.1	2.7	0.6922			
Week 76																	
Placebo		134	30.3	1.8	133 (58.1%)												
Nera 18mg		136	32.1	1.8	136 (56.9%)												
Week 88																	
Placebo		33	31.2	3.3	33 (14.4%)												
Nera 18mg		30	30.1	3.7	30 (12.6%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	15.0	NC	1 (0.4%)												
Sex																	
Test for homogeneity (H0)^																	

Study: 1305-0014. 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 H.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 (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														0.9417			
Week 26														0.9437			
Week 36														0.8022			
Week 44														0.9693			
Week 52														0.6319			
Week 64														0.3303			
Male																	
Baseline																	
Placebo	269	268	26.1	1.1	261 (100.0%)												
Nera 18mg	255	254	26.9	1.1	251 (100.0%)												
Week 12																	
Placebo		261	26.7	1.1	260 (99.6%)	0.8	0.8	-0.9	2.4								
Nera 18mg		249	29.8	1.2	248 (98.8%)	3.3	0.9	1.6	5.0	2.6	1.2	0.2	5.0	0.0343	0.19	0.01	0.36
Week 26																	
Placebo		245	28.9	1.2	244 (93.5%)	3.5	1.0	1.6	5.4								
Nera 18mg		239	31.1	1.2	238 (94.8%)	5.0	1.0	3.1	6.9	1.5	1.4	-1.2	4.1	0.2869			
Week 36																	
Placebo		233	29.9	1.3	232 (88.9%)	5.3	1.0	3.4	7.3								
Nera 18mg		230	31.7	1.3	229 (91.2%)	6.2	1.0	4.2	8.2	0.9	1.4	-1.9	3.7	0.5184			
Week 44																	
Placebo		230	31.2	1.4	229 (87.7%)	6.2	1.1	4.1	8.3								
Nera 18mg		221	32.8	1.4	220 (87.6%)	8.0	1.1	5.8	10.1	1.8	1.5	-1.2	4.8	0.2504			
Week 52																	
Placebo		223	30.3	1.4	222 (85.1%)	6.3	1.0	4.2	8.3								
Nera 18mg		219	31.6	1.3	218 (86.9%)	6.4	1.1	4.3	8.4	0.1	1.5	-2.8	3.0	0.9328			
Week 64																	
Placebo		205	30.9	1.4	204 (78.2%)	7.8	1.1	5.5	10.1								
Nera 18mg		201	32.3	1.5	200 (79.7%)	7.4	1.2	5.2	9.7	-0.4	1.6	-3.6	2.8	0.8238			
Week 76																	
Placebo		149	29.3	1.6	148 (56.7%)												
Nera 18mg		148	31.6	1.6	147 (58.6%)												
Week 88																	
Placebo		42	30.5	2.8	42 (16.1%)												
Nera 18mg		32	32.0	3.9	32 (12.7%)												
Week 100																	

Study: 1305-0014. 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, 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 H.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 (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		0	NC	NC	0 (0.0%)												
Nera 18mg		1	15.0	NC	1 (0.4%)												
Female																	
Baseline																	
Placebo	37	37	28.7	2.7	37 (100.0%)												
Nera 18mg	50	50	29.5	2.7	50 (100.0%)												
Week 12																	
Placebo		36	28.3	3.3	36 (97.3%)	0.6	2.3	-3.9	5.1								
Nera 18mg		50	31.4	2.7	50 (100.0%)	3.0	1.9	-0.9	6.8	2.3	3.0	-3.5	8.2	0.4338			
Week 26																	
Placebo		36	30.7	2.8	36 (97.3%)	3.1	2.5	-1.8	8.0								
Nera 18mg		47	31.9	3.1	47 (94.0%)	4.3	2.2	-0.0	8.6	1.2	3.3	-5.3	7.7	0.7181			
Week 36																	
Placebo		36	31.4	3.2	36 (97.3%)	3.5	2.6	-1.5	8.6								
Nera 18mg		43	31.1	3.1	43 (86.0%)	3.5	2.3	-1.0	8.1	-0.0	3.5	-6.8	6.8	0.9958			
Week 44																	
Placebo		36	32.5	3.3	36 (97.3%)	4.8	2.7	-0.6	10.1								
Nera 18mg		41	33.8	3.2	41 (82.0%)	6.7	2.5	1.8	11.6	1.9	3.7	-5.4	9.2	0.6061			
Week 52																	
Placebo		35	34.1	3.6	35 (94.6%)	6.6	2.7	1.3	11.8								
Nera 18mg		41	35.9	3.4	41 (82.0%)	8.5	2.4	3.8	13.3	2.0	3.6	-5.0	9.0	0.5802			
Week 64																	
Placebo		35	36.2	4.1	35 (94.6%)	9.3	2.9	3.7	14.9								
Nera 18mg		34	31.4	4.0	34 (68.0%)	4.8	2.7	-0.6	10.2	-4.5	4.0	-12.3	3.2	0.2524			
Week 76																	
Placebo		23	32.1	4.8	23 (62.2%)												
Nera 18mg		23	37.0	5.6	23 (46.0%)												
Week 88																	
Placebo		7	26.8	8.2	7 (18.9%)												
Nera 18mg		5	35.8	10.4	5 (10.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Baseline FVC percent predicted

Study: 1305-0014. 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, 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 H.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 (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
Test for homogeneity (H0)^																	
Week 12														0.5745			
Week 26														0.3776			
Week 36														0.8477			
Week 44														0.9828			
Week 52														0.9576			
Week 64														0.2399			
<=70%																	
Baseline																	
Placebo	109	109	30.8	1.7	103 (100.0%)												
Nera 18mg	112	111	32.5	1.8	108 (100.0%)												
Week 12																	
Placebo		103	30.9	1.9	103 (100.0%)	1.8	1.4	-0.9	4.5								
Nera 18mg		107	33.7	1.9	106 (98.1%)	3.5	1.3	0.8	6.1	1.7	1.9	-2.1	5.4	0.3795			
Week 26																	
Placebo		96	34.5	2.0	96 (93.2%)	6.6	1.5	3.6	9.6								
Nera 18mg		99	35.9	1.8	98 (90.7%)	6.4	1.5	3.5	9.4	-0.1	2.1	-4.3	4.1	0.9494			
Week 36																	
Placebo		88	36.3	2.3	88 (85.4%)	8.8	1.6	5.7	12.0								
Nera 18mg		93	37.4	2.2	92 (85.2%)	9.2	1.6	6.1	12.3	0.4	2.2	-4.0	4.8	0.8653			
Week 44																	
Placebo		88	37.5	2.4	88 (85.4%)	9.3	1.7	5.9	12.7								
Nera 18mg		85	38.2	1.9	84 (77.8%)	11.1	1.7	7.7	14.5	1.8	2.4	-2.9	6.6	0.4503			
Week 52																	
Placebo		86	36.1	2.4	86 (83.5%)	8.8	1.7	5.6	12.1								
Nera 18mg		85	37.6	1.9	84 (77.8%)	9.4	1.7	6.1	12.6	0.5	2.3	-4.1	5.1	0.8227			
Week 64																	
Placebo		78	38.5	2.7	78 (75.7%)	12.7	1.8	9.1	16.3								
Nera 18mg		73	37.2	2.2	72 (66.7%)	9.2	1.9	5.5	12.9	-3.5	2.6	-8.6	1.7	0.1839			
Week 76																	
Placebo		54	36.5	2.6	54 (52.4%)												
Nera 18mg		57	36.8	2.2	56 (51.9%)												
Week 88																	
Placebo		14	33.9	4.2	14 (13.6%)												
Nera 18mg		9	37.2	7.7	9 (8.3%)												

Study: 1305-0014. 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 H.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 (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		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	197	196	24.0	1.2	195 (100.0%)												
Nera 18mg	193	193	24.4	1.2	193 (100.0%)												
Week 12																	
Placebo		194	24.8	1.2	193 (99.0%)	0.2	1.0	-1.8	2.1								
Nera 18mg		192	28.0	1.4	192 (99.5%)	3.2	1.0	1.2	5.1	3.0	1.4	0.2	5.7	0.0327	0.22	0.02	0.42
Week 26																	
Placebo		185	26.3	1.3	184 (94.4%)	1.8	1.1	-0.3	4.0								
Nera 18mg		187	28.8	1.5	187 (96.9%)	4.0	1.1	1.9	6.2	2.2	1.5	-0.8	5.2	0.1575			
Week 36																	
Placebo		181	27.0	1.4	180 (92.3%)	3.1	1.1	0.9	5.4								
Nera 18mg		180	28.6	1.4	180 (93.3%)	4.1	1.1	1.8	6.3	0.9	1.6	-2.2	4.1	0.5703			
Week 44																	
Placebo		178	28.3	1.5	177 (90.8%)	4.3	1.2	1.9	6.7								
Nera 18mg		177	30.4	1.6	177 (91.7%)	6.1	1.2	3.7	8.5	1.8	1.7	-1.6	5.1	0.3031			
Week 52																	
Placebo		172	28.1	1.5	171 (87.7%)	5.0	1.2	2.7	7.3								
Nera 18mg		175	29.8	1.5	175 (90.7%)	5.4	1.2	3.1	7.7	0.4	1.7	-2.9	3.6	0.8227			
Week 64																	
Placebo		162	28.4	1.5	161 (82.6%)	5.7	1.3	3.1	8.2								
Nera 18mg		162	29.9	1.7	162 (83.9%)	5.9	1.3	3.4	8.5	0.3	1.8	-3.3	3.9	0.8821			
Week 76																	
Placebo		118	26.6	1.8	117 (60.0%)												
Nera 18mg		114	30.1	2.1	114 (59.1%)												
Week 88																	
Placebo		35	28.4	3.3	35 (17.9%)												
Nera 18mg		28	31.0	4.1	28 (14.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	15.0	NC	1 (0.5%)												

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

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Table H.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 (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
Type of AF therapy																	
Test for homogeneity (H0)^																	
Week 12														0.2072			
Week 26														0.4857			
Week 36														0.2800			
Week 44														0.3419			
Week 52														0.8555			
Week 64														0.6028			
Nintedanib																	
Baseline																	
Placebo	173	173	25.6	1.3	169 (100.0%)												
Nera 18mg	178	178	27.3	1.4	176 (100.0%)												
Week 12																	
Placebo		167	25.3	1.3	167 (98.8%)	-0.1	1.1	-2.2	2.0								
Nera 18mg		173	30.3	1.4	173 (98.3%)	3.7	1.0	1.6	5.7	3.8	1.5	0.9	6.7	0.0114	0.27	0.06	0.49
Week 26																	
Placebo		158	28.3	1.4	158 (93.5%)	3.3	1.2	0.9	5.6								
Nera 18mg		163	31.2	1.6	163 (92.6%)	5.4	1.2	3.1	7.7	2.2	1.7	-1.1	5.4	0.1982			
Week 36																	
Placebo		153	29.0	1.6	153 (90.5%)	4.7	1.2	2.2	7.1								
Nera 18mg		153	31.7	1.7	153 (86.9%)	6.6	1.2	4.2	9.0	2.0	1.7	-1.5	5.4	0.2600			
Week 44																	
Placebo		149	30.4	1.7	149 (88.2%)	5.8	1.3	3.2	8.4								
Nera 18mg		144	30.6	1.7	144 (81.8%)	6.3	1.3	3.7	8.9	0.5	1.9	-3.2	4.2	0.7815			
Week 52																	
Placebo		147	30.3	1.7	147 (87.0%)	6.1	1.3	3.6	8.7								
Nera 18mg		147	31.2	1.6	147 (83.5%)	6.3	1.3	3.8	8.8	0.2	1.8	-3.4	3.7	0.9232			
Week 64																	
Placebo		134	29.5	1.6	134 (79.3%)	6.8	1.4	4.0	9.6								
Nera 18mg		128	30.6	1.9	128 (72.7%)	6.5	1.4	3.7	9.3	-0.3	2.0	-4.3	3.6	0.8759			
Week 76																	
Placebo		99	28.1	2.0	99 (58.6%)												
Nera 18mg		93	31.9	2.3	93 (52.8%)												
Week 88																	
Placebo		28	35.2	3.7	28 (16.6%)												

Study: 1305-0014. 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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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 H.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 (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		22	35.3	4.9	22 (12.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Pirfenidone																	
Baseline																	
Placebo	133	132	27.5	1.6	129 (100.0%)												
Nera 18mg	127	126	27.4	1.6	125 (100.0%)												
Week 12																	
Placebo		130	28.9	1.7	129 (100.0%)	1.8	1.2	-0.6	4.2								
Nera 18mg		126	29.7	1.7	125 (100.0%)	2.7	1.2	0.3	5.1	0.9	1.7	-2.5	4.3	0.6004			
Week 26																	
Placebo		123	30.2	1.7	122 (94.6%)	3.7	1.4	1.1	6.4								
Nera 18mg		123	31.3	1.7	122 (97.6%)	4.1	1.4	1.4	6.8	0.4	1.9	-3.4	4.1	0.8440			
Week 36																	
Placebo		116	31.5	2.0	115 (89.1%)	5.6	1.4	2.8	8.4								
Nera 18mg		120	31.5	1.8	119 (95.2%)	4.7	1.4	2.0	7.5	-0.9	2.0	-4.8	3.0	0.6524			
Week 44																	
Placebo		117	32.6	1.9	116 (89.9%)	6.4	1.5	3.4	9.3								
Nera 18mg		118	35.8	1.9	117 (93.6%)	9.6	1.5	6.6	12.5	3.2	2.1	-1.0	7.4	0.1306			
Week 52																	
Placebo		111	31.4	2.0	110 (85.3%)	6.5	1.5	3.6	9.4								
Nera 18mg		113	33.8	1.9	112 (89.6%)	7.2	1.5	4.3	10.1	0.7	2.1	-3.4	4.8	0.7451			
Week 64																	
Placebo		106	34.5	2.2	105 (81.4%)	9.6	1.6	6.4	12.7								
Nera 18mg		107	34.1	2.1	106 (84.8%)	7.7	1.6	4.5	10.8	-1.9	2.3	-6.4	2.6	0.4050			
Week 76																	
Placebo		73	31.8	2.4	72 (55.8%)												
Nera 18mg		78	32.7	2.2	77 (61.6%)												
Week 88																	
Placebo		21	22.9	3.2	21 (16.3%)												
Nera 18mg		15	28.3	5.2	15 (12.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	15.0	NC	1 (0.8%)												

Study: 1305-0014. 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 H.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 (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
Region																	
Test for homogeneity (H0)^																	
Week 12														0.1436			
Week 26														0.2530			
Week 36														0.0930			
Week 44														0.5303			
Week 52														0.6829			
Week 64														0.3642			
Europe																	
Baseline																	
Placebo	136	136	24.2	1.4	134 (100.0%)												
Nera 18mg	136	136	26.8	1.6	135 (100.0%)												
Week 12																	
Placebo		133	26.5	1.5	133 (99.3%)	1.9	1.2	-0.4	4.2								
Nera 18mg		133	29.2	1.7	133 (98.5%)	2.7	1.2	0.3	5.0	0.7	1.7	-2.6	4.0	0.6599			
Week 26																	
Placebo		125	27.3	1.6	125 (93.3%)	3.4	1.3	0.8	6.0								
Nera 18mg		128	32.2	1.8	128 (94.8%)	6.5	1.3	3.9	9.1	3.1	1.9	-0.6	6.8	0.0953			
Week 36																	
Placebo		121	27.8	1.8	121 (90.3%)	4.8	1.4	2.1	7.5								
Nera 18mg		121	33.1	1.9	121 (89.6%)	7.4	1.4	4.7	10.2	2.7	2.0	-1.2	6.5	0.1737			
Week 44																	
Placebo		121	31.1	1.9	121 (90.3%)	7.1	1.5	4.2	10.0								
Nera 18mg		116	34.5	2.1	116 (85.9%)	9.6	1.5	6.7	12.6	2.5	2.1	-1.6	6.6	0.2356			
Week 52																	
Placebo		118	29.1	1.8	118 (88.1%)	6.3	1.4	3.5	9.1								
Nera 18mg		116	32.2	1.8	116 (85.9%)	7.1	1.4	4.2	9.9	0.8	2.0	-3.3	4.8	0.7120			
Week 64																	
Placebo		111	29.4	1.8	111 (82.8%)	6.9	1.6	3.9	10.0								
Nera 18mg		102	32.9	2.0	102 (75.6%)	8.4	1.6	5.3	11.6	1.5	2.2	-2.9	5.9	0.5116			
Week 76																	
Placebo		80	27.3	2.2	80 (59.7%)												
Nera 18mg		73	33.3	2.4	73 (54.1%)												
Week 88																	
Placebo		22	29.6	3.9	22 (16.4%)												

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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 H.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 (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		18	31.5	6.0	18 (13.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Asia																	
Baseline																	
Placebo	72	72	27.6	2.2	70 (100.0%)												
Nera 18mg	79	78	26.6	2.0	76 (100.0%)												
Week 12																	
Placebo		70	26.6	2.3	70 (100.0%)	-0.2	1.6	-3.4	3.0								
Nera 18mg		77	29.7	2.1	76 (100.0%)	3.7	1.6	0.6	6.8	3.9	2.3	-0.6	8.3	0.0871			
Week 26																	
Placebo		63	29.4	2.1	63 (90.0%)	3.3	1.9	-0.3	7.0								
Nera 18mg		74	28.1	2.2	73 (96.1%)	1.7	1.8	-1.8	5.1	-1.7	2.6	-6.7	3.4	0.5181			
Week 36																	
Placebo		62	30.0	2.7	62 (88.6%)	4.1	1.9	0.3	7.9								
Nera 18mg		72	30.3	2.4	71 (93.4%)	5.0	1.8	1.4	8.6	0.9	2.7	-4.3	6.1	0.7394			
Week 44																	
Placebo		60	30.4	2.9	60 (85.7%)	4.8	2.1	0.7	8.9								
Nera 18mg		70	31.0	2.2	69 (90.8%)	6.0	2.0	2.1	9.8	1.2	2.9	-4.5	6.8	0.6837			
Week 52																	
Placebo		57	31.1	2.9	57 (81.4%)	6.3	2.0	2.3	10.3								
Nera 18mg		66	32.6	2.5	65 (85.5%)	7.1	1.9	3.4	10.9	0.9	2.8	-4.7	6.4	0.7613			
Week 64																	
Placebo		55	37.4	3.5	55 (78.6%)	12.3	2.2	8.0	16.7								
Nera 18mg		64	30.5	2.7	63 (82.9%)	5.2	2.1	1.2	9.3	-7.1	3.0	-13.1	-1.1	0.0196	-0.43	-0.79	-0.07
Week 76																	
Placebo		38	34.5	3.4	38 (54.3%)												
Nera 18mg		51	28.8	2.9	50 (65.8%)												
Week 88																	
Placebo		11	28.8	5.2	11 (15.7%)												
Nera 18mg		8	34.4	7.0	8 (10.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	

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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 H.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 (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
Baseline																	
Placebo	75	75	29.7	2.1	72 (100.0%)												
Nera 18mg	56	56	28.8	2.4	56 (100.0%)												
Week 12																	
Placebo		71	28.8	2.3	71 (98.6%)	0.5	1.6	-2.7	3.7								
Nera 18mg		55	33.1	2.7	55 (98.2%)	5.4	1.8	1.8	9.1	4.9	2.5	0.1	9.8	0.0447	0.36	0.01	0.71
Week 26																	
Placebo		70	31.4	2.3	70 (97.2%)	3.4	1.8	-0.1	7.0								
Nera 18mg		55	33.8	2.9	55 (98.2%)	5.8	2.0	1.8	9.8	2.4	2.7	-2.9	7.7	0.3809			
Week 36																	
Placebo		64	32.1	2.4	64 (88.9%)	4.5	1.9	0.8	8.2								
Nera 18mg		53	30.7	2.8	53 (94.6%)	3.3	2.1	-0.8	7.5	-1.1	2.8	-6.7	4.4	0.6853			
Week 44																	
Placebo		64	31.7	2.5	64 (88.9%)	4.7	2.0	0.7	8.6								
Nera 18mg		50	33.5	3.0	50 (89.3%)	7.5	2.3	3.1	12.0	2.9	3.0	-3.1	8.8	0.3464			
Week 52																	
Placebo		64	32.7	2.8	64 (88.9%)	5.8	2.0	2.0	9.7								
Nera 18mg		52	33.2	2.8	52 (92.9%)	6.4	2.2	2.1	10.7	0.6	2.9	-5.2	6.3	0.8450			
Week 64																	
Placebo		57	30.8	2.4	57 (79.2%)	6.5	2.2	2.3	10.8								
Nera 18mg		47	30.8	3.5	47 (83.9%)	5.3	2.4	0.6	10.0	-1.2	3.2	-7.5	5.1	0.7098			
Week 76																	
Placebo		40	31.1	3.1	40 (55.6%)												
Nera 18mg		35	32.7	3.7	35 (62.5%)												
Week 88																	
Placebo		13	34.4	6.1	13 (18.1%)												
Nera 18mg		8	25.6	4.8	8 (14.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	15.0	NC	1 (1.8%)												
Rest of the World																	
Baseline																	
Placebo	23	22	25.5	4.0	22 (100.0%)												
Nera 18mg	34	34	29.1	3.3	34 (100.0%)												
Week 12																	
Placebo		23	24.3	4.0	22 (100.0%)	-2.6	2.9	-8.3	3.1								

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Table H.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 (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		34	29.3	3.5	34 (100.0%)	1.2	2.3	-3.4	5.8	3.8	3.7	-3.6	11.2	0.3109			
Week 26																	
Placebo		23	30.7	4.6	22 (100.0%)	4.2	3.2	-2.0	10.5								
Nera 18mg		29	30.1	2.8	29 (85.3%)	3.8	2.8	-1.6	9.3	-0.4	4.2	-8.7	7.9	0.9238			
Week 36																	
Placebo		22	37.3	4.6	21 (95.5%)	11.4	3.3	4.8	17.9								
Nera 18mg		27	30.5	3.2	27 (79.4%)	5.6	2.9	-0.1	11.4	-5.7	4.4	-14.4	3.0	0.1962			
Week 44																	
Placebo		21	34.8	3.7	20 (90.9%)	7.2	3.6	0.1	14.3								
Nera 18mg		26	30.2	3.7	26 (76.5%)	5.1	3.1	-1.1	11.2	-2.2	4.8	-11.6	7.2	0.6513			
Week 52																	
Placebo		19	33.8	5.2	18 (81.8%)	7.8	3.6	0.7	14.9								
Nera 18mg		26	30.3	3.7	26 (76.5%)	5.1	3.0	-0.9	11.0	-2.7	4.7	-12.0	6.5	0.5630			
Week 64																	
Placebo		17	31.0	5.1	16 (72.7%)	6.0	4.0	-1.9	13.8								
Nera 18mg		22	36.8	3.7	22 (64.7%)	10.0	3.4	3.3	16.6	4.0	5.3	-6.3	14.3	0.4473			
Week 76																	
Placebo		14	26.2	5.0	13 (59.1%)												
Nera 18mg		12	39.8	5.4	12 (35.3%)												
Week 88																	
Placebo		3	17.5	6.3	3 (13.6%)												
Nera 18mg		3	51.7	8.8	3 (8.8%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0014. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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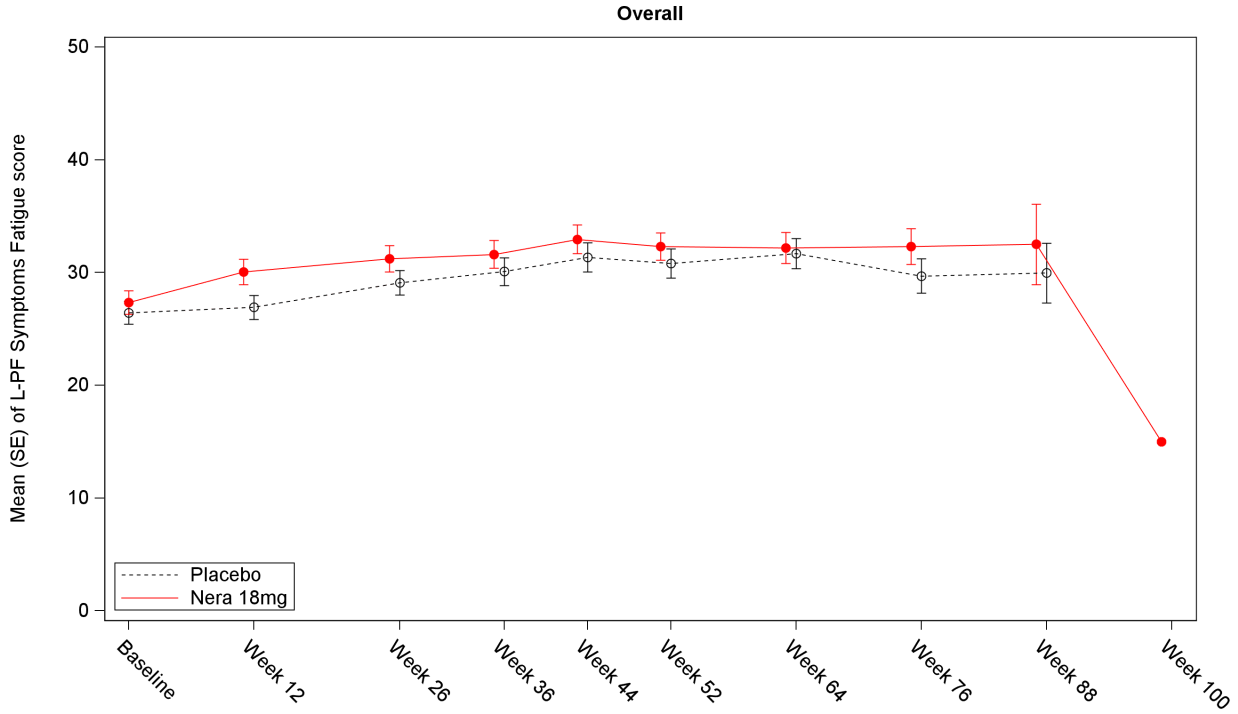

Number of patients

Placebo	305	297	281	269	266	258	240	172	49	0
Nera 18mg	304	299	286	273	262	260	235	171	37	1

Study: 1305-0014. Number of patients refers to the number of patients with observed data at visit.

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

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Table H.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 (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
Overall																	
Baseline																	
Placebo	306	299	73.8	1.0	295 (100.0%)												
Nera 18mg	305	298	74.0	1.0	297 (100.0%)												
Week 6																	
Placebo		300	77.0	0.9	293 (99.3%)	2.8	0.7	1.4	4.1								
Nera 18mg		300	75.6	0.9	293 (98.7%)	1.7	0.7	0.4	3.1	-1.1	1.0	-3.0	0.8	0.2712			
Week 12																	
Placebo		291	74.9	1.0	285 (96.6%)	0.5	0.8	-1.0	2.0								
Nera 18mg		288	73.3	1.0	283 (95.3%)	-1.3	0.8	-2.8	0.2	-1.8	1.1	-3.9	0.3	0.0959			
Week 18																	
Placebo		286	75.4	1.0	279 (94.6%)	1.1	0.7	-0.4	2.5								
Nera 18mg		293	75.5	0.9	288 (97.0%)	1.2	0.7	-0.2	2.6	0.1	1.0	-1.9	2.1	0.9220			
Week 26																	
Placebo		274	73.7	1.0	270 (91.5%)	-0.9	0.8	-2.5	0.7								
Nera 18mg		280	72.8	1.0	275 (92.6%)	-1.6	0.8	-3.2	-0.0	-0.7	1.1	-2.9	1.5	0.5503			
Week 36																	
Placebo		270	72.8	1.1	265 (89.8%)	-2.0	0.9	-3.6	-0.3								
Nera 18mg		271	71.5	1.1	266 (89.6%)	-2.9	0.9	-4.6	-1.2	-0.9	1.2	-3.3	1.4	0.4355			
Week 44																	
Placebo		267	71.2	1.2	261 (88.5%)	-3.6	0.9	-5.3	-1.9								
Nera 18mg		260	72.3	1.1	254 (85.5%)	-3.1	0.9	-4.8	-1.3	0.5	1.2	-1.9	3.0	0.6703			
Week 52																	
Placebo		257	71.6	1.2	253 (85.8%)	-4.1	0.9	-5.9	-2.4								
Nera 18mg		257	72.0	1.1	251 (84.5%)	-3.0	0.9	-4.8	-1.3	1.1	1.3	-1.4	3.6	0.3976			
Week 64																	
Placebo		239	72.1	1.2	235 (79.7%)	-3.6	0.9	-5.4	-1.7								
Nera 18mg		232	71.8	1.3	228 (76.8%)	-3.7	0.9	-5.5	-1.8	-0.1	1.3	-2.7	2.5	0.9548			
Week 76																	
Placebo		174	73.0	1.3	170 (57.6%)												
Nera 18mg		170	71.1	1.5	166 (55.9%)												
Week 88																	
Placebo		49	75.9	2.4	48 (16.3%)												
Nera 18mg		36	70.5	3.4	36 (12.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												

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

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Table H.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 (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		1	90.0	NC	1 (0.3%)												
Age																	
Test for homogeneity (H0)^																	
Week 6														0.9861			
Week 12														0.9575			
Week 18														0.9889			
Week 26														0.9405			
Week 36														0.8601			
Week 44														0.5136			
Week 52														0.5104			
Week 64														0.7093			
<65 years																	
Baseline																	
Placebo	69	67	75.1	2.3	67 (100.0%)												
Nera 18mg	63	62	75.6	2.2	62 (100.0%)												
Week 6																	
Placebo		68	78.6	1.7	66 (98.5%)	3.9	1.5	1.0	6.7								
Nera 18mg		63	77.6	1.8	62 (100.0%)	2.8	1.5	-0.2	5.7	-1.1	2.1	-5.2	3.0	0.6048			
Week 12																	
Placebo		66	77.3	2.2	65 (97.0%)	2.5	1.6	-0.7	5.6								
Nera 18mg		61	75.8	1.9	60 (96.8%)	0.6	1.7	-2.7	3.9	-1.9	2.3	-6.4	2.7	0.4184			
Week 18																	
Placebo		65	77.2	2.0	63 (94.0%)	2.3	1.5	-0.8	5.3								
Nera 18mg		62	77.5	1.8	61 (98.4%)	2.4	1.6	-0.7	5.6	0.2	2.2	-4.2	4.5	0.9438			
Week 26																	
Placebo		65	74.5	2.0	63 (94.0%)	-0.5	1.7	-3.7	2.8								
Nera 18mg		62	74.3	2.2	61 (98.4%)	-1.0	1.7	-4.3	2.4	-0.5	2.4	-5.2	4.2	0.8335			
Week 36																	
Placebo		66	74.9	2.2	64 (95.5%)	-0.3	1.8	-3.7	3.2								
Nera 18mg		60	74.3	2.2	59 (95.2%)	-1.6	1.8	-5.1	2.0	-1.3	2.5	-6.3	3.7	0.6097			
Week 44																	
Placebo		64	72.5	2.6	62 (92.5%)	-2.4	1.8	-5.9	1.2								
Nera 18mg		56	72.3	2.3	55 (88.7%)	-3.3	1.9	-7.1	0.4	-1.0	2.6	-6.1	4.2	0.7124			

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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 H.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 (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 52																	
Placebo		63	75.4	2.4	61 (91.0%)	-1.0	1.8	-4.6	2.6								
Nera 18mg		55	73.8	2.2	54 (87.1%)	-1.4	1.9	-5.2	2.4	-0.4	2.7	-5.6	4.8	0.8825			
Week 64																	
Placebo		59	73.0	2.5	57 (85.1%)	-2.5	1.9	-6.2	1.3								
Nera 18mg		49	71.3	2.8	48 (77.4%)	-3.4	2.0	-7.5	0.6	-1.0	2.8	-6.5	4.5	0.7269			
Week 76																	
Placebo		38	72.7	3.5	37 (55.2%)												
Nera 18mg		35	71.0	3.2	34 (54.8%)												
Week 88																	
Placebo		16	73.5	4.7	15 (22.4%)												
Nera 18mg		7	64.3	8.7	7 (11.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	237	232	73.4	1.1	228 (100.0%)												
Nera 18mg	242	236	73.5	1.1	235 (100.0%)												
Week 6																	
Placebo		232	76.6	1.0	227 (99.6%)	2.5	0.8	0.9	4.0								
Nera 18mg		237	75.1	1.1	231 (98.3%)	1.4	0.8	-0.1	2.9	-1.0	1.1	-3.2	1.1	0.3458			
Week 12																	
Placebo		225	74.3	1.1	220 (96.5%)	-0.1	0.9	-1.8	1.6								
Nera 18mg		227	72.6	1.2	223 (94.9%)	-1.9	0.9	-3.5	-0.2	-1.7	1.2	-4.1	0.7	0.1577			
Week 18																	
Placebo		221	74.9	1.1	216 (94.7%)	0.7	0.8	-0.9	2.4								
Nera 18mg		231	75.0	1.1	227 (96.6%)	0.8	0.8	-0.8	2.5	0.1	1.2	-2.2	2.4	0.9176			
Week 26																	
Placebo		209	73.5	1.1	207 (90.8%)	-1.0	0.9	-2.8	0.8								
Nera 18mg		218	72.3	1.2	214 (91.1%)	-1.7	0.9	-3.5	0.0	-0.7	1.3	-3.2	1.8	0.5826			
Week 36																	
Placebo		204	72.2	1.2	201 (88.2%)	-2.5	1.0	-4.4	-0.6								
Nera 18mg		211	70.7	1.3	207 (88.1%)	-3.3	1.0	-5.2	-1.4	-0.8	1.4	-3.5	1.9	0.5659			
Week 44																	
Placebo		203	70.8	1.3	199 (87.3%)	-4.0	1.0	-5.9	-2.0								

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

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Table H.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 (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		204	72.3	1.2	199 (84.7%)	-3.0	1.0	-4.9	-1.0	1.0	1.4	-1.8	3.8	0.4880			
Week 52																	
Placebo		194	70.3	1.4	192 (84.2%)	-5.1	1.0	-7.1	-3.1								
Nera 18mg		202	71.5	1.3	197 (83.8%)	-3.5	1.0	-5.5	-1.5	1.6	1.4	-1.2	4.4	0.2653			
Week 64																	
Placebo		180	71.9	1.4	178 (78.1%)	-3.9	1.1	-6.0	-1.8								
Nera 18mg		183	71.9	1.4	180 (76.6%)	-3.7	1.1	-5.8	-1.6	0.2	1.5	-2.8	3.2	0.8905			
Week 76																	
Placebo		136	73.0	1.4	133 (58.3%)												
Nera 18mg		135	71.1	1.7	132 (56.2%)												
Week 88																	
Placebo		33	77.1	2.8	33 (14.5%)												
Nera 18mg		29	72.0	3.7	29 (12.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	90.0	NC	1 (0.4%)												
Sex																	
Test for homogeneity (H0)^																	
Week 6														0.1161			
Week 12														0.0816			
Week 18														0.9094			
Week 26														0.3817			
Week 36														0.5342			
Week 44														0.1361			
Week 52														0.0788			
Week 64														0.9078			
Male																	
Baseline																	
Placebo	269	263	73.9	1.1	259 (100.0%)												
Nera 18mg	255	248	73.3	1.1	247 (100.0%)												
Week 6																	
Placebo		263	77.0	0.9	257 (99.2%)	2.7	0.7	1.3	4.2								
Nera 18mg		251	75.8	1.0	244 (98.8%)	2.4	0.8	0.9	3.9	-0.4	1.1	-2.4	1.7	0.7396			

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

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Table H.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 (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		256	74.7	1.1	250 (96.5%)	0.2	0.8	-1.4	1.8								
Nera 18mg		240	73.4	1.1	235 (95.1%)	-0.8	0.8	-2.5	0.8	-1.0	1.2	-3.3	1.3	0.3938			
Week 18																	
Placebo		250	75.8	1.0	244 (94.2%)	1.5	0.8	-0.1	3.0								
Nera 18mg		244	75.7	1.0	239 (96.8%)	1.8	0.8	0.2	3.3	0.3	1.1	-1.9	2.5	0.7992			
Week 26																	
Placebo		238	73.7	1.1	235 (90.7%)	-1.1	0.9	-2.8	0.6								
Nera 18mg		235	72.7	1.1	230 (93.1%)	-1.3	0.9	-3.0	0.4	-0.2	1.2	-2.7	2.2	0.8388			
Week 36																	
Placebo		234	72.7	1.2	230 (88.8%)	-2.2	0.9	-4.0	-0.4								
Nera 18mg		228	71.1	1.3	223 (90.3%)	-2.8	0.9	-4.6	-1.0	-0.6	1.3	-3.2	1.9	0.6283			
Week 44																	
Placebo		231	70.8	1.3	226 (87.3%)	-4.1	0.9	-6.0	-2.3								
Nera 18mg		219	72.1	1.2	213 (86.2%)	-2.8	1.0	-4.7	-0.9	1.3	1.3	-1.4	3.9	0.3385			
Week 52																	
Placebo		222	71.4	1.3	219 (84.6%)	-4.5	1.0	-6.4	-2.6								
Nera 18mg		216	72.1	1.2	210 (85.0%)	-2.5	1.0	-4.4	-0.5	2.0	1.4	-0.7	4.7	0.1400			
Week 64																	
Placebo		204	71.9	1.3	201 (77.6%)	-4.1	1.0	-6.0	-2.1								
Nera 18mg		198	70.9	1.4	194 (78.5%)	-4.1	1.0	-6.1	-2.1	-0.0	1.4	-2.8	2.8	0.9930			
Week 76																	
Placebo		151	72.5	1.5	148 (57.1%)												
Nera 18mg		147	71.4	1.6	143 (57.9%)												
Week 88																	
Placebo		42	76.3	2.6	42 (16.2%)												
Nera 18mg		31	71.8	3.7	31 (12.6%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	90.0	NC	1 (0.4%)												
Female																	
Baseline																	
Placebo	37	36	72.9	2.6	36 (100.0%)												
Nera 18mg	50	50	77.3	2.1	50 (100.0%)												
Week 6																	
Placebo		37	76.8	2.4	36 (100.0%)	3.1	2.0	-0.8	7.0								

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

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Table H.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 (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		49	74.4	2.4	49 (98.0%)	-1.7	1.7	-5.0	1.6	-4.8	2.6	-9.8	0.3	0.0671			
Week 12																	
Placebo		35	76.6	2.4	35 (97.2%)	2.5	2.2	-1.8	6.8								
Nera 18mg		48	72.8	2.4	48 (96.0%)	-3.9	1.9	-7.6	-0.2	-6.4	2.9	-12.1	-0.8	0.0260	-0.49	-0.93	-0.05
Week 18																	
Placebo		36	72.4	2.8	35 (97.2%)	-1.6	2.1	-5.7	2.5								
Nera 18mg		49	75.0	2.3	49 (98.0%)	-1.6	1.8	-5.1	1.8	-0.1	2.7	-5.4	5.3	0.9848			
Week 26																	
Placebo		36	74.1	2.5	35 (97.2%)	0.2	2.3	-4.3	4.6								
Nera 18mg		45	73.5	2.6	45 (90.0%)	-2.9	2.0	-6.8	0.9	-3.1	3.0	-9.0	2.8	0.3037			
Week 36																	
Placebo		36	73.4	2.7	35 (97.2%)	-0.4	2.4	-5.1	4.3								
Nera 18mg		43	73.7	2.4	43 (86.0%)	-3.2	2.1	-7.3	0.9	-2.8	3.2	-9.0	3.5	0.3841			
Week 44																	
Placebo		36	73.8	2.8	35 (97.2%)	-0.1	2.4	-4.9	4.7								
Nera 18mg		41	72.9	3.0	41 (82.0%)	-4.1	2.2	-8.3	0.2	-4.0	3.3	-10.4	2.4	0.2230			
Week 52																	
Placebo		35	72.6	2.9	34 (94.4%)	-1.7	2.5	-6.5	3.2								
Nera 18mg		41	71.3	2.9	41 (82.0%)	-6.0	2.2	-10.3	-1.6	-4.3	3.3	-10.8	2.2	0.1955			
Week 64																	
Placebo		35	73.7	2.7	34 (94.4%)	-0.4	2.5	-5.4	4.5								
Nera 18mg		34	76.7	2.8	34 (68.0%)	-0.9	2.4	-5.5	3.8	-0.4	3.5	-7.3	6.4	0.8974			
Week 76																	
Placebo		23	76.0	3.2	22 (61.1%)												
Nera 18mg		23	69.5	4.6	23 (46.0%)												
Week 88																	
Placebo		7	73.6	7.4	6 (16.7%)												
Nera 18mg		5	62.4	8.0	5 (10.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 6														0.6939			

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Table H.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 (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 95% CI value	lower	upper
Week 12														0.7501			
Week 18														0.9315			
Week 26														0.9454			
Week 36														0.7748			
Week 44														0.6100			
Week 52														0.8549			
Week 64														0.6501			
<=70%																	
Baseline																	
Placebo	109	107	71.1	1.7	104 (100.0%)												
Nera 18mg	112	107	69.7	1.8	106 (100.0%)												
Week 6																	
Placebo		106	74.0	1.5	104 (100.0%)	1.6	1.2	-0.7	3.9								
Nera 18mg		110	72.3	1.6	105 (99.1%)	1.0	1.2	-1.3	3.3	-0.6	1.6	-3.8	2.7	0.7369			
Week 12																	
Placebo		101	72.8	1.6	99 (95.2%)	0.2	1.3	-2.4	2.7								
Nera 18mg		100	71.0	1.7	97 (91.5%)	-1.2	1.3	-3.7	1.4	-1.3	1.8	-4.9	2.3	0.4715			
Week 18																	
Placebo		96	73.8	1.6	94 (90.4%)	0.8	1.3	-1.7	3.3								
Nera 18mg		104	73.2	1.7	101 (95.3%)	1.0	1.2	-1.4	3.4	0.2	1.8	-3.2	3.7	0.9027			
Week 26																	
Placebo		93	71.0	1.7	92 (88.5%)	-2.7	1.4	-5.4	-0.0								
Nera 18mg		96	69.0	1.7	93 (87.7%)	-3.3	1.4	-6.0	-0.6	-0.6	1.9	-4.3	3.2	0.7694			
Week 36																	
Placebo		89	69.1	1.8	87 (83.7%)	-4.4	1.5	-7.3	-1.6								
Nera 18mg		91	67.8	2.1	88 (83.0%)	-4.9	1.5	-7.8	-2.0	-0.4	2.1	-4.5	3.6	0.8278			
Week 44																	
Placebo		89	67.1	2.0	87 (83.7%)	-6.0	1.5	-8.9	-3.0								
Nera 18mg		84	69.2	2.0	80 (75.5%)	-4.5	1.5	-7.6	-1.5	1.4	2.2	-2.8	5.7	0.5072			
Week 52																	
Placebo		86	67.9	2.0	85 (81.7%)	-6.4	1.5	-9.4	-3.4								
Nera 18mg		83	68.0	1.9	79 (74.5%)	-5.0	1.6	-8.1	-2.0	1.4	2.2	-2.9	5.7	0.5259			
Week 64																	
Placebo		78	65.3	2.2	77 (74.0%)	-8.3	1.6	-11.5	-5.2								
Nera 18mg		71	65.5	2.5	68 (64.2%)	-7.7	1.6	-10.9	-4.4	0.7	2.3	-3.8	5.2	0.7663			

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Table H.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 (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		54	67.5	2.4	54 (51.9%)												
Nera 18mg		56	66.7	2.6	53 (50.0%)												
Week 88																	
Placebo		14	67.6	3.8	14 (13.5%)												
Nera 18mg		9	65.4	8.4	9 (8.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	197	192	75.3	1.2	191 (100.0%)												
Nera 18mg	193	191	76.4	1.2	191 (100.0%)												
Week 6																	
Placebo		194	78.6	1.1	189 (99.0%)	3.4	0.9	1.7	5.1								
Nera 18mg		190	77.5	1.1	188 (98.4%)	2.1	0.9	0.4	3.8	-1.4	1.2	-3.7	1.0	0.2664			
Week 12																	
Placebo		190	76.1	1.3	186 (97.4%)	0.6	1.0	-1.2	2.5								
Nera 18mg		188	74.5	1.2	186 (97.4%)	-1.4	1.0	-3.3	0.4	-2.1	1.3	-4.7	0.6	0.1271			
Week 18																	
Placebo		190	76.2	1.2	185 (96.9%)	1.2	0.9	-0.5	3.0								
Nera 18mg		189	76.8	1.1	187 (97.9%)	1.3	0.9	-0.5	3.1	0.0	1.3	-2.5	2.5	0.9827			
Week 26																	
Placebo		181	75.1	1.2	178 (93.2%)	0.0	1.0	-1.9	2.0								
Nera 18mg		184	74.8	1.3	182 (95.3%)	-0.7	1.0	-2.6	1.2	-0.7	1.4	-3.5	2.0	0.6022			
Week 36																	
Placebo		181	74.6	1.3	178 (93.2%)	-0.7	1.0	-2.8	1.4								
Nera 18mg		180	73.4	1.3	178 (93.2%)	-1.9	1.0	-3.9	0.2	-1.2	1.5	-4.1	1.7	0.4260			
Week 44																	
Placebo		178	73.3	1.4	174 (91.1%)	-2.4	1.1	-4.5	-0.3								
Nera 18mg		176	73.7	1.3	174 (91.1%)	-2.3	1.1	-4.4	-0.2	0.1	1.5	-2.9	3.1	0.9569			
Week 52																	
Placebo		171	73.4	1.5	168 (88.0%)	-2.9	1.1	-5.1	-0.8								
Nera 18mg		174	73.9	1.3	172 (90.1%)	-2.0	1.1	-4.2	0.1	0.9	1.6	-2.1	3.9	0.5636			
Week 64																	
Placebo		161	75.5	1.4	158 (82.7%)	-1.2	1.1	-3.4	1.0								

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

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Table H.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 (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		161	74.5	1.4	160 (83.8%)	-1.8	1.1	-4.0	0.4	-0.6	1.6	-3.7	2.5	0.7135			
Week 76																	
Placebo		120	75.4	1.6	116 (60.7%)												
Nera 18mg		114	73.3	1.8	113 (59.2%)												
Week 88																	
Placebo		35	79.3	2.8	34 (17.8%)												
Nera 18mg		27	72.2	3.6	27 (14.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	90.0	NC	1 (0.5%)												
Type of AF therapy																	
Test for homogeneity (H0)^																	
Week 6														0.0028			
Week 12														0.9656			
Week 18														0.1031			
Week 26														0.3642			
Week 36														0.6177			
Week 44														0.8738			
Week 52														0.8248			
Week 64														0.8598			
Nintedanib																	
Baseline																	
Placebo	173	171	73.9	1.3	168 (100.0%)												
Nera 18mg	178	172	74.2	1.4	171 (100.0%)												
Week 6																	
Placebo		168	78.0	1.1	166 (98.8%)	3.8	0.9	2.0	5.6								
Nera 18mg		175	74.2	1.2	169 (98.8%)	0.2	0.9	-1.6	2.0	-3.6	1.3	-6.1	-1.1	0.0053	-0.30	-0.52	-0.09
Week 12																	
Placebo		163	74.5	1.4	162 (96.4%)	0.1	1.0	-1.9	2.1								
Nera 18mg		165	72.9	1.4	161 (94.2%)	-1.7	1.0	-3.7	0.3	-1.8	1.4	-4.7	1.0	0.2029			
Week 18																	
Placebo		162	75.3	1.3	160 (95.2%)	1.5	1.0	-0.4	3.4								
Nera 18mg		167	74.7	1.4	163 (95.3%)	0.1	1.0	-1.8	2.0	-1.4	1.4	-4.0	1.3	0.3223			

Study: 1305-0014. 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, 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 H.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 (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		155	74.3	1.3	154 (91.7%)	-0.2	1.1	-2.3	1.9								
Nera 18mg		158	72.8	1.4	154 (90.1%)	-1.7	1.1	-3.8	0.4	-1.5	1.5	-4.5	1.4	0.3051			
Week 36																	
Placebo		154	73.1	1.5	153 (91.1%)	-1.8	1.1	-4.0	0.4								
Nera 18mg		151	72.4	1.5	147 (86.0%)	-2.2	1.1	-4.4	0.0	-0.4	1.6	-3.5	2.8	0.8195			
Week 44																	
Placebo		150	71.6	1.6	149 (88.7%)	-3.2	1.2	-5.5	-0.9								
Nera 18mg		143	73.4	1.5	138 (80.7%)	-2.4	1.2	-4.8	-0.1	0.8	1.7	-2.5	4.0	0.6468			
Week 52																	
Placebo		147	71.8	1.6	146 (86.9%)	-3.4	1.2	-5.7	-1.1								
Nera 18mg		145	73.3	1.4	140 (81.9%)	-2.0	1.2	-4.4	0.3	1.4	1.7	-1.9	4.7	0.4146			
Week 64																	
Placebo		134	73.5	1.6	133 (79.2%)	-2.5	1.2	-5.0	-0.1								
Nera 18mg		126	73.9	1.7	123 (71.9%)	-2.3	1.3	-4.8	0.2	0.2	1.8	-3.2	3.7	0.8975			
Week 76																	
Placebo		101	73.6	1.9	100 (59.5%)												
Nera 18mg		92	71.5	2.2	89 (52.0%)												
Week 88																	
Placebo		28	74.6	3.5	27 (16.1%)												
Nera 18mg		22	66.5	4.5	22 (12.9%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Pirfenidone																	
Baseline																	
Placebo	133	128	73.7	1.5	127 (100.0%)												
Nera 18mg	127	126	73.7	1.5	126 (100.0%)												
Week 6																	
Placebo		132	75.8	1.4	127 (100.0%)	1.5	1.0	-0.6	3.5								
Nera 18mg		125	77.6	1.3	124 (98.4%)	3.8	1.1	1.7	5.8	2.3	1.5	-0.6	5.2	0.1224			
Week 12																	
Placebo		128	75.5	1.4	123 (96.9%)	0.9	1.2	-1.3	3.2								
Nera 18mg		123	73.7	1.4	122 (96.8%)	-0.8	1.2	-3.1	1.5	-1.7	1.7	-5.0	1.5	0.2939			
Week 18																	
Placebo		124	75.6	1.4	119 (93.7%)	0.6	1.1	-1.6	2.8								

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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 H.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 (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		126	76.7	1.3	125 (99.2%)	2.6	1.1	0.4	4.8	2.1	1.6	-1.0	5.2	0.1934			
Week 26																	
Placebo		119	73.0	1.5	116 (91.3%)	-1.9	1.2	-4.3	0.5								
Nera 18mg		122	72.8	1.5	121 (96.0%)	-1.4	1.2	-3.7	1.0	0.5	1.7	-2.8	3.9	0.7570			
Week 36																	
Placebo		116	72.4	1.6	112 (88.2%)	-2.1	1.3	-4.7	0.5								
Nera 18mg		120	70.4	1.7	119 (94.4%)	-3.7	1.3	-6.2	-1.2	-1.6	1.8	-5.2	2.0	0.3887			
Week 44																	
Placebo		117	70.7	1.7	112 (88.2%)	-4.1	1.3	-6.7	-1.5								
Nera 18mg		117	70.8	1.6	116 (92.1%)	-3.7	1.3	-6.3	-1.1	0.4	1.9	-3.3	4.1	0.8475			
Week 52																	
Placebo		110	71.3	1.9	107 (84.3%)	-5.0	1.4	-7.7	-2.3								
Nera 18mg		112	70.2	1.7	111 (88.1%)	-4.2	1.4	-6.9	-1.6	0.8	1.9	-3.0	4.6	0.6754			
Week 64																	
Placebo		105	70.4	1.8	102 (80.3%)	-4.9	1.4	-7.7	-2.1								
Nera 18mg		106	69.3	1.9	105 (83.3%)	-5.2	1.4	-7.9	-2.4	-0.2	2.0	-4.2	3.7	0.9028			
Week 76																	
Placebo		73	72.1	1.9	70 (55.1%)												
Nera 18mg		78	70.7	2.1	77 (61.1%)												
Week 88																	
Placebo		21	77.8	3.1	21 (16.5%)												
Nera 18mg		14	76.7	4.8	14 (11.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	90.0	NC	1 (0.8%)												
Region																	
Test for homogeneity (H0)^																	
Week 6														0.0874			
Week 12														0.4941			
Week 18														0.0731			
Week 26														0.3790			
Week 36														0.1404			
Week 44														0.2500			
Week 52														0.9523			

Study: 1305-0014. 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 H.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 (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 64														0.3424			
Europe																	
Baseline																	
Placebo	136	132	70.4	1.6	132 (100.0%)												
Nera 18mg	136	132	72.4	1.5	131 (100.0%)												
Week 6																	
Placebo		134	74.8	1.4	130 (98.5%)	2.4	1.0	0.4	4.5								
Nera 18mg		132	72.0	1.5	128 (97.7%)	-0.8	1.0	-2.8	1.3	-3.2	1.5	-6.1	-0.4	0.0273	-0.27	-0.52	-0.03
Week 12																	
Placebo		132	72.5	1.6	128 (97.0%)	-0.4	1.1	-2.6	1.9								
Nera 18mg		125	70.6	1.6	122 (93.1%)	-3.2	1.2	-5.5	-0.9	-2.8	1.6	-6.0	0.4	0.0814			
Week 18																	
Placebo		128	73.8	1.3	124 (93.9%)	0.5	1.1	-1.7	2.7								
Nera 18mg		130	71.8	1.5	127 (96.9%)	-1.8	1.1	-3.9	0.3	-2.3	1.5	-5.3	0.7	0.1381			
Week 26																	
Placebo		121	71.4	1.4	118 (89.4%)	-1.4	1.2	-3.8	0.9								
Nera 18mg		124	70.4	1.6	121 (92.4%)	-3.4	1.2	-5.7	-1.0	-1.9	1.7	-5.3	1.4	0.2643			
Week 36																	
Placebo		121	71.0	1.7	118 (89.4%)	-2.3	1.3	-4.8	0.2								
Nera 18mg		119	67.0	1.8	116 (88.5%)	-5.7	1.3	-8.3	-3.2	-3.4	1.8	-6.9	0.1	0.0597			
Week 44																	
Placebo		122	67.8	1.9	118 (89.4%)	-5.0	1.3	-7.5	-2.4								
Nera 18mg		115	67.8	1.7	111 (84.7%)	-6.3	1.3	-8.9	-3.7	-1.3	1.9	-5.0	2.3	0.4736			
Week 52																	
Placebo		117	69.6	1.7	114 (86.4%)	-4.7	1.3	-7.3	-2.0								
Nera 18mg		114	69.0	1.7	110 (84.0%)	-4.3	1.4	-7.0	-1.6	0.4	1.9	-3.4	4.1	0.8455			
Week 64																	
Placebo		110	70.2	1.8	107 (81.1%)	-3.4	1.4	-6.2	-0.7								
Nera 18mg		100	68.8	1.9	98 (74.8%)	-6.0	1.4	-8.8	-3.2	-2.6	2.0	-6.5	1.3	0.1936			
Week 76																	
Placebo		81	71.7	2.0	78 (59.1%)												
Nera 18mg		73	67.0	2.4	70 (53.4%)												
Week 88																	
Placebo		22	71.5	3.8	22 (16.7%)												
Nera 18mg		18	66.3	5.3	18 (13.7%)												

Study: 1305-0014. 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, continuous 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 H.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 (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 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Asia																	
Baseline																	
Placebo	72	70	76.7	2.0	68 (100.0%)												
Nera 18mg	79	78	75.4	1.9	78 (100.0%)												
Week 6																	
Placebo		70	78.5	1.8	68 (100.0%)	2.7	1.4	-0.1	5.5								
Nera 18mg		78	77.1	1.6	77 (98.7%)	2.3	1.3	-0.3	4.9	-0.3	2.0	-4.2	3.5	0.8627			
Week 12																	
Placebo		68	77.8	1.9	67 (98.5%)	1.8	1.6	-1.3	4.9								
Nera 18mg		74	75.3	1.8	73 (93.6%)	-0.5	1.5	-3.4	2.5	-2.3	2.2	-6.6	2.0	0.2968			
Week 18																	
Placebo		65	76.5	2.1	63 (92.6%)	2.0	1.5	-1.0	5.0								
Nera 18mg		75	78.7	1.7	74 (94.9%)	3.1	1.4	0.4	5.9	1.2	2.1	-2.9	5.3	0.5779			
Week 26																	
Placebo		63	75.3	2.0	62 (91.2%)	-0.4	1.7	-3.7	2.9								
Nera 18mg		74	75.0	2.1	73 (93.6%)	-0.9	1.6	-3.9	2.2	-0.4	2.3	-4.9	4.1	0.8458			
Week 36																	
Placebo		62	73.6	2.0	61 (89.7%)	-2.4	1.8	-5.9	1.1								
Nera 18mg		72	75.8	2.0	71 (91.0%)	-0.9	1.7	-4.1	2.4	1.5	2.4	-3.2	6.3	0.5250			
Week 44																	
Placebo		60	75.1	2.1	59 (86.8%)	-1.0	1.8	-4.6	2.5								
Nera 18mg		69	75.6	1.9	68 (87.2%)	-1.7	1.7	-5.1	1.6	-0.7	2.5	-5.6	4.2	0.7857			
Week 52																	
Placebo		57	71.9	2.6	56 (82.4%)	-4.6	1.9	-8.3	-0.8								
Nera 18mg		66	73.7	2.2	65 (83.3%)	-3.6	1.8	-7.0	-0.1	1.0	2.6	-4.1	6.1	0.6976			
Week 64																	
Placebo		55	70.2	2.6	54 (79.4%)	-5.6	1.9	-9.4	-1.7								
Nera 18mg		63	74.3	2.4	62 (79.5%)	-2.2	1.8	-5.7	1.4	3.4	2.7	-1.8	8.6	0.2027			
Week 76																	
Placebo		38	72.3	2.8	37 (54.4%)												
Nera 18mg		51	75.1	2.4	50 (64.1%)												
Week 88																	
Placebo		11	79.9	3.7	10 (14.7%)												

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

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Table H.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 (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		8	70.6	6.6	8 (10.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	
Baseline																	
Placebo	75	75	76.7	1.5	73 (100.0%)												
Nera 18mg	56	55	75.2	2.4	55 (100.0%)												
Week 6																	
Placebo		73	78.8	1.5	73 (100.0%)	2.9	1.4	0.2	5.6								
Nera 18mg		56	81.0	1.7	55 (100.0%)	6.0	1.6	2.8	9.1	3.1	2.1	-1.0	7.2	0.1409			
Week 12																	
Placebo		69	76.2	1.9	69 (94.5%)	-0.2	1.5	-3.3	2.8								
Nera 18mg		56	74.6	2.3	55 (100.0%)	0.1	1.8	-3.4	3.5	0.3	2.3	-4.3	4.9	0.9015			
Week 18																	
Placebo		70	76.8	1.9	70 (95.9%)	0.7	1.5	-2.2	3.6								
Nera 18mg		56	78.9	2.1	55 (100.0%)	4.3	1.7	1.1	7.6	3.6	2.2	-0.7	8.0	0.0999			
Week 26																	
Placebo		69	75.9	2.0	69 (94.5%)	-0.6	1.6	-3.8	2.5								
Nera 18mg		53	74.7	2.0	52 (94.5%)	1.1	1.8	-2.5	4.7	1.8	2.4	-3.0	6.5	0.4707			
Week 36																	
Placebo		65	76.0	2.0	65 (89.0%)	-1.0	1.7	-4.3	2.4								
Nera 18mg		53	76.0	2.1	52 (94.5%)	1.6	1.9	-2.1	5.4	2.6	2.6	-2.4	7.7	0.3109			
Week 44																	
Placebo		64	73.3	2.4	64 (87.7%)	-4.4	1.8	-7.9	-1.0								
Nera 18mg		50	76.3	2.4	49 (89.1%)	0.7	2.0	-3.3	4.6	5.1	2.7	-0.1	10.3	0.0565			
Week 52																	
Placebo		64	73.5	2.4	64 (87.7%)	-4.5	1.8	-8.0	-0.9								
Nera 18mg		51	76.3	2.3	50 (90.9%)	0.3	2.0	-3.7	4.3	4.8	2.7	-0.5	10.1	0.0778			
Week 64																	
Placebo		57	75.4	2.4	57 (78.1%)	-3.8	1.9	-7.6	-0.1								
Nera 18mg		47	75.4	2.9	46 (83.6%)	0.1	2.1	-4.1	4.2	3.9	2.8	-1.6	9.5	0.1644			
Week 76																	
Placebo		41	73.6	2.9	41 (56.2%)												
Nera 18mg		34	74.9	3.6	34 (61.8%)												
Week 88																	

Study: 1305-0014. 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 H.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 (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		13	76.0	4.9	13 (17.8%)												
Nera 18mg		8	83.4	4.9	8 (14.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	90.0	NC	1 (1.8%)												
Rest of the World																	
Baseline																	
Placebo	23	22	75.1	4.3	22 (100.0%)												
Nera 18mg	34	33	74.8	3.0	33 (100.0%)												
Week 6																	
Placebo		23	79.8	3.8	22 (100.0%)	4.8	2.5	-0.1	9.8								
Nera 18mg		34	77.4	2.7	33 (100.0%)	2.9	2.0	-1.1	7.0	-1.9	3.2	-8.3	4.5	0.5563			
Week 12																	
Placebo		22	77.0	3.9	21 (95.5%)	3.6	2.8	-1.9	9.1								
Nera 18mg		33	76.5	3.0	33 (100.0%)	1.7	2.3	-2.7	6.2	-1.8	3.6	-8.9	5.2	0.6084			
Week 18																	
Placebo		23	77.1	4.1	22 (100.0%)	3.2	2.6	-2.0	8.3								
Nera 18mg		32	77.3	2.5	32 (97.0%)	3.1	2.2	-1.1	7.4	-0.0	3.4	-6.7	6.7	0.9982			
Week 26																	
Placebo		21	74.9	4.8	21 (95.5%)	-0.3	2.9	-6.0	5.4								
Nera 18mg		29	73.8	3.2	29 (87.9%)	-1.0	2.4	-5.8	3.8	-0.7	3.8	-8.1	6.7	0.8526			
Week 36																	
Placebo		22	71.6	4.7	21 (95.5%)	-1.5	3.0	-7.5	4.5								
Nera 18mg		27	71.1	3.6	27 (81.8%)	-4.6	2.6	-9.8	0.5	-3.1	4.0	-11.0	4.7	0.4350			
Week 44																	
Placebo		21	73.6	4.3	20 (90.9%)	-0.3	3.1	-6.5	5.8								
Nera 18mg		26	75.2	3.1	26 (78.8%)	0.3	2.7	-5.0	5.6	0.6	4.1	-7.5	8.8	0.8766			
Week 52																	
Placebo		19	76.5	4.8	19 (86.4%)	1.4	3.2	-5.0	7.8								
Nera 18mg		26	72.3	3.2	26 (78.8%)	-2.8	2.8	-8.2	2.6	-4.2	4.3	-12.6	4.2	0.3260			
Week 64																	
Placebo		17	79.8	4.5	17 (77.3%)	2.5	3.4	-4.2	9.3								
Nera 18mg		22	70.5	4.1	22 (66.7%)	-4.5	3.0	-10.3	1.3	-7.1	4.5	-15.9	1.8	0.1178			
Week 76																	
Placebo		14	80.1	4.8	14 (63.6%)												
Nera 18mg		12	68.7	6.3	12 (36.4%)												

Study: 1305-0014. 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, 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 H.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 (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 88																	
Placebo		3	94.0	3.8	3 (13.6%)												
Nera 18mg		2	56.0	9.0	2 (6.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0014. 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, 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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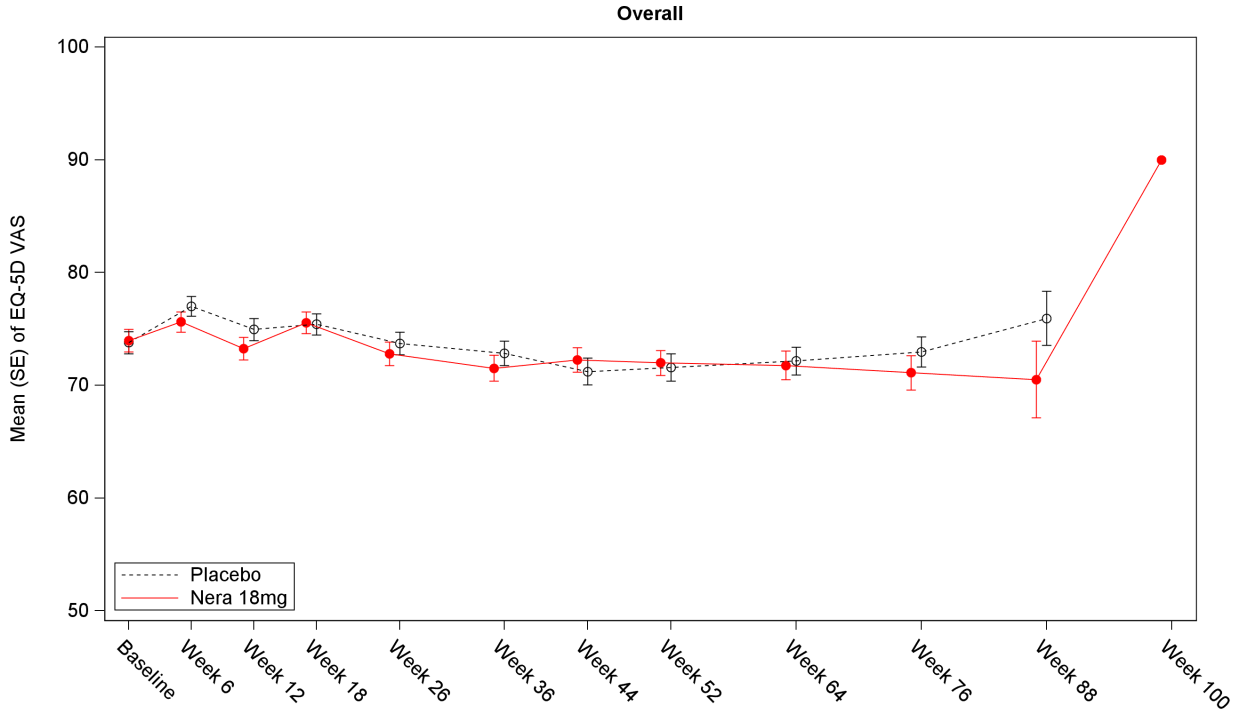

Number of patients

Placebo	299	300	291	286	274	270	267	257	239	174	49	0
Nera 18mg	298	300	288	293	280	271	260	257	232	170	36	1

Study: 1305-0014. Number of patients refers to the number of patients with observed data at visit.

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

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Table H.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 (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	306	298	1.7	0.1	291 (100.0%)												
Nera 18mg	305	299	1.8	0.1	296 (100.0%)												
Week 12																	
Placebo		295	1.6	0.1	289 (99.3%)	-0.0	0.1	-0.1	0.1								
Nera 18mg		295	1.9	0.1	290 (98.0%)	0.2	0.1	0.1	0.3	0.2	0.1	0.0	0.3	0.0160	0.20	0.04	0.36
Week 26																	
Placebo		276	1.8	0.1	271 (93.1%)	0.2	0.1	0.1	0.3								
Nera 18mg		277	1.9	0.1	273 (92.2%)	0.2	0.1	0.1	0.3	0.0	0.1	-0.1	0.2	0.8087			
Week 36																	
Placebo		268	1.8	0.1	263 (90.4%)	0.2	0.1	0.0	0.3								
Nera 18mg		270	2.0	0.1	266 (89.9%)	0.2	0.1	0.1	0.4	0.1	0.1	-0.1	0.2	0.4019			
Week 44																	
Placebo		267	1.8	0.1	261 (89.7%)	0.2	0.1	0.1	0.3								
Nera 18mg		259	2.0	0.1	255 (86.1%)	0.3	0.1	0.1	0.4	0.0	0.1	-0.1	0.2	0.5950			
Week 52																	
Placebo		258	1.8	0.1	254 (87.3%)	0.2	0.1	0.1	0.3								
Nera 18mg		258	1.9	0.1	254 (85.8%)	0.1	0.1	0.0	0.3	-0.1	0.1	-0.2	0.1	0.5171			
Week 64																	
Placebo		239	1.8	0.1	235 (80.8%)	0.2	0.1	0.1	0.3								
Nera 18mg		232	1.8	0.1	230 (77.7%)	0.0	0.1	-0.1	0.2	-0.1	0.1	-0.3	0.0	0.1228			
Week 76																	
Placebo		172	1.8	0.1	168 (57.7%)												
Nera 18mg		169	1.8	0.1	166 (56.1%)												
Week 88																	
Placebo		49	1.8	0.2	48 (16.5%)												
Nera 18mg		34	1.7	0.2	34 (11.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (0.3%)												
Age																	
Test for homogeneity (H0)^																	
Week 12														0.7496			

Study: 1305-0014. 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, 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 H.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 (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 26														0.1969			
Week 36														0.2076			
Week 44														0.3731			
Week 52														0.6744			
Week 64														0.6652			
<65 years																	
Baseline																	
Placebo	69	67	1.6	0.1	67 (100.0%)												
Nera 18mg	63	61	1.8	0.2	61 (100.0%)												
Week 12																	
Placebo		67	1.8	0.1	66 (98.5%)	0.1	0.1	-0.1	0.3								
Nera 18mg		62	2.0	0.2	60 (98.4%)	0.2	0.1	0.0	0.5	0.1	0.2	-0.2	0.5	0.3908			
Week 26																	
Placebo		65	1.7	0.1	63 (94.0%)	0.0	0.1	-0.2	0.3								
Nera 18mg		62	2.0	0.2	60 (98.4%)	0.3	0.1	0.0	0.5	0.2	0.2	-0.1	0.6	0.2128			
Week 36																	
Placebo		66	2.0	0.1	64 (95.5%)	0.3	0.1	0.1	0.6								
Nera 18mg		60	2.0	0.2	58 (95.1%)	0.2	0.1	-0.0	0.5	-0.1	0.2	-0.5	0.2	0.4953			
Week 44																	
Placebo		64	2.0	0.1	62 (92.5%)	0.4	0.1	0.1	0.6								
Nera 18mg		56	2.0	0.2	55 (90.2%)	0.3	0.1	0.0	0.5	-0.1	0.2	-0.5	0.3	0.6083			
Week 52																	
Placebo		63	1.9	0.2	61 (91.0%)	0.3	0.1	0.1	0.6								
Nera 18mg		54	2.0	0.2	53 (86.9%)	0.2	0.1	-0.1	0.5	-0.1	0.2	-0.5	0.3	0.5130			
Week 64																	
Placebo		59	1.8	0.2	57 (85.1%)	0.2	0.1	-0.0	0.5								
Nera 18mg		49	2.0	0.2	48 (78.7%)	0.2	0.1	-0.1	0.4	-0.1	0.2	-0.4	0.3	0.7417			
Week 76																	
Placebo		37	1.9	0.2	36 (53.7%)												
Nera 18mg		35	1.8	0.2	34 (55.7%)												
Week 88																	
Placebo		16	1.8	0.3	15 (22.4%)												
Nera 18mg		6	2.2	0.5	6 (9.8%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												

Study: 1305-0014. 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 H.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 (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		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	237	231	1.7	0.1	224 (100.0%)												
Nera 18mg	242	238	1.8	0.1	235 (100.0%)												
Week 12																	
Placebo		228	1.6	0.1	223 (99.6%)	-0.0	0.1	-0.2	0.1								
Nera 18mg		233	1.9	0.1	230 (97.9%)	0.2	0.1	0.0	0.3	0.2	0.1	0.0	0.4	0.0212	0.22	0.03	0.40
Week 26																	
Placebo		211	1.8	0.1	208 (92.9%)	0.2	0.1	0.1	0.4								
Nera 18mg		215	1.9	0.1	213 (90.6%)	0.2	0.1	0.0	0.3	-0.0	0.1	-0.2	0.1	0.6846			
Week 36																	
Placebo		202	1.7	0.1	199 (88.8%)	0.1	0.1	-0.0	0.2								
Nera 18mg		210	2.0	0.1	208 (88.5%)	0.2	0.1	0.1	0.4	0.1	0.1	-0.1	0.3	0.1672			
Week 44																	
Placebo		203	1.8	0.1	199 (88.8%)	0.2	0.1	0.0	0.3								
Nera 18mg		203	2.0	0.1	200 (85.1%)	0.3	0.1	0.1	0.4	0.1	0.1	-0.1	0.3	0.3551			
Week 52																	
Placebo		195	1.8	0.1	193 (86.2%)	0.2	0.1	0.0	0.3								
Nera 18mg		204	1.8	0.1	201 (85.5%)	0.1	0.1	-0.0	0.3	-0.0	0.1	-0.2	0.2	0.7406			
Week 64																	
Placebo		180	1.7	0.1	178 (79.5%)	0.2	0.1	0.0	0.3								
Nera 18mg		183	1.7	0.1	182 (77.4%)	0.0	0.1	-0.1	0.1	-0.2	0.1	-0.4	0.0	0.1279			
Week 76																	
Placebo		135	1.7	0.1	132 (58.9%)												
Nera 18mg		134	1.8	0.1	132 (56.2%)												
Week 88																	
Placebo		33	1.8	0.2	33 (14.7%)												
Nera 18mg		28	1.6	0.2	28 (11.9%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (0.4%)												
Sex																	
Test for homogeneity (H0)^																	

Study: 1305-0014. 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 H.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 (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														0.8152			
Week 26														0.5176			
Week 36														0.9472			
Week 44														0.9772			
Week 52														0.4656			
Week 64														0.7419			
Male																	
Baseline																	
Placebo	269	262	1.6	0.1	255 (100.0%)												
Nera 18mg	255	250	1.8	0.1	247 (100.0%)												
Week 12																	
Placebo		259	1.6	0.1	253 (99.2%)	-0.0	0.1	-0.1	0.1								
Nera 18mg		246	1.9	0.1	242 (98.0%)	0.2	0.1	0.1	0.3	0.2	0.1	0.0	0.4	0.0204	0.21	0.03	0.39
Week 26																	
Placebo		240	1.8	0.1	236 (92.5%)	0.2	0.1	0.0	0.3								
Nera 18mg		232	1.9	0.1	229 (92.7%)	0.2	0.1	0.0	0.3	-0.0	0.1	-0.2	0.2	0.9616			
Week 36																	
Placebo		233	1.8	0.1	229 (89.8%)	0.2	0.1	0.1	0.3								
Nera 18mg		227	2.0	0.1	224 (90.7%)	0.3	0.1	0.1	0.4	0.1	0.1	-0.1	0.3	0.4225			
Week 44																	
Placebo		231	1.8	0.1	226 (88.6%)	0.2	0.1	0.1	0.4								
Nera 18mg		219	2.0	0.1	216 (87.4%)	0.3	0.1	0.1	0.4	0.0	0.1	-0.1	0.2	0.6183			
Week 52																	
Placebo		223	1.8	0.1	220 (86.3%)	0.2	0.1	0.1	0.4								
Nera 18mg		217	1.9	0.1	214 (86.6%)	0.1	0.1	0.0	0.3	-0.1	0.1	-0.3	0.1	0.3883			
Week 64																	
Placebo		205	1.7	0.1	202 (79.2%)	0.2	0.1	0.0	0.3								
Nera 18mg		198	1.8	0.1	197 (79.8%)	0.0	0.1	-0.1	0.2	-0.1	0.1	-0.3	0.1	0.1948			
Week 76																	
Placebo		150	1.8	0.1	147 (57.6%)												
Nera 18mg		146	1.7	0.1	144 (58.3%)												
Week 88																	
Placebo		42	1.9	0.2	42 (16.5%)												
Nera 18mg		29	1.7	0.2	29 (11.7%)												
Week 100																	

Study: 1305-0014. 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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PGI-S for Cough 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 H.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 (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		1	0.0	NC	1 (0.4%)												
Female																	
Baseline																	
Placebo	37	36	1.7	0.2	36 (100.0%)												
Nera 18mg	50	49	1.8	0.2	49 (100.0%)												
Week 12																	
Placebo		36	1.7	0.2	36 (100.0%)	0.0	0.2	-0.3	0.3								
Nera 18mg		49	1.9	0.2	48 (98.0%)	0.1	0.1	-0.1	0.4	0.1	0.2	-0.3	0.5	0.4862			
Week 26																	
Placebo		36	1.8	0.2	35 (97.2%)	0.2	0.2	-0.1	0.5								
Nera 18mg		45	2.1	0.2	44 (89.8%)	0.3	0.1	0.0	0.6	0.2	0.2	-0.3	0.6	0.4972			
Week 36																	
Placebo		35	1.6	0.2	34 (94.4%)	-0.0	0.2	-0.4	0.3								
Nera 18mg		43	1.9	0.2	42 (85.7%)	0.1	0.2	-0.2	0.4	0.1	0.2	-0.4	0.5	0.6898			
Week 44																	
Placebo		36	1.8	0.2	35 (97.2%)	0.1	0.2	-0.2	0.5								
Nera 18mg		40	2.0	0.2	39 (79.6%)	0.2	0.2	-0.1	0.5	0.1	0.2	-0.4	0.5	0.8143			
Week 52																	
Placebo		35	1.7	0.2	34 (94.4%)	0.1	0.2	-0.3	0.4								
Nera 18mg		41	2.0	0.2	40 (81.6%)	0.2	0.2	-0.1	0.5	0.1	0.2	-0.4	0.6	0.6649			
Week 64																	
Placebo		34	1.9	0.2	33 (91.7%)	0.2	0.2	-0.1	0.6								
Nera 18mg		34	1.7	0.3	33 (67.3%)	0.0	0.2	-0.3	0.3	-0.2	0.2	-0.7	0.3	0.3757			
Week 76																	
Placebo		22	1.7	0.3	21 (58.3%)												
Nera 18mg		23	2.1	0.3	22 (44.9%)												
Week 88																	
Placebo		7	1.4	0.4	6 (16.7%)												
Nera 18mg		5	1.6	0.6	5 (10.2%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Baseline FVC percent predicted

Study: 1305-0014. 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, 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 H.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 (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
Test for homogeneity (H0)^																	
Week 12														0.4596			
Week 26														0.2908			
Week 36														0.9964			
Week 44														0.6581			
Week 52														0.5655			
Week 64														0.8226			
<=70%																	
Baseline																	
Placebo	109	105	1.9	0.1	99 (100.0%)												
Nera 18mg	112	108	1.9	0.1	105 (100.0%)												
Week 12																	
Placebo		102	1.9	0.1	99 (100.0%)	0.1	0.1	-0.1	0.2								
Nera 18mg		104	2.1	0.1	101 (96.2%)	0.3	0.1	0.1	0.5	0.3	0.1	0.0	0.5	0.0442	0.28	0.01	0.56
Week 26																	
Placebo		93	2.1	0.1	90 (90.9%)	0.3	0.1	0.1	0.5								
Nera 18mg		96	2.2	0.1	94 (89.5%)	0.4	0.1	0.2	0.6	0.1	0.1	-0.1	0.4	0.3221			
Week 36																	
Placebo		89	2.1	0.1	86 (86.9%)	0.3	0.1	0.1	0.5								
Nera 18mg		91	2.2	0.1	89 (84.8%)	0.4	0.1	0.2	0.6	0.1	0.2	-0.2	0.4	0.6354			
Week 44																	
Placebo		89	2.2	0.1	86 (86.9%)	0.4	0.1	0.2	0.6								
Nera 18mg		84	2.2	0.1	82 (78.1%)	0.5	0.1	0.3	0.7	0.1	0.2	-0.2	0.4	0.5012			
Week 52																	
Placebo		86	2.1	0.1	84 (84.8%)	0.3	0.1	0.1	0.5								
Nera 18mg		84	2.0	0.1	82 (78.1%)	0.2	0.1	-0.0	0.4	-0.1	0.2	-0.4	0.2	0.3847			
Week 64																	
Placebo		78	2.1	0.1	76 (76.8%)	0.3	0.1	0.1	0.5								
Nera 18mg		71	2.0	0.1	70 (66.7%)	0.1	0.1	-0.1	0.4	-0.2	0.2	-0.5	0.1	0.2804			
Week 76																	
Placebo		53	2.2	0.2	52 (52.5%)												
Nera 18mg		56	1.9	0.2	54 (51.4%)												
Week 88																	
Placebo		14	2.4	0.3	14 (14.1%)												
Nera 18mg		9	2.2	0.4	9 (8.6%)												

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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, 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 H.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 (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 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	197	193	1.5	0.1	192 (100.0%)												
Nera 18mg	193	191	1.8	0.1	191 (100.0%)												
Week 12																	
Placebo		193	1.5	0.1	190 (99.0%)	-0.0	0.1	-0.2	0.1								
Nera 18mg		191	1.8	0.1	189 (99.0%)	0.1	0.1	-0.0	0.2	0.1	0.1	-0.0	0.3	0.1329			
Week 26																	
Placebo		183	1.7	0.1	181 (94.3%)	0.1	0.1	-0.0	0.3								
Nera 18mg		181	1.8	0.1	179 (93.7%)	0.1	0.1	-0.1	0.2	-0.0	0.1	-0.2	0.2	0.6648			
Week 36																	
Placebo		179	1.6	0.1	177 (92.2%)	0.1	0.1	-0.1	0.2								
Nera 18mg		179	1.9	0.1	177 (92.7%)	0.2	0.1	0.0	0.3	0.1	0.1	-0.1	0.3	0.5003			
Week 44																	
Placebo		178	1.6	0.1	175 (91.1%)	0.1	0.1	-0.0	0.3								
Nera 18mg		175	1.9	0.1	173 (90.6%)	0.1	0.1	-0.0	0.3	0.0	0.1	-0.2	0.2	0.8533			
Week 52																	
Placebo		172	1.7	0.1	170 (88.5%)	0.2	0.1	-0.0	0.3								
Nera 18mg		174	1.8	0.1	172 (90.1%)	0.1	0.1	-0.0	0.3	-0.0	0.1	-0.2	0.2	0.8155			
Week 64																	
Placebo		161	1.6	0.1	159 (82.8%)	0.1	0.1	-0.0	0.3								
Nera 18mg		161	1.7	0.1	160 (83.8%)	-0.0	0.1	-0.2	0.1	-0.1	0.1	-0.3	0.1	0.2446			
Week 76																	
Placebo		119	1.5	0.1	116 (60.4%)												
Nera 18mg		113	1.7	0.1	112 (58.6%)												
Week 88																	
Placebo		35	1.5	0.2	34 (17.7%)												
Nera 18mg		25	1.5	0.2	25 (13.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (0.5%)												

Study: 1305-0014. 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, 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 H.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 (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
Type of AF therapy																	
Test for homogeneity (H0)^																	
Week 12														0.3431			
Week 26														0.1967			
Week 36														0.5029			
Week 44														0.3190			
Week 52														0.8205			
Week 64														0.9830			
Nintedanib																	
Baseline																	
Placebo	173	170	1.6	0.1	166 (100.0%)												
Nera 18mg	178	173	1.8	0.1	171 (100.0%)												
Week 12																	
Placebo		167	1.6	0.1	165 (99.4%)	-0.0	0.1	-0.2	0.1								
Nera 18mg		172	1.9	0.1	168 (98.2%)	0.2	0.1	0.1	0.4	0.2	0.1	0.0	0.4	0.0147	0.27	0.05	0.48
Week 26																	
Placebo		155	1.7	0.1	154 (92.8%)	0.1	0.1	-0.1	0.3								
Nera 18mg		157	1.9	0.1	154 (90.1%)	0.2	0.1	0.1	0.4	0.1	0.1	-0.1	0.3	0.3062			
Week 36																	
Placebo		153	1.7	0.1	152 (91.6%)	0.1	0.1	-0.1	0.3								
Nera 18mg		150	2.0	0.1	147 (86.0%)	0.2	0.1	0.1	0.4	0.1	0.1	-0.1	0.4	0.2903			
Week 44																	
Placebo		150	1.8	0.1	149 (89.8%)	0.2	0.1	0.0	0.4								
Nera 18mg		142	1.9	0.1	139 (81.3%)	0.2	0.1	0.0	0.3	-0.0	0.1	-0.3	0.2	0.7692			
Week 52																	
Placebo		147	1.8	0.1	146 (88.0%)	0.2	0.1	0.0	0.4								
Nera 18mg		146	1.8	0.1	143 (83.6%)	0.1	0.1	-0.0	0.3	-0.1	0.1	-0.3	0.2	0.5193			
Week 64																	
Placebo		133	1.6	0.1	132 (79.5%)	0.1	0.1	-0.1	0.2								
Nera 18mg		126	1.7	0.1	125 (73.1%)	-0.1	0.1	-0.2	0.1	-0.1	0.1	-0.4	0.1	0.2244			
Week 76																	
Placebo		99	1.7	0.1	98 (59.0%)												
Nera 18mg		92	1.7	0.1	90 (52.6%)												
Week 88																	
Placebo		28	1.9	0.2	27 (16.3%)												

Study: 1305-0014. 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, 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 H.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 (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	1.9	0.3	21 (12.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Pirfenidone																	
Baseline																	
Placebo	133	128	1.7	0.1	125 (100.0%)												
Nera 18mg	127	126	1.8	0.1	125 (100.0%)												
Week 12																	
Placebo		128	1.7	0.1	124 (99.2%)	0.0	0.1	-0.1	0.2								
Nera 18mg		123	1.9	0.1	122 (97.6%)	0.1	0.1	-0.0	0.3	0.1	0.1	-0.1	0.3	0.3928			
Week 26																	
Placebo		121	1.9	0.1	117 (93.6%)	0.3	0.1	0.1	0.5								
Nera 18mg		120	2.0	0.1	119 (95.2%)	0.2	0.1	-0.0	0.4	-0.1	0.1	-0.4	0.1	0.4128			
Week 36																	
Placebo		115	1.9	0.1	111 (88.8%)	0.2	0.1	0.1	0.4								
Nera 18mg		120	2.0	0.1	119 (95.2%)	0.2	0.1	0.1	0.4	0.0	0.1	-0.3	0.3	0.9710			
Week 44																	
Placebo		117	1.8	0.1	112 (89.6%)	0.2	0.1	0.0	0.4								
Nera 18mg		117	2.1	0.1	116 (92.8%)	0.4	0.1	0.2	0.5	0.1	0.1	-0.1	0.4	0.2853			
Week 52																	
Placebo		111	1.8	0.1	108 (86.4%)	0.2	0.1	0.0	0.4								
Nera 18mg		112	1.9	0.1	111 (88.8%)	0.2	0.1	-0.0	0.4	-0.0	0.1	-0.3	0.2	0.7945			
Week 64																	
Placebo		106	1.9	0.1	103 (82.4%)	0.3	0.1	0.1	0.5								
Nera 18mg		106	1.9	0.1	105 (84.0%)	0.2	0.1	-0.0	0.4	-0.1	0.1	-0.4	0.1	0.2936			
Week 76																	
Placebo		73	1.9	0.2	70 (56.0%)												
Nera 18mg		77	2.0	0.1	76 (60.8%)												
Week 88																	
Placebo		21	1.6	0.3	21 (16.8%)												
Nera 18mg		13	1.4	0.4	13 (10.4%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (0.8%)												

Study: 1305-0014. 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 H.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 (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
Region																	
Test for homogeneity (H0)^																	
Week 12														0.8823			
Week 26														0.3164			
Week 36														0.3086			
Week 44														0.3666			
Week 52														0.9949			
Week 64														0.2842			
Europe																	
Baseline																	
Placebo	136	133	1.6	0.1	131 (100.0%)												
Nera 18mg	136	133	2.0	0.1	132 (100.0%)												
Week 12																	
Placebo		132	1.7	0.1	129 (98.5%)	0.0	0.1	-0.1	0.2								
Nera 18mg		131	2.1	0.1	129 (97.7%)	0.2	0.1	0.0	0.4	0.2	0.1	-0.0	0.4	0.1257			
Week 26																	
Placebo		122	1.8	0.1	120 (91.6%)	0.2	0.1	0.0	0.4								
Nera 18mg		121	2.2	0.1	119 (90.2%)	0.3	0.1	0.1	0.5	0.1	0.1	-0.1	0.4	0.3305			
Week 36																	
Placebo		120	1.7	0.1	118 (90.1%)	0.1	0.1	-0.1	0.3								
Nera 18mg		118	2.2	0.1	116 (87.9%)	0.3	0.1	0.1	0.5	0.2	0.1	-0.1	0.4	0.2129			
Week 44																	
Placebo		122	1.8	0.1	119 (90.8%)	0.3	0.1	0.1	0.4								
Nera 18mg		114	2.1	0.1	112 (84.8%)	0.2	0.1	0.0	0.4	-0.0	0.1	-0.3	0.2	0.8302			
Week 52																	
Placebo		118	1.7	0.1	116 (88.5%)	0.2	0.1	0.0	0.4								
Nera 18mg		114	2.0	0.1	112 (84.8%)	0.1	0.1	-0.1	0.3	-0.1	0.1	-0.3	0.2	0.6478			
Week 64																	
Placebo		110	1.7	0.1	108 (82.4%)	0.1	0.1	-0.0	0.3								
Nera 18mg		100	2.1	0.1	100 (75.8%)	0.2	0.1	-0.0	0.4	0.0	0.1	-0.2	0.3	0.8395			
Week 76																	
Placebo		80	1.8	0.1	78 (59.5%)												
Nera 18mg		72	1.9	0.2	71 (53.8%)												
Week 88																	
Placebo		22	2.0	0.3	22 (16.8%)												

Study: 1305-0014. 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, 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 H.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 (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		16	1.8	0.3	16 (12.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Asia																	
Baseline																	
Placebo	72	70	1.7	0.1	68 (100.0%)												
Nera 18mg	79	77	1.6	0.1	75 (100.0%)												
Week 12																	
Placebo		69	1.7	0.1	68 (100.0%)	0.0	0.1	-0.2	0.2								
Nera 18mg		75	1.7	0.1	73 (97.3%)	0.0	0.1	-0.2	0.3	0.0	0.2	-0.3	0.3	0.8780			
Week 26																	
Placebo		63	1.8	0.2	62 (91.2%)	0.2	0.1	-0.1	0.4								
Nera 18mg		74	1.6	0.1	72 (96.0%)	-0.1	0.1	-0.3	0.2	-0.2	0.2	-0.6	0.1	0.1784			
Week 36																	
Placebo		61	1.8	0.2	60 (88.2%)	0.1	0.1	-0.1	0.4								
Nera 18mg		72	1.8	0.1	70 (93.3%)	0.2	0.1	-0.1	0.4	0.0	0.2	-0.3	0.4	0.9794			
Week 44																	
Placebo		60	1.9	0.2	59 (86.8%)	0.2	0.1	-0.0	0.5								
Nera 18mg		69	1.8	0.1	67 (89.3%)	0.2	0.1	-0.0	0.5	-0.0	0.2	-0.4	0.3	0.8908			
Week 52																	
Placebo		57	1.9	0.2	56 (82.4%)	0.2	0.1	-0.0	0.5								
Nera 18mg		66	1.8	0.2	64 (85.3%)	0.2	0.1	-0.1	0.4	-0.1	0.2	-0.5	0.3	0.6506			
Week 64																	
Placebo		55	2.0	0.2	54 (79.4%)	0.3	0.1	0.1	0.6								
Nera 18mg		64	1.4	0.1	62 (82.7%)	-0.2	0.1	-0.4	0.0	-0.5	0.2	-0.9	-0.2	0.0027	-0.56	-0.93	-0.19
Week 76																	
Placebo		38	1.9	0.2	37 (54.4%)												
Nera 18mg		51	1.6	0.2	49 (65.3%)												
Week 88																	
Placebo		11	1.4	0.3	10 (14.7%)												
Nera 18mg		8	1.1	0.4	8 (10.7%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	

Study: 1305-0014. 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, 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 H.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 (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
Baseline																	
Placebo	75	73	1.6	0.1	70 (100.0%)												
Nera 18mg	56	56	1.6	0.1	56 (100.0%)												
Week 12																	
Placebo		72	1.5	0.1	70 (100.0%)	-0.1	0.1	-0.3	0.1								
Nera 18mg		55	1.9	0.2	55 (98.2%)	0.3	0.1	0.1	0.6	0.4	0.2	0.1	0.7	0.0150	0.44	0.08	0.79
Week 26																	
Placebo		68	1.8	0.1	67 (95.7%)	0.2	0.1	-0.1	0.4								
Nera 18mg		53	2.1	0.2	53 (94.6%)	0.4	0.1	0.1	0.7	0.2	0.2	-0.1	0.6	0.1852			
Week 36																	
Placebo		65	1.8	0.1	64 (91.4%)	0.2	0.1	-0.0	0.5								
Nera 18mg		53	2.0	0.2	53 (94.6%)	0.3	0.1	0.1	0.6	0.1	0.2	-0.3	0.5	0.5439			
Week 44																	
Placebo		64	1.8	0.1	63 (90.0%)	0.2	0.1	-0.1	0.4								
Nera 18mg		50	1.9	0.2	50 (89.3%)	0.4	0.1	0.1	0.7	0.2	0.2	-0.2	0.6	0.2495			
Week 52																	
Placebo		64	1.8	0.1	63 (90.0%)	0.2	0.1	-0.1	0.4								
Nera 18mg		52	1.7	0.2	52 (92.9%)	0.2	0.1	-0.1	0.4	-0.0	0.2	-0.4	0.4	0.8988			
Week 64																	
Placebo		57	1.6	0.1	56 (80.0%)	0.1	0.1	-0.2	0.3								
Nera 18mg		47	1.4	0.2	47 (83.9%)	-0.0	0.1	-0.3	0.2	-0.1	0.2	-0.5	0.3	0.5316			
Week 76																	
Placebo		40	1.6	0.2	39 (55.7%)												
Nera 18mg		34	1.7	0.2	34 (60.7%)												
Week 88																	
Placebo		13	1.8	0.3	13 (18.6%)												
Nera 18mg		8	1.8	0.5	8 (14.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (1.8%)												
Rest of the World																	
Baseline																	
Placebo	23	22	1.8	0.2	22 (100.0%)												
Nera 18mg	34	33	1.8	0.2	33 (100.0%)												
Week 12																	
Placebo		22	1.7	0.3	22 (100.0%)	-0.0	0.2	-0.4	0.4								

Study: 1305-0014. 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, 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 H.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 (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		34	1.9	0.2	33 (100.0%)	0.2	0.2	-0.2	0.5	0.2	0.3	-0.3	0.7	0.4966			
Week 26																	
Placebo		23	1.9	0.2	22 (100.0%)	0.2	0.2	-0.2	0.6								
Nera 18mg		29	1.7	0.3	29 (87.9%)	-0.0	0.2	-0.4	0.4	-0.2	0.3	-0.7	0.4	0.5332			
Week 36																	
Placebo		22	2.0	0.3	21 (95.5%)	0.2	0.2	-0.2	0.7								
Nera 18mg		27	1.7	0.2	27 (81.8%)	0.0	0.2	-0.3	0.4	-0.2	0.3	-0.8	0.4	0.5160			
Week 44																	
Placebo		21	1.9	0.2	20 (90.9%)	0.1	0.2	-0.3	0.5								
Nera 18mg		26	2.0	0.2	26 (78.8%)	0.3	0.2	-0.1	0.7	0.2	0.3	-0.4	0.8	0.4439			
Week 52																	
Placebo		19	2.1	0.3	19 (86.4%)	0.3	0.2	-0.1	0.8								
Nera 18mg		26	1.9	0.2	26 (78.8%)	0.2	0.2	-0.1	0.6	-0.1	0.3	-0.7	0.5	0.8081			
Week 64																	
Placebo		17	1.9	0.2	17 (77.3%)	0.2	0.2	-0.2	0.7								
Nera 18mg		21	2.2	0.3	21 (63.6%)	0.4	0.2	-0.0	0.8	0.1	0.3	-0.5	0.7	0.6717			
Week 76																	
Placebo		14	2.0	0.2	14 (63.6%)												
Nera 18mg		12	2.3	0.3	12 (36.4%)												
Week 88																	
Placebo		3	1.7	0.3	3 (13.6%)												
Nera 18mg		2	3.0	0.0	2 (6.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0014. 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, 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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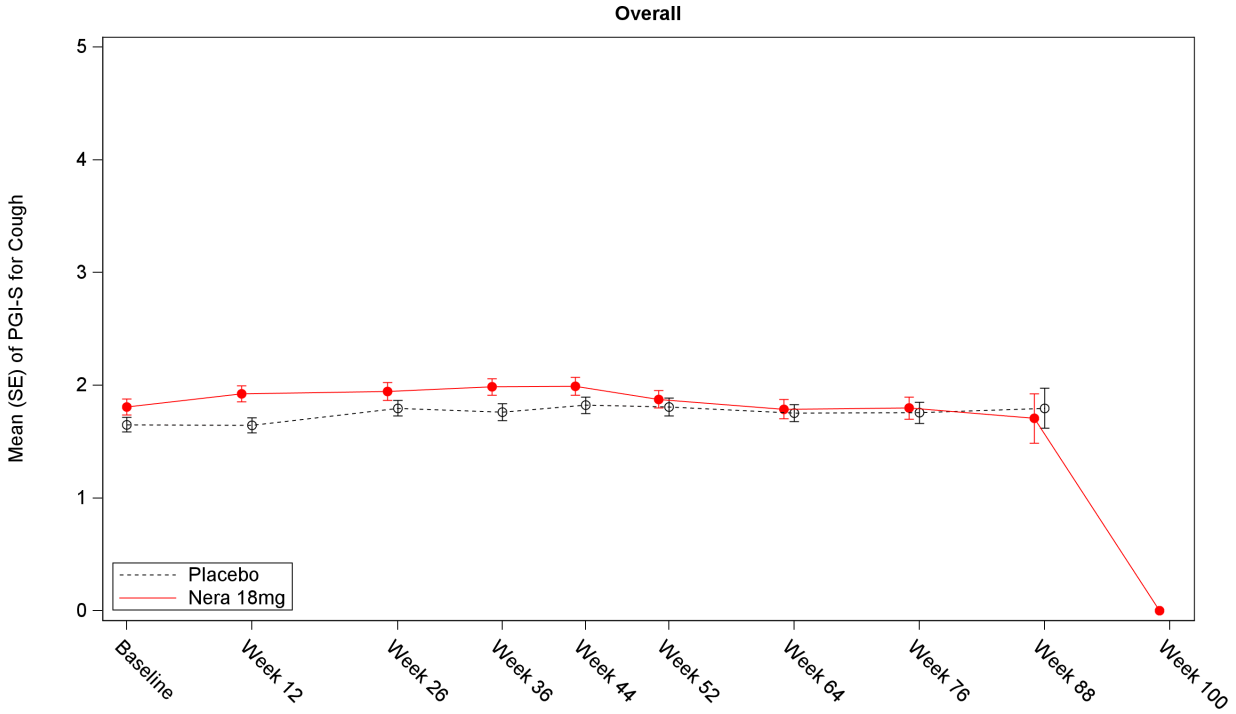

Number of patients

Placebo	298	295	276	268	267	258	239	172	49	0
Nera 18mg	299	295	277	270	259	258	232	169	34	1

Study: 1305-0014. Number of patients refers to the number of patients with observed data at visit.

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

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Table H.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 (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
Overall																	
Baseline																	
Placebo	306	295	1.8	0.1	287 (100.0%)												
Nera 18mg	305	293	1.9	0.1	290 (100.0%)												
Week 12																	
Placebo		291	1.9	0.1	282 (98.3%)	0.1	0.1	-0.0	0.2								
Nera 18mg		290	2.0	0.1	280 (96.6%)	0.1	0.1	0.0	0.2	0.0	0.1	-0.1	0.2	0.5485			
Week 26																	
Placebo		277	1.9	0.1	269 (93.7%)	0.2	0.1	0.1	0.3								
Nera 18mg		277	1.9	0.1	268 (92.4%)	0.1	0.1	0.0	0.2	-0.1	0.1	-0.2	0.1	0.4649			
Week 36																	
Placebo		266	2.0	0.1	258 (89.9%)	0.2	0.1	0.1	0.3								
Nera 18mg		271	1.9	0.1	261 (90.0%)	0.1	0.1	0.0	0.2	-0.1	0.1	-0.3	0.1	0.2110			
Week 44																	
Placebo		267	2.0	0.1	258 (89.9%)	0.3	0.1	0.2	0.4								
Nera 18mg		258	2.0	0.1	248 (85.5%)	0.2	0.1	0.0	0.3	-0.1	0.1	-0.3	0.0	0.1087			
Week 52																	
Placebo		256	2.0	0.1	249 (86.8%)	0.4	0.1	0.2	0.5								
Nera 18mg		259	2.0	0.1	249 (85.9%)	0.2	0.1	0.1	0.4	-0.1	0.1	-0.3	0.0	0.1456			
Week 64																	
Placebo		239	2.0	0.1	232 (80.8%)	0.4	0.1	0.3	0.5								
Nera 18mg		233	2.0	0.1	225 (77.6%)	0.2	0.1	0.1	0.3	-0.2	0.1	-0.4	-0.0	0.0451	-0.19	-0.37	-0.00
Week 76																	
Placebo		171	1.9	0.1	164 (57.1%)												
Nera 18mg		170	2.0	0.1	163 (56.2%)												
Week 88																	
Placebo		49	1.7	0.2	47 (16.4%)												
Nera 18mg		34	1.9	0.2	34 (11.7%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (0.3%)												
Age																	
Test for homogeneity (H0)^																	
Week 12														0.3021			

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Model is based on fixed, categorical effects of treatment at each visit, continuous 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 H.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 (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 26														0.7768			
Week 36														0.4196			
Week 44														0.4725			
Week 52														0.1003			
Week 64														0.6421			
<65 years																	
Baseline																	
Placebo	69	67	1.6	0.1	66 (100.0%)												
Nera 18mg	63	60	1.8	0.1	60 (100.0%)												
Week 12																	
Placebo		63	1.9	0.2	62 (93.9%)	0.1	0.1	-0.1	0.4								
Nera 18mg		61	1.8	0.2	58 (96.7%)	0.0	0.1	-0.2	0.3	-0.1	0.2	-0.4	0.2	0.5222			
Week 26																	
Placebo		65	1.9	0.1	63 (95.5%)	0.1	0.1	-0.1	0.4								
Nera 18mg		61	1.8	0.1	58 (96.7%)	0.0	0.1	-0.2	0.3	-0.1	0.2	-0.4	0.2	0.5440			
Week 36																	
Placebo		65	1.9	0.2	63 (95.5%)	0.3	0.1	0.0	0.5								
Nera 18mg		60	1.8	0.2	57 (95.0%)	0.0	0.1	-0.2	0.3	-0.2	0.2	-0.6	0.1	0.1896			
Week 44																	
Placebo		64	2.0	0.2	62 (93.9%)	0.3	0.1	0.0	0.5								
Nera 18mg		55	2.0	0.2	53 (88.3%)	0.2	0.1	-0.0	0.5	-0.0	0.2	-0.4	0.3	0.8948			
Week 52																	
Placebo		63	2.1	0.2	61 (92.4%)	0.4	0.1	0.2	0.7								
Nera 18mg		55	1.8	0.2	53 (88.3%)	-0.0	0.1	-0.3	0.3	-0.4	0.2	-0.8	-0.0	0.0314	-0.40	-0.77	-0.03
Week 64																	
Placebo		59	1.9	0.2	57 (86.4%)	0.3	0.1	0.1	0.6								
Nera 18mg		49	2.1	0.2	47 (78.3%)	0.2	0.1	-0.1	0.5	-0.1	0.2	-0.5	0.3	0.5807			
Week 76																	
Placebo		37	1.6	0.2	36 (54.5%)												
Nera 18mg		35	2.0	0.2	33 (55.0%)												
Week 88																	
Placebo		16	1.8	0.3	15 (22.7%)												
Nera 18mg		6	1.8	0.5	6 (10.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												

Study: 1305-0014. 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 H.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 (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		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	237	228	1.8	0.1	221 (100.0%)												
Nera 18mg	242	233	1.9	0.1	230 (100.0%)												
Week 12																	
Placebo		228	1.9	0.1	220 (99.5%)	0.1	0.1	-0.0	0.2								
Nera 18mg		229	2.0	0.1	222 (96.5%)	0.2	0.1	0.0	0.3	0.1	0.1	-0.1	0.3	0.3156			
Week 26																	
Placebo		212	2.0	0.1	206 (93.2%)	0.2	0.1	0.1	0.3								
Nera 18mg		216	2.0	0.1	210 (91.3%)	0.2	0.1	0.0	0.3	-0.0	0.1	-0.2	0.1	0.5952			
Week 36																	
Placebo		201	2.0	0.1	195 (88.2%)	0.2	0.1	0.1	0.4								
Nera 18mg		211	2.0	0.1	204 (88.7%)	0.1	0.1	0.0	0.3	-0.1	0.1	-0.3	0.1	0.4671			
Week 44																	
Placebo		203	2.1	0.1	196 (88.7%)	0.3	0.1	0.2	0.5								
Nera 18mg		203	1.9	0.1	195 (84.8%)	0.2	0.1	0.0	0.3	-0.2	0.1	-0.4	0.0	0.0791			
Week 52																	
Placebo		193	2.0	0.1	188 (85.1%)	0.3	0.1	0.2	0.5								
Nera 18mg		204	2.1	0.1	196 (85.2%)	0.3	0.1	0.1	0.4	-0.1	0.1	-0.3	0.2	0.5960			
Week 64																	
Placebo		180	2.1	0.1	175 (79.2%)	0.4	0.1	0.3	0.6								
Nera 18mg		184	2.0	0.1	178 (77.4%)	0.2	0.1	0.0	0.3	-0.2	0.1	-0.4	-0.0	0.0456	-0.21	-0.42	-0.00
Week 76																	
Placebo		134	2.0	0.1	128 (57.9%)												
Nera 18mg		135	2.0	0.1	130 (56.5%)												
Week 88																	
Placebo		33	1.7	0.2	32 (14.5%)												
Nera 18mg		28	1.9	0.2	28 (12.2%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (0.4%)												
Sex																	
Test for homogeneity (H0)^																	

Study: 1305-0014. 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 H.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 (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														0.5876			
Week 26														0.9877			
Week 36														0.9073			
Week 44														0.6958			
Week 52														0.2611			
Week 64														0.8202			
Male																	
Baseline																	
Placebo	269	259	1.8	0.1	251 (100.0%)												
Nera 18mg	255	245	1.9	0.1	242 (100.0%)												
Week 12																	
Placebo		255	1.9	0.1	246 (98.0%)	0.1	0.1	-0.0	0.2								
Nera 18mg		241	2.0	0.1	233 (96.3%)	0.1	0.1	0.0	0.3	0.0	0.1	-0.1	0.2	0.6890			
Week 26																	
Placebo		241	2.0	0.1	234 (93.2%)	0.2	0.1	0.1	0.3								
Nera 18mg		232	2.0	0.1	225 (93.0%)	0.1	0.1	0.0	0.3	-0.1	0.1	-0.2	0.1	0.5390			
Week 36																	
Placebo		232	2.0	0.1	225 (89.6%)	0.2	0.1	0.1	0.4								
Nera 18mg		228	2.0	0.1	220 (90.9%)	0.1	0.1	0.0	0.3	-0.1	0.1	-0.3	0.1	0.2500			
Week 44																	
Placebo		231	2.1	0.1	223 (88.8%)	0.4	0.1	0.2	0.5								
Nera 18mg		217	2.0	0.1	209 (86.4%)	0.2	0.1	0.1	0.3	-0.2	0.1	-0.3	0.0	0.1175			
Week 52																	
Placebo		221	2.1	0.1	215 (85.7%)	0.4	0.1	0.3	0.5								
Nera 18mg		218	2.1	0.1	210 (86.8%)	0.2	0.1	0.1	0.4	-0.2	0.1	-0.4	0.0	0.0869			
Week 64																	
Placebo		205	2.0	0.1	199 (79.3%)	0.4	0.1	0.3	0.6								
Nera 18mg		199	2.0	0.1	193 (79.8%)	0.2	0.1	0.1	0.4	-0.2	0.1	-0.4	0.0	0.0581			
Week 76																	
Placebo		149	1.9	0.1	143 (57.0%)												
Nera 18mg		147	2.1	0.1	141 (58.3%)												
Week 88																	
Placebo		42	1.8	0.2	41 (16.3%)												
Nera 18mg		29	2.0	0.2	29 (12.0%)												
Week 100																	

Study: 1305-0014. 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 H.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 (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		1	0.0	NC	1 (0.4%)												
Female																	
Baseline																	
Placebo	37	36	1.8	0.2	36 (100.0%)												
Nera 18mg	50	48	1.7	0.2	48 (100.0%)												
Week 12																	
Placebo		36	1.7	0.2	36 (100.0%)	-0.1	0.2	-0.4	0.2								
Nera 18mg		49	1.8	0.2	47 (97.9%)	0.1	0.1	-0.2	0.3	0.2	0.2	-0.2	0.5	0.4525			
Week 26																	
Placebo		36	1.8	0.2	35 (97.2%)	0.1	0.2	-0.2	0.4								
Nera 18mg		45	1.7	0.2	43 (89.6%)	0.0	0.1	-0.3	0.3	-0.1	0.2	-0.5	0.4	0.7882			
Week 36																	
Placebo		34	1.9	0.2	33 (91.7%)	0.1	0.2	-0.2	0.4								
Nera 18mg		43	1.7	0.2	41 (85.4%)	0.0	0.1	-0.3	0.3	-0.1	0.2	-0.5	0.4	0.7310			
Week 44																	
Placebo		36	1.9	0.2	35 (97.2%)	0.1	0.2	-0.3	0.4								
Nera 18mg		41	1.7	0.2	39 (81.3%)	0.0	0.2	-0.3	0.3	-0.1	0.2	-0.5	0.4	0.8234			
Week 52																	
Placebo		35	1.8	0.2	34 (94.4%)	0.1	0.2	-0.3	0.4								
Nera 18mg		41	1.8	0.2	39 (81.3%)	0.2	0.2	-0.1	0.5	0.1	0.2	-0.4	0.6	0.6109			
Week 64																	
Placebo		34	2.0	0.2	33 (91.7%)	0.3	0.2	-0.1	0.6								
Nera 18mg		34	1.7	0.2	32 (66.7%)	0.1	0.2	-0.2	0.5	-0.1	0.3	-0.6	0.4	0.5951			
Week 76																	
Placebo		22	1.9	0.3	21 (58.3%)												
Nera 18mg		23	1.8	0.3	22 (45.8%)												
Week 88																	
Placebo		7	1.4	0.4	6 (16.7%)												
Nera 18mg		5	1.6	0.5	5 (10.4%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Baseline FVC percent predicted

Study: 1305-0014. 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, 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 H.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 (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
Test for homogeneity (H0)^																	
Week 12														0.6614			
Week 26														0.4821			
Week 36														0.9976			
Week 44														0.6967			
Week 52														0.8680			
Week 64														0.4926			
<=70%																	
Baseline																	
Placebo	109	104	2.1	0.1	97 (100.0%)												
Nera 18mg	112	105	2.2	0.1	102 (100.0%)												
Week 12																	
Placebo		100	2.2	0.1	96 (99.0%)	0.2	0.1	-0.0	0.4								
Nera 18mg		101	2.3	0.1	96 (94.1%)	0.2	0.1	-0.0	0.4	-0.0	0.1	-0.3	0.3	0.9900			
Week 26																	
Placebo		94	2.2	0.1	90 (92.8%)	0.3	0.1	0.1	0.5								
Nera 18mg		95	2.3	0.1	91 (89.2%)	0.3	0.1	0.1	0.5	0.0	0.1	-0.3	0.3	0.8851			
Week 36																	
Placebo		88	2.3	0.1	84 (86.6%)	0.4	0.1	0.2	0.6								
Nera 18mg		91	2.3	0.1	86 (84.3%)	0.3	0.1	0.1	0.5	-0.1	0.1	-0.4	0.2	0.4685			
Week 44																	
Placebo		89	2.4	0.1	85 (87.6%)	0.4	0.1	0.2	0.6								
Nera 18mg		83	2.3	0.1	78 (76.5%)	0.3	0.1	0.1	0.6	-0.1	0.2	-0.4	0.2	0.5492			
Week 52																	
Placebo		85	2.4	0.1	82 (84.5%)	0.5	0.1	0.3	0.7								
Nera 18mg		85	2.4	0.1	80 (78.4%)	0.4	0.1	0.2	0.6	-0.1	0.2	-0.4	0.2	0.4874			
Week 64																	
Placebo		78	2.5	0.1	75 (77.3%)	0.6	0.1	0.4	0.9								
Nera 18mg		72	2.4	0.1	68 (66.7%)	0.4	0.1	0.1	0.6	-0.3	0.2	-0.6	0.0	0.0912			
Week 76																	
Placebo		53	2.5	0.2	51 (52.6%)												
Nera 18mg		56	2.6	0.2	52 (51.0%)												
Week 88																	
Placebo		14	2.4	0.2	14 (14.4%)												
Nera 18mg		9	2.4	0.4	9 (8.8%)												

Study: 1305-0014. 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, 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 H.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 (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 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	197	191	1.6	0.1	190 (100.0%)												
Nera 18mg	193	188	1.7	0.1	188 (100.0%)												
Week 12																	
Placebo		191	1.7	0.1	186 (97.9%)	0.0	0.1	-0.1	0.2								
Nera 18mg		189	1.8	0.1	184 (97.9%)	0.1	0.1	-0.0	0.2	0.1	0.1	-0.1	0.3	0.4649			
Week 26																	
Placebo		183	1.8	0.1	179 (94.2%)	0.2	0.1	0.0	0.3								
Nera 18mg		182	1.8	0.1	177 (94.1%)	0.0	0.1	-0.1	0.2	-0.1	0.1	-0.3	0.1	0.3149			
Week 36																	
Placebo		178	1.8	0.1	174 (91.6%)	0.2	0.1	0.0	0.3								
Nera 18mg		180	1.8	0.1	175 (93.1%)	0.0	0.1	-0.1	0.2	-0.1	0.1	-0.3	0.1	0.3026			
Week 44																	
Placebo		178	1.9	0.1	173 (91.1%)	0.3	0.1	0.1	0.4								
Nera 18mg		175	1.8	0.1	170 (90.4%)	0.1	0.1	-0.1	0.2	-0.2	0.1	-0.4	0.0	0.1253			
Week 52																	
Placebo		171	1.9	0.1	167 (87.9%)	0.3	0.1	0.1	0.4								
Nera 18mg		174	1.9	0.1	169 (89.9%)	0.1	0.1	-0.0	0.3	-0.1	0.1	-0.4	0.1	0.2016			
Week 64																	
Placebo		161	1.8	0.1	157 (82.6%)	0.3	0.1	0.1	0.4								
Nera 18mg		161	1.8	0.1	157 (83.5%)	0.1	0.1	-0.0	0.3	-0.1	0.1	-0.4	0.1	0.2126			
Week 76																	
Placebo		118	1.7	0.1	113 (59.5%)												
Nera 18mg		114	1.7	0.1	111 (59.0%)												
Week 88																	
Placebo		35	1.5	0.2	33 (17.4%)												
Nera 18mg		25	1.7	0.2	25 (13.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (0.5%)												

Study: 1305-0014. 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, 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 H.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 (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
Type of AF therapy																	
Test for homogeneity (H0)^																	
Week 12														0.9060			
Week 26														0.0711			
Week 36														0.6071			
Week 44														0.2504			
Week 52														0.8755			
Week 64														0.6892			
Nintedanib																	
Baseline																	
Placebo	173	169	1.8	0.1	164 (100.0%)												
Nera 18mg	178	168	1.9	0.1	166 (100.0%)												
Week 12																	
Placebo		163	1.9	0.1	160 (97.6%)	0.1	0.1	-0.1	0.2								
Nera 18mg		167	2.0	0.1	159 (95.8%)	0.1	0.1	-0.0	0.3	0.0	0.1	-0.2	0.2	0.7099			
Week 26																	
Placebo		155	1.8	0.1	153 (93.3%)	0.1	0.1	-0.1	0.2								
Nera 18mg		156	1.9	0.1	149 (89.8%)	0.1	0.1	-0.0	0.3	0.1	0.1	-0.1	0.3	0.5262			
Week 36																	
Placebo		152	1.9	0.1	150 (91.5%)	0.2	0.1	0.1	0.4								
Nera 18mg		151	2.0	0.1	143 (86.1%)	0.2	0.1	-0.0	0.3	-0.1	0.1	-0.3	0.2	0.5633			
Week 44																	
Placebo		150	2.0	0.1	148 (90.2%)	0.3	0.1	0.1	0.5								
Nera 18mg		141	1.8	0.1	133 (80.1%)	0.1	0.1	-0.1	0.2	-0.2	0.1	-0.5	-0.0	0.0452	-0.24	-0.47	-0.00
Week 52																	
Placebo		147	2.0	0.1	145 (88.4%)	0.3	0.1	0.1	0.4								
Nera 18mg		146	1.9	0.1	138 (83.1%)	0.1	0.1	-0.0	0.3	-0.2	0.1	-0.4	0.1	0.2135			
Week 64																	
Placebo		133	1.9	0.1	131 (79.9%)	0.3	0.1	0.1	0.5								
Nera 18mg		127	1.9	0.1	121 (72.9%)	0.1	0.1	-0.1	0.3	-0.2	0.1	-0.4	0.1	0.2046			
Week 76																	
Placebo		98	1.9	0.1	96 (58.5%)												
Nera 18mg		93	2.0	0.1	88 (53.0%)												
Week 88																	
Placebo		28	1.9	0.2	27 (16.5%)												

Study: 1305-0014. 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, 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 H.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 (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	2.0	0.3	21 (12.7%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Pirfenidone																	
Baseline																	
Placebo	133	126	1.8	0.1	123 (100.0%)												
Nera 18mg	127	125	1.9	0.1	124 (100.0%)												
Week 12																	
Placebo		128	1.9	0.1	122 (99.2%)	0.1	0.1	-0.1	0.2								
Nera 18mg		123	2.0	0.1	121 (97.6%)	0.1	0.1	-0.0	0.3	0.1	0.1	-0.2	0.3	0.6308			
Week 26																	
Placebo		122	2.1	0.1	116 (94.3%)	0.3	0.1	0.2	0.5								
Nera 18mg		121	2.0	0.1	119 (96.0%)	0.1	0.1	-0.1	0.3	-0.2	0.1	-0.5	0.0	0.0650			
Week 36																	
Placebo		114	2.0	0.1	108 (87.8%)	0.2	0.1	0.1	0.4								
Nera 18mg		120	1.9	0.1	118 (95.2%)	0.1	0.1	-0.1	0.3	-0.2	0.1	-0.4	0.1	0.2343			
Week 44																	
Placebo		117	2.1	0.1	110 (89.4%)	0.3	0.1	0.2	0.5								
Nera 18mg		117	2.1	0.1	115 (92.7%)	0.3	0.1	0.1	0.5	-0.0	0.1	-0.3	0.2	0.8096			
Week 52																	
Placebo		109	2.1	0.1	104 (84.6%)	0.5	0.1	0.3	0.7								
Nera 18mg		113	2.2	0.1	111 (89.5%)	0.4	0.1	0.2	0.6	-0.1	0.1	-0.4	0.2	0.3793			
Week 64																	
Placebo		106	2.2	0.1	101 (82.1%)	0.5	0.1	0.3	0.7								
Nera 18mg		106	2.1	0.1	104 (83.9%)	0.3	0.1	0.1	0.5	-0.2	0.1	-0.5	0.0	0.0962			
Week 76																	
Placebo		73	2.0	0.2	68 (55.3%)												
Nera 18mg		77	2.1	0.1	75 (60.5%)												
Week 88																	
Placebo		21	1.5	0.2	20 (16.3%)												
Nera 18mg		13	1.8	0.3	13 (10.5%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (0.8%)												

Study: 1305-0014. 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 H.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 (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
Region																	
Test for homogeneity (H0)^																	
Week 12														0.6988			
Week 26														0.3521			
Week 36														0.0741			
Week 44														0.2687			
Week 52														0.6835			
Week 64														0.6587			
Europe																	
Baseline																	
Placebo	136	131	1.8	0.1	128 (100.0%)												
Nera 18mg	136	127	2.0	0.1	126 (100.0%)												
Week 12																	
Placebo		129	1.9	0.1	124 (96.9%)	0.1	0.1	-0.0	0.3								
Nera 18mg		126	2.1	0.1	119 (94.4%)	0.2	0.1	0.0	0.3	0.1	0.1	-0.2	0.3	0.6482			
Week 26																	
Placebo		122	2.0	0.1	118 (92.2%)	0.2	0.1	0.0	0.4								
Nera 18mg		121	2.1	0.1	114 (90.5%)	0.2	0.1	0.0	0.4	0.0	0.1	-0.2	0.3	0.8231			
Week 36																	
Placebo		119	1.8	0.1	115 (89.8%)	0.2	0.1	-0.0	0.3								
Nera 18mg		119	2.1	0.1	111 (88.1%)	0.2	0.1	0.0	0.4	0.1	0.1	-0.2	0.3	0.5933			
Week 44																	
Placebo		122	2.1	0.1	117 (91.4%)	0.4	0.1	0.2	0.6								
Nera 18mg		113	2.0	0.1	105 (83.3%)	0.2	0.1	0.0	0.4	-0.2	0.1	-0.5	0.0	0.0950			
Week 52																	
Placebo		118	2.0	0.1	114 (89.1%)	0.3	0.1	0.2	0.5								
Nera 18mg		116	2.1	0.1	108 (85.7%)	0.2	0.1	0.0	0.4	-0.1	0.1	-0.4	0.1	0.3395			
Week 64																	
Placebo		110	2.0	0.1	106 (82.8%)	0.4	0.1	0.2	0.6								
Nera 18mg		101	2.1	0.1	95 (75.4%)	0.2	0.1	0.0	0.4	-0.2	0.1	-0.5	0.1	0.2088			
Week 76																	
Placebo		79	1.8	0.1	75 (58.6%)												
Nera 18mg		72	2.1	0.2	67 (53.2%)												
Week 88																	
Placebo		22	1.8	0.3	21 (16.4%)												

Study: 1305-0014. 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, 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 H.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 (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		16	1.9	0.4	16 (12.7%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Asia																	
Baseline																	
Placebo	72	70	1.7	0.1	68 (100.0%)												
Nera 18mg	79	77	1.6	0.1	75 (100.0%)												
Week 12																	
Placebo		69	1.8	0.1	68 (100.0%)	0.1	0.1	-0.1	0.3								
Nera 18mg		75	1.8	0.1	73 (97.3%)	0.1	0.1	-0.1	0.3	0.0	0.2	-0.3	0.3	0.8338			
Week 26																	
Placebo		63	1.9	0.1	62 (91.2%)	0.2	0.1	-0.0	0.5								
Nera 18mg		74	1.6	0.1	72 (96.0%)	-0.1	0.1	-0.3	0.2	-0.3	0.2	-0.6	0.1	0.1019			
Week 36																	
Placebo		60	1.9	0.2	59 (86.8%)	0.2	0.1	-0.0	0.5								
Nera 18mg		72	1.6	0.1	70 (93.3%)	-0.1	0.1	-0.3	0.2	-0.3	0.2	-0.6	0.0	0.0851			
Week 44																	
Placebo		60	2.0	0.2	59 (86.8%)	0.3	0.1	0.1	0.6								
Nera 18mg		69	1.9	0.1	67 (89.3%)	0.2	0.1	-0.0	0.5	-0.1	0.2	-0.5	0.2	0.5607			
Week 52																	
Placebo		57	2.1	0.2	56 (82.4%)	0.5	0.1	0.2	0.7								
Nera 18mg		66	1.8	0.1	64 (85.3%)	0.2	0.1	-0.1	0.4	-0.3	0.2	-0.7	0.1	0.1201			
Week 64																	
Placebo		55	2.2	0.2	54 (79.4%)	0.5	0.1	0.3	0.8								
Nera 18mg		64	1.9	0.2	62 (82.7%)	0.2	0.1	-0.0	0.5	-0.3	0.2	-0.7	0.1	0.0932			
Week 76																	
Placebo		38	1.9	0.2	37 (54.4%)												
Nera 18mg		51	1.8	0.2	49 (65.3%)												
Week 88																	
Placebo		11	1.5	0.3	10 (14.7%)												
Nera 18mg		8	1.6	0.3	8 (10.7%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Canada and USA																	

Study: 1305-0014. 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, 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 H.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 (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
Baseline																	
Placebo	75	72	1.9	0.1	69 (100.0%)												
Nera 18mg	56	56	2.0	0.1	56 (100.0%)												
Week 12																	
Placebo		71	1.8	0.1	68 (98.6%)	-0.0	0.1	-0.2	0.2								
Nera 18mg		55	2.1	0.2	55 (98.2%)	0.1	0.1	-0.1	0.4	0.2	0.2	-0.2	0.5	0.3241			
Week 26																	
Placebo		69	1.9	0.1	67 (97.1%)	0.1	0.1	-0.1	0.4								
Nera 18mg		53	2.3	0.2	53 (94.6%)	0.3	0.1	0.0	0.5	0.1	0.2	-0.2	0.5	0.4702			
Week 36																	
Placebo		65	2.1	0.1	63 (91.3%)	0.3	0.1	0.0	0.5								
Nera 18mg		53	2.2	0.2	53 (94.6%)	0.2	0.1	-0.1	0.4	-0.1	0.2	-0.5	0.3	0.5663			
Week 44																	
Placebo		64	2.0	0.2	62 (89.9%)	0.3	0.1	0.0	0.5								
Nera 18mg		50	2.0	0.2	50 (89.3%)	0.1	0.1	-0.2	0.4	-0.1	0.2	-0.5	0.2	0.4857			
Week 52																	
Placebo		62	2.1	0.2	60 (87.0%)	0.4	0.1	0.1	0.6								
Nera 18mg		51	2.1	0.2	51 (91.1%)	0.3	0.1	-0.0	0.6	-0.1	0.2	-0.5	0.3	0.6071			
Week 64																	
Placebo		57	2.0	0.2	55 (79.7%)	0.4	0.1	0.1	0.6								
Nera 18mg		47	2.0	0.2	47 (83.9%)	0.1	0.1	-0.2	0.4	-0.3	0.2	-0.7	0.1	0.2002			
Week 76																	
Placebo		40	2.1	0.2	38 (55.1%)												
Nera 18mg		35	2.2	0.2	35 (62.5%)												
Week 88																	
Placebo		13	2.1	0.3	13 (18.8%)												
Nera 18mg		8	1.9	0.4	8 (14.3%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	0.0	NC	1 (1.8%)												
Rest of the World																	
Baseline																	
Placebo	23	22	1.8	0.3	22 (100.0%)												
Nera 18mg	34	33	1.8	0.2	33 (100.0%)												
Week 12																	
Placebo		22	2.0	0.3	22 (100.0%)	0.2	0.2	-0.2	0.6								

Study: 1305-0014. 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, 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 H.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 (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		34	1.8	0.2	33 (100.0%)	-0.0	0.2	-0.3	0.3	-0.2	0.2	-0.7	0.3	0.3732			
Week 26																	
Placebo		23	2.1	0.3	22 (100.0%)	0.2	0.2	-0.2	0.6								
Nera 18mg		29	1.7	0.2	29 (87.9%)	-0.0	0.2	-0.4	0.3	-0.3	0.3	-0.8	0.3	0.3416			
Week 36																	
Placebo		22	2.3	0.3	21 (95.5%)	0.4	0.2	0.0	0.9								
Nera 18mg		27	1.8	0.2	27 (81.8%)	0.1	0.2	-0.3	0.4	-0.4	0.3	-0.9	0.2	0.2035			
Week 44																	
Placebo		21	1.7	0.2	20 (90.9%)	-0.1	0.2	-0.6	0.3								
Nera 18mg		26	1.8	0.2	26 (78.8%)	0.1	0.2	-0.3	0.5	0.2	0.3	-0.4	0.8	0.5275			
Week 52																	
Placebo		19	1.8	0.3	19 (86.4%)	0.1	0.2	-0.4	0.6								
Nera 18mg		26	2.0	0.3	26 (78.8%)	0.3	0.2	-0.1	0.7	0.2	0.3	-0.4	0.8	0.4509			
Week 64																	
Placebo		17	1.6	0.3	17 (77.3%)	0.0	0.2	-0.5	0.5								
Nera 18mg		21	2.1	0.2	21 (63.6%)	0.3	0.2	-0.1	0.8	0.3	0.3	-0.3	0.9	0.3480			
Week 76																	
Placebo		14	1.7	0.4	14 (63.6%)												
Nera 18mg		12	2.1	0.3	12 (36.4%)												
Week 88																	
Placebo		3	0.7	0.3	3 (13.6%)												
Nera 18mg		2	3.0	0.0	2 (6.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0014. 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, 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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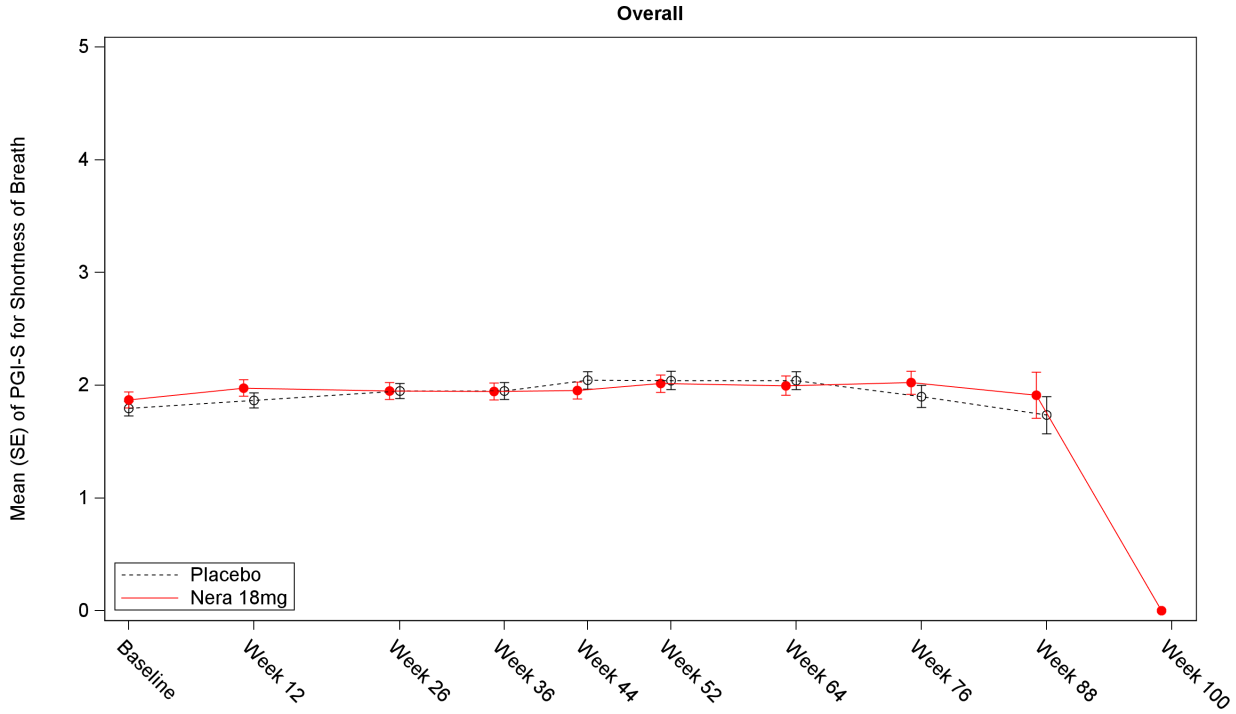

Number of patients

Placebo	295	291	277	266	267	256	239	171	49	0
Nera 18mg	293	290	277	271	258	259	233	170	34	1

Study: 1305-0014. Number of patients refers to the number of patients with observed data at visit.

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

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Table H.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (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
Overall																	
Baseline																	
Placebo	306	8	1.3	0.2													
Nera 18mg	305	6	1.2	0.4													
Week 12																	
Placebo		111	1.2	0.1													
Nera 18mg		120	1.3	0.1													
Week 26																	
Placebo		245	1.3	0.1													
Nera 18mg		239	1.3	0.1													
Week 36																	
Placebo		262	1.3	0.1													
Nera 18mg		257	1.4	0.1													
Week 44																	
Placebo		264	1.3	0.1													
Nera 18mg		253	1.3	0.1													
Week 52																	
Placebo		256	1.3	0.1													
Nera 18mg		257	1.3	0.1													
Week 64																	
Placebo		234	1.3	0.1													
Nera 18mg		230	1.3	0.1													
Week 76																	
Placebo		169	1.3	0.1													
Nera 18mg		169	1.4	0.1													
Week 88																	
Placebo		49	1.2	0.1													
Nera 18mg		33	1.3	0.1													
Week 100																	
Placebo		0	NC	NC													
Nera 18mg		1	1.0	NC													
Age																	
<65 years																	
Baseline																	
Placebo	69	3	1.3	0.3													
Nera 18mg	63	1	0.0	NC													
Week 12																	
Placebo		25	1.0	0.1													
Nera 18mg		24	1.0	0.2													

Study: 1305-0014. 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 H.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (AF 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 95% CI value	lower	upper
Week 26																	
Placebo		59	1.1	0.1													
Nera 18mg		53	1.3	0.1													
Week 36																	
Placebo		64	1.3	0.1													
Nera 18mg		57	1.4	0.1													
Week 44																	
Placebo		63	1.3	0.1													
Nera 18mg		54	1.3	0.1													
Week 52																	
Placebo		62	1.2	0.1													
Nera 18mg		55	1.4	0.1													
Week 64																	
Placebo		57	1.2	0.1													
Nera 18mg		49	1.3	0.1													
Week 76																	
Placebo		37	1.2	0.1													
Nera 18mg		35	1.4	0.1													
Week 88																	
Placebo		16	1.2	0.2													
Nera 18mg		6	1.5	0.3													
Week 100																	
Placebo		0	NC	NC													
Nera 18mg		0	NC	NC													
>=65 years																	
Baseline																	
Placebo	237	5	1.2	0.2													
Nera 18mg	242	5	1.4	0.4													
Week 12																	
Placebo		86	1.2	0.1													
Nera 18mg		96	1.3	0.1													
Week 26																	
Placebo		186	1.3	0.1													
Nera 18mg		186	1.3	0.1													
Week 36																	
Placebo		198	1.3	0.1													
Nera 18mg		200	1.3	0.1													
Week 44																	
Placebo		201	1.3	0.1													
Nera 18mg		199	1.3	0.1													
Week 52																	

Study: 1305-0014. 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 H.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (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		194	1.3	0.1													
Nera 18mg		202	1.3	0.1													
Week 64																	
Placebo		177	1.4	0.1													
Nera 18mg		181	1.3	0.1													
Week 76																	
Placebo		132	1.3	0.1													
Nera 18mg		134	1.4	0.1													
Week 88																	
Placebo		33	1.2	0.1													
Nera 18mg		27	1.2	0.2													
Week 100																	
Placebo		0	NC	NC													
Nera 18mg		1	1.0	NC													
Sex																	
Male																	
Baseline																	
Placebo	269	5	1.2	0.2													
Nera 18mg	255	5	1.4	0.4													
Week 12																	
Placebo		97	1.2	0.1													
Nera 18mg		101	1.3	0.1													
Week 26																	
Placebo		214	1.2	0.1													
Nera 18mg		202	1.3	0.1													
Week 36																	
Placebo		228	1.3	0.1													
Nera 18mg		218	1.4	0.1													
Week 44																	
Placebo		229	1.3	0.1													
Nera 18mg		213	1.3	0.1													
Week 52																	
Placebo		222	1.3	0.1													
Nera 18mg		216	1.3	0.1													
Week 64																	
Placebo		201	1.3	0.1													
Nera 18mg		197	1.3	0.1													
Week 76																	
Placebo		148	1.2	0.1													

Study: 1305-0014. 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 H.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (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		146	1.4	0.1													
Week 88																	
Placebo		42	1.2	0.1													
Nera 18mg		28	1.3	0.2													
Week 100																	
Placebo		0	NC	NC													
Nera 18mg		1	1.0	NC													
Female																	
Baseline																	
Placebo	37	3	1.3	0.3													
Nera 18mg	50	1	0.0	NC													
Week 12																	
Placebo		14	1.4	0.2													
Nera 18mg		19	1.2	0.2													
Week 26																	
Placebo		31	1.4	0.2													
Nera 18mg		37	1.2	0.1													
Week 36																	
Placebo		34	1.4	0.1													
Nera 18mg		39	1.3	0.1													
Week 44																	
Placebo		35	1.4	0.2													
Nera 18mg		40	1.2	0.2													
Week 52																	
Placebo		34	1.4	0.2													
Nera 18mg		41	1.4	0.1													
Week 64																	
Placebo		33	1.5	0.2													
Nera 18mg		33	1.0	0.2													
Week 76																	
Placebo		21	1.4	0.2													
Nera 18mg		23	1.3	0.2													
Week 88																	
Placebo		7	1.1	0.4													
Nera 18mg		5	1.4	0.2													
Week 100																	
Placebo		0	NC	NC													
Nera 18mg		0	NC	NC													

Baseline FVC percent predicted

Study: 1305-0014. 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 H.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (AF 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
<=70%																	
Baseline																	
Placebo	109	5	1.0	0.0													
Nera 18mg	112	3	1.7	0.3													
Week 12																	
Placebo		40	1.4	0.1													
Nera 18mg		38	1.5	0.1													
Week 26																	
Placebo		84	1.4	0.1													
Nera 18mg		83	1.6	0.1													
Week 36																	
Placebo		86	1.5	0.1													
Nera 18mg		83	1.6	0.1													
Week 44																	
Placebo		89	1.6	0.1													
Nera 18mg		80	1.4	0.1													
Week 52																	
Placebo		86	1.5	0.1													
Nera 18mg		82	1.5	0.1													
Week 64																	
Placebo		77	1.5	0.1													
Nera 18mg		70	1.5	0.1													
Week 76																	
Placebo		52	1.5	0.1													
Nera 18mg		56	1.6	0.1													
Week 88																	
Placebo		14	1.4	0.2													
Nera 18mg		9	1.6	0.2													
Week 100																	
Placebo		0	NC	NC													
Nera 18mg		0	NC	NC													
>70%																	
Baseline																	
Placebo	197	3	1.7	0.3													
Nera 18mg	193	3	0.7	0.7													
Week 12																	
Placebo		71	1.0	0.1													
Nera 18mg		82	1.2	0.1													
Week 26																	
Placebo		161	1.2	0.1													
Nera 18mg		156	1.2	0.1													

Study: 1305-0014. 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 H.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (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 36																	
Placebo		176	1.2	0.1													
Nera 18mg		174	1.2	0.1													
Week 44																	
Placebo		175	1.2	0.1													
Nera 18mg		173	1.2	0.1													
Week 52																	
Placebo		170	1.2	0.1													
Nera 18mg		175	1.2	0.1													
Week 64																	
Placebo		157	1.2	0.1													
Nera 18mg		160	1.2	0.1													
Week 76																	
Placebo		117	1.2	0.1													
Nera 18mg		113	1.3	0.1													
Week 88																	
Placebo		35	1.1	0.1													
Nera 18mg		24	1.2	0.2													
Week 100																	
Placebo		0	NC	NC													
Nera 18mg		1	1.0	NC													
Type of AF therapy																	
Nintedanib																	
Baseline																	
Placebo	173	5	1.4	0.2													
Nera 18mg	178	5	1.0	0.4													
Week 12																	
Placebo		59	1.2	0.1													
Nera 18mg		67	1.2	0.1													
Week 26																	
Placebo		138	1.1	0.1													
Nera 18mg		132	1.3	0.1													
Week 36																	
Placebo		148	1.2	0.1													
Nera 18mg		141	1.3	0.1													
Week 44																	
Placebo		150	1.2	0.1													
Nera 18mg		139	1.2	0.1													
Week 52																	

Study: 1305-0014. 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 H.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (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		146	1.3	0.1													
Nera 18mg		145	1.3	0.1													
Week 64																	
Placebo		130	1.2	0.1													
Nera 18mg		125	1.2	0.1													
Week 76																	
Placebo		97	1.2	0.1													
Nera 18mg		92	1.3	0.1													
Week 88																	
Placebo		28	1.3	0.2													
Nera 18mg		20	1.4	0.2													
Week 100																	
Placebo		0	NC	NC													
Nera 18mg		0	NC	NC													
Pirfenidone																	
Baseline																	
Placebo	133	3	1.0	0.0													
Nera 18mg	127	1	2.0	NC													
Week 12																	
Placebo		52	1.2	0.1													
Nera 18mg		53	1.4	0.1													
Week 26																	
Placebo		107	1.4	0.1													
Nera 18mg		107	1.3	0.1													
Week 36																	
Placebo		114	1.3	0.1													
Nera 18mg		116	1.4	0.1													
Week 44																	
Placebo		114	1.4	0.1													
Nera 18mg		114	1.4	0.1													
Week 52																	
Placebo		110	1.3	0.1													
Nera 18mg		112	1.4	0.1													
Week 64																	
Placebo		104	1.5	0.1													
Nera 18mg		105	1.4	0.1													
Week 76																	
Placebo		72	1.4	0.1													
Nera 18mg		77	1.4	0.1													
Week 88																	
Placebo		21	1.0	0.1													

Study: 1305-0014. 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 H.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (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		13	1.2	0.2													
Week 100																	
Placebo		0	NC	NC													
Nera 18mg		1	1.0	NC													
Region																	
Europe																	
Baseline																	
Placebo	136	2	1.0	0.0													
Nera 18mg	136	3	1.3	0.7													
Week 12																	
Placebo		54	1.3	0.1													
Nera 18mg		59	1.3	0.1													
Week 26																	
Placebo		109	1.3	0.1													
Nera 18mg		105	1.3	0.1													
Week 36																	
Placebo		117	1.3	0.1													
Nera 18mg		111	1.5	0.1													
Week 44																	
Placebo		122	1.3	0.1													
Nera 18mg		112	1.4	0.1													
Week 52																	
Placebo		117	1.3	0.1													
Nera 18mg		115	1.4	0.1													
Week 64																	
Placebo		106	1.3	0.1													
Nera 18mg		100	1.3	0.1													
Week 76																	
Placebo		79	1.3	0.1													
Nera 18mg		72	1.5	0.1													
Week 88																	
Placebo		22	1.1	0.1													
Nera 18mg		16	1.4	0.2													
Week 100																	
Placebo		0	NC	NC													
Nera 18mg		0	NC	NC													
Asia																	
Baseline																	
Placebo	72	2	1.0	0.0													

Study: 1305-0014. 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 H.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (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	79	0	NC	NC													
Week 12																	
Placebo		23	1.0	0.1													
Nera 18mg		31	1.0	0.1													
Week 26																	
Placebo		59	1.2	0.1													
Nera 18mg		69	1.1	0.1													
Week 36																	
Placebo		60	1.2	0.1													
Nera 18mg		71	1.2	0.1													
Week 44																	
Placebo		59	1.2	0.1													
Nera 18mg		67	1.1	0.1													
Week 52																	
Placebo		56	1.2	0.1													
Nera 18mg		65	1.2	0.1													
Week 64																	
Placebo		54	1.4	0.1													
Nera 18mg		63	1.1	0.1													
Week 76																	
Placebo		37	1.2	0.2													
Nera 18mg		51	1.2	0.1													
Week 88																	
Placebo		11	1.0	0.2													
Nera 18mg		8	1.3	0.3													
Week 100																	
Placebo		0	NC	NC													
Nera 18mg		0	NC	NC													
Canada and USA																	
Baseline																	
Placebo	75	4	1.5	0.3													
Nera 18mg	56	3	1.0	0.6													
Week 12																	
Placebo		26	1.2	0.2													
Nera 18mg		24	1.4	0.2													
Week 26																	
Placebo		60	1.3	0.1													
Nera 18mg		45	1.6	0.1													
Week 36																	
Placebo		63	1.3	0.1													
Nera 18mg		48	1.3	0.1													

Study: 1305-0014. 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 H.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (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		62	1.4	0.1													
Nera 18mg		49	1.2	0.1													
Week 52																	
Placebo		64	1.4	0.1													
Nera 18mg		51	1.3	0.1													
Week 64																	
Placebo		57	1.4	0.1													
Nera 18mg		46	1.2	0.1													
Week 76																	
Placebo		39	1.2	0.1													
Nera 18mg		34	1.4	0.2													
Week 88																	
Placebo		13	1.5	0.3													
Nera 18mg		7	0.9	0.1													
Week 100																	
Placebo		0	NC	NC													
Nera 18mg		1	1.0	NC													
Rest of the World																	
Baseline																	
Placebo	23	0	NC	NC													
Nera 18mg	34	0	NC	NC													
Week 12																	
Placebo		8	0.9	0.3													
Nera 18mg		6	1.7	0.2													
Week 26																	
Placebo		17	1.3	0.2													
Nera 18mg		20	1.3	0.1													
Week 36																	
Placebo		22	1.4	0.2													
Nera 18mg		27	1.3	0.1													
Week 44																	
Placebo		21	1.3	0.2													
Nera 18mg		25	1.2	0.2													
Week 52																	
Placebo		19	1.2	0.2													
Nera 18mg		26	1.3	0.2													
Week 64																	
Placebo		17	1.2	0.2													
Nera 18mg		21	1.5	0.2													
Week 76																	

Study: 1305-0014. 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 H.1.1.1.2.1: 10 Mean (SE) of PGI-S for Fatigue
over the whole trial - 18mg - FAS (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
Placebo		14	1.1	0.3													
Nera 18mg		12	1.7	0.3													
Week 88																	
Placebo		3	0.7	0.3													
Nera 18mg		2	2.0	0.0													
Week 100																	
Placebo		0	NC	NC													
Nera 18mg		0	NC	NC													

Study: 1305-0014. 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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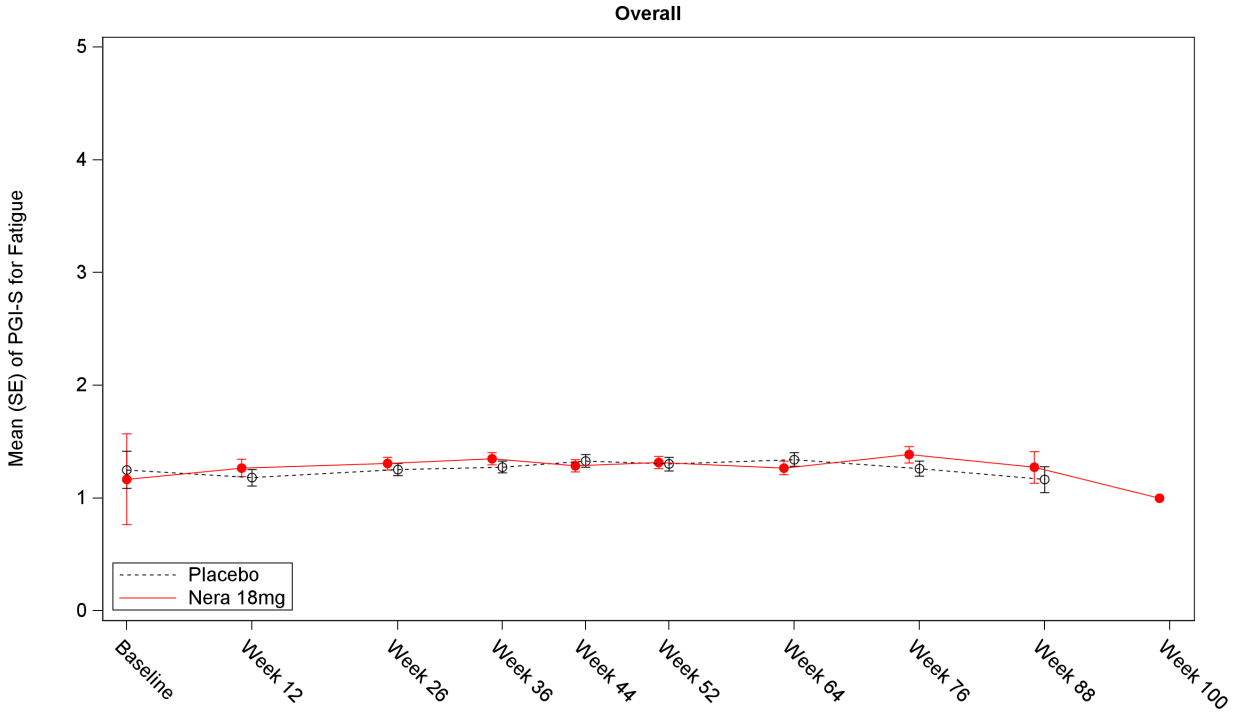

Number of patients

Placebo	8	111	245	262	264	256	234	169	49	0
Nera 18mg	6	120	239	257	253	257	230	169	33	1

Study: 1305-0014. Number of patients refers to the number of patients with observed data at visit.

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

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Table H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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
Overall																	
Baseline																	
Placebo	306	306	2872.6	44.7	304 (100.0%)												
Nera 18mg	305	305	2846.2	43.1	304 (100.0%)												
Week 2																	
Placebo		293	2885.9	46.0	293 (96.4%)	-3.5	9.2	-21.6	14.6								
Nera 18mg		297	2862.2	43.8	297 (97.7%)	15.3	9.2	-2.7	33.4	18.8	13.0	-6.8	44.4	0.1489			
Week 6																	
Placebo		299	2858.4	44.8	299 (98.4%)	-27.8	9.6	-46.7	-8.9								
Nera 18mg		300	2859.7	43.7	300 (98.7%)	9.3	9.6	-9.6	28.2	37.1	13.6	10.4	63.8	0.0066	0.22	0.06	0.38
Week 12																	
Placebo		292	2866.2	45.3	292 (96.1%)	-37.2	11.6	-59.9	-14.4								
Nera 18mg		292	2845.8	44.9	292 (96.1%)	-16.4	11.6	-39.2	6.3	20.7	16.4	-11.4	52.9	0.2058			
Week 18																	
Placebo		286	2851.9	45.5	286 (94.1%)	-49.8	11.2	-71.8	-27.9								
Nera 18mg		293	2851.1	44.2	293 (96.4%)	-9.3	11.1	-31.1	12.4	40.5	15.7	9.6	71.4	0.0103	0.21	0.05	0.38
Week 26																	
Placebo		279	2817.2	46.2	279 (91.8%)	-79.4	12.5	-104.0	-54.8								
Nera 18mg		278	2843.7	45.3	278 (91.4%)	-36.7	12.5	-61.2	-12.1	42.7	17.7	8.0	77.5	0.0161	0.20	0.04	0.37
Week 36																	
Placebo		267	2802.5	47.2	267 (87.8%)	-118.4	13.6	-145.2	-91.6								
Nera 18mg		274	2818.1	45.2	274 (90.1%)	-85.7	13.5	-112.3	-59.2	32.7	19.2	-5.0	70.4	0.0892			
Week 44																	
Placebo		261	2763.3	47.9	261 (85.9%)	-153.1	14.5	-181.6	-124.6								
Nera 18mg		254	2819.6	47.1	254 (83.6%)	-103.5	14.5	-132.0	-75.1	49.6	20.5	9.3	89.8	0.0160	0.21	0.04	0.39
Week 52																	
Placebo		255	2765.3	48.5	255 (83.9%)	-185.8	15.6	-216.3	-155.2								
Nera 18mg		263	2800.3	46.7	263 (86.5%)	-115.1	15.4	-145.4	-84.8	70.7	21.9	27.7	113.7	0.0013	0.28	0.11	0.46
Week 64																	
Placebo		241	2716.0	51.1	241 (79.3%)	-216.7	18.2	-252.5	-180.9								
Nera 18mg		238	2803.2	49.6	238 (78.3%)	-150.8	18.2	-186.6	-115.1	65.9	25.7	15.3	116.5	0.0108	0.23	0.05	0.41
Week 76																	
Placebo		174	2737.1	60.6	174 (57.2%)												
Nera 18mg		166	2850.7	62.1	166 (54.6%)												
Week 88																	
Placebo		50	2808.7	112.8	50 (16.4%)												

Study: 1305-0014. 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, 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 H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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		36	3112.4	164.1	36 (11.8%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	2852.0	NC	1 (0.3%)												
Age																	
Test for homogeneity (H0)^																	
Week 6														0.1250			
Week 12														0.4987			
Week 18														0.6979			
Week 26														0.6076			
Week 36														0.7070			
Week 44														0.6092			
Week 52														0.9003			
Week 64														0.8572			
<65 years																	
Baseline																	
Placebo	69	69	3054.0	95.3	69 (100.0%)												
Nera 18mg	63	63	3160.0	98.8	63 (100.0%)												
Week 2																	
Placebo		65	3047.1	98.2	65 (94.2%)	-21.0	19.6	-59.4	17.5								
Nera 18mg		63	3190.5	102.0	63 (100.0%)	35.9	20.1	-3.7	75.5	56.9	28.0	2.0	111.8	0.0424	0.36	0.01	0.70
Week 6																	
Placebo		68	3046.0	95.7	68 (98.6%)	-23.4	20.3	-63.2	16.5								
Nera 18mg		63	3183.3	103.5	63 (100.0%)	31.4	21.2	-10.2	73.1	54.8	29.2	-2.5	112.2	0.0610			
Week 12																	
Placebo		67	3045.1	97.9	67 (97.1%)	-37.5	24.4	-85.4	10.3								
Nera 18mg		62	3147.5	101.8	62 (98.4%)	-4.6	25.4	-54.6	45.4	32.9	35.1	-35.9	101.8	0.3479			
Week 18																	
Placebo		66	3032.3	94.0	66 (95.7%)	-65.6	23.5	-111.6	-19.5								
Nera 18mg		62	3142.5	102.8	62 (98.4%)	-9.9	24.4	-57.8	37.9	55.7	33.6	-10.4	121.7	0.0985			
Week 26																	
Placebo		64	2990.1	97.4	64 (92.8%)	-81.3	26.3	-133.0	-29.6								
Nera 18mg		59	3095.9	106.7	59 (93.7%)	-51.2	27.4	-105.0	2.6	30.1	37.8	-44.1	104.3	0.4256			

Study: 1305-0014. 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, 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 H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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 36																	
Placebo		64	2938.7	99.9	64 (92.8%)	-144.8	28.3	-200.4	-89.1								
Nera 18mg		61	3063.6	104.2	61 (96.8%)	-94.1	29.3	-151.7	-36.5	50.7	40.5	-29.0	130.3	0.2120			
Week 44																	
Placebo		59	2931.2	107.5	59 (85.5%)	-187.7	30.3	-247.2	-128.3								
Nera 18mg		56	3078.3	110.6	56 (88.9%)	-133.7	31.3	-195.2	-72.1	54.1	43.3	-31.0	139.1	0.2122			
Week 52																	
Placebo		61	2911.5	103.8	61 (88.4%)	-207.9	32.2	-271.0	-144.7								
Nera 18mg		57	3057.9	113.3	57 (90.5%)	-144.7	33.4	-210.2	-79.1	63.2	46.1	-27.3	153.7	0.1709			
Week 64																	
Placebo		60	2869.2	113.0	60 (87.0%)	-240.4	37.5	-314.1	-166.7								
Nera 18mg		51	3116.3	116.1	51 (81.0%)	-154.9	39.6	-232.7	-77.1	85.5	54.2	-21.0	192.0	0.1153			
Week 76																	
Placebo		38	2996.4	141.7	38 (55.1%)												
Nera 18mg		35	3244.4	145.6	35 (55.6%)												
Week 88																	
Placebo		16	3050.5	224.8	16 (23.2%)												
Nera 18mg		7	4090.4	258.2	7 (11.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>=65 years																	
Baseline																	
Placebo	237	237	2819.8	50.2	235 (100.0%)												
Nera 18mg	242	242	2764.5	46.5	241 (100.0%)												
Week 2																	
Placebo		228	2839.9	51.8	228 (97.0%)	1.5	10.5	-19.1	22.1								
Nera 18mg		234	2773.8	46.7	234 (97.1%)	9.8	10.4	-10.6	30.2	8.3	14.7	-20.6	37.2	0.5722			
Week 6																	
Placebo		231	2803.2	50.3	231 (98.3%)	-29.1	11.0	-50.7	-7.6								
Nera 18mg		237	2773.7	46.5	237 (98.3%)	3.3	10.9	-18.0	24.7	32.5	15.4	2.2	62.7	0.0356	0.19	0.01	0.38
Week 12																	
Placebo		225	2812.9	50.6	225 (95.7%)	-37.1	13.2	-63.0	-11.1								
Nera 18mg		230	2764.5	48.7	230 (95.4%)	-19.6	13.1	-45.3	6.2	17.5	18.6	-18.9	54.0	0.3456			
Week 18																	
Placebo		220	2797.8	51.6	220 (93.6%)	-45.1	12.7	-70.2	-20.1								

Study: 1305-0014. 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, 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 H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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		231	2772.8	47.6	231 (95.9%)	-9.0	12.5	-33.7	15.6	36.1	17.8	1.1	71.1	0.0434	0.19	0.01	0.37
Week 26																	
Placebo		215	2765.7	52.1	215 (91.5%)	-78.8	14.3	-106.9	-50.7								
Nera 18mg		219	2775.7	48.9	219 (90.9%)	-32.6	14.1	-60.4	-4.8	46.2	20.1	6.8	85.6	0.0216	0.22	0.03	0.41
Week 36																	
Placebo		203	2759.5	53.4	203 (86.4%)	-110.3	15.6	-141.0	-79.7								
Nera 18mg		213	2747.8	48.9	213 (88.4%)	-83.2	15.3	-113.4	-53.1	27.1	21.8	-15.8	70.0	0.2156			
Week 44																	
Placebo		202	2714.2	53.0	202 (86.0%)	-142.7	16.6	-175.2	-110.2								
Nera 18mg		198	2746.5	50.6	198 (82.2%)	-94.8	16.4	-127.0	-62.6	47.9	23.3	2.2	93.6	0.0400	0.21	0.01	0.40
Week 52																	
Placebo		194	2719.3	54.6	194 (82.6%)	-179.1	17.8	-214.1	-144.2								
Nera 18mg		206	2729.0	49.8	206 (85.5%)	-106.5	17.5	-140.8	-72.2	72.6	24.9	23.7	121.5	0.0037	0.29	0.09	0.49
Week 64																	
Placebo		181	2665.2	56.5	181 (77.0%)	-209.6	20.9	-250.7	-168.5								
Nera 18mg		187	2717.8	53.0	187 (77.6%)	-149.2	20.6	-189.7	-108.7	60.4	29.3	2.8	118.0	0.0400	0.21	0.01	0.42
Week 76																	
Placebo		136	2664.7	65.6	136 (57.9%)												
Nera 18mg		131	2745.5	65.8	131 (54.4%)												
Week 88																	
Placebo		34	2694.9	125.6	34 (14.5%)												
Nera 18mg		29	2876.3	167.7	29 (12.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	2852.0	NC	1 (0.4%)												
Sex																	
Test for homogeneity (H0)^																	
Week 6														0.2803			
Week 12														0.2554			
Week 18														0.7090			
Week 26														0.4605			
Week 36														0.2648			
Week 44														0.4045			
Week 52														0.2468			

Study: 1305-0014. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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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 H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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 64														0.6360			
Male																	
Baseline																	
Placebo	269	269	2963.2	46.3	267 (100.0%)												
Nera 18mg	255	255	2994.3	44.5	254 (100.0%)												
Week 2																	
Placebo		259	2967.4	48.1	259 (97.0%)	-5.5	9.9	-24.8	13.9								
Nera 18mg		248	3010.3	45.5	248 (97.6%)	19.3	10.1	-0.6	39.1	24.8	14.1	-2.9	52.4	0.0787			
Week 6																	
Placebo		262	2949.3	46.6	262 (98.1%)	-28.9	10.3	-49.1	-8.6								
Nera 18mg		250	3012.6	45.0	250 (98.4%)	15.1	10.6	-5.7	35.9	44.0	14.7	15.1	72.9	0.0029	0.26	0.09	0.44
Week 12																	
Placebo		256	2960.6	46.8	256 (95.9%)	-37.3	12.4	-61.8	-12.9								
Nera 18mg		244	2994.4	46.6	244 (96.1%)	-13.8	12.8	-38.8	11.3	23.6	17.7	-11.2	58.4	0.1841			
Week 18																	
Placebo		250	2950.0	47.0	250 (93.6%)	-47.7	12.0	-71.2	-24.2								
Nera 18mg		244	3005.7	45.4	244 (96.1%)	-1.3	12.2	-25.2	22.6	46.4	17.0	13.0	79.8	0.0065	0.24	0.07	0.42
Week 26																	
Placebo		243	2911.8	48.0	243 (91.0%)	-82.5	13.5	-109.0	-56.1								
Nera 18mg		234	2987.1	46.5	234 (92.1%)	-31.4	13.7	-58.4	-4.4	51.1	19.1	13.5	88.7	0.0078	0.24	0.06	0.42
Week 36																	
Placebo		231	2903.1	49.3	231 (86.5%)	-125.6	14.7	-154.5	-96.7								
Nera 18mg		229	2967.5	46.1	229 (90.2%)	-86.9	14.9	-116.2	-57.7	38.7	20.8	-2.2	79.6	0.0634			
Week 44																	
Placebo		227	2862.0	49.7	227 (85.0%)	-162.0	15.7	-192.8	-131.2								
Nera 18mg		216	2955.2	48.1	216 (85.0%)	-103.4	15.9	-134.7	-72.1	58.6	22.2	15.0	102.2	0.0085	0.25	0.06	0.44
Week 52																	
Placebo		220	2869.4	50.7	220 (82.4%)	-191.5	16.8	-224.5	-158.4								
Nera 18mg		221	2944.2	47.7	221 (87.0%)	-117.2	17.0	-150.6	-83.8	74.3	23.7	27.7	120.9	0.0018	0.30	0.11	0.48
Week 64																	
Placebo		206	2824.0	53.8	206 (77.2%)	-224.0	19.7	-262.8	-185.3								
Nera 18mg		202	2926.6	52.1	202 (79.5%)	-157.9	20.0	-197.3	-118.6	66.1	27.9	11.4	120.8	0.0180	0.23	0.04	0.43
Week 76																	
Placebo		151	2837.5	64.0	151 (56.6%)												
Nera 18mg		143	2965.8	65.6	143 (56.3%)												

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Model is based on fixed, categorical effects of treatment 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 H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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		43	2924.3	118.1	43 (16.1%)												
Nera 18mg		31	3277.6	166.5	31 (12.2%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	2852.0	NC	1 (0.4%)												
Female																	
Baseline																	
Placebo	37	37	2213.9	99.2	37 (100.0%)												
Nera 18mg	50	50	2090.9	61.7	50 (100.0%)												
Week 2																	
Placebo		34	2264.6	102.9	34 (91.9%)	11.1	27.6	-43.1	65.3								
Nera 18mg		49	2112.5	60.7	49 (98.0%)	-5.1	23.8	-51.8	41.6	-16.2	35.2	-85.3	52.9	0.6458			
Week 6																	
Placebo		37	2215.1	98.5	37 (100.0%)	-20.3	28.2	-75.8	35.1								
Nera 18mg		50	2095.5	65.0	50 (100.0%)	-20.9	24.9	-69.7	27.9	-0.6	36.3	-71.8	70.6	0.9874			
Week 12																	
Placebo		36	2195.1	102.2	36 (97.3%)	-36.3	34.0	-103.1	30.6								
Nera 18mg		48	2090.9	64.8	48 (96.0%)	-30.3	30.0	-89.3	28.6	5.9	43.7	-80.0	91.9	0.8919			
Week 18																	
Placebo		36	2170.8	99.5	36 (97.3%)	-64.1	32.6	-128.0	-0.1								
Nera 18mg		49	2081.2	64.3	49 (98.0%)	-50.9	28.6	-107.0	5.2	13.1	41.7	-68.8	95.1	0.7531			
Week 26																	
Placebo		36	2178.5	101.1	36 (97.3%)	-58.2	36.3	-129.6	13.1								
Nera 18mg		44	2081.0	71.5	44 (88.0%)	-63.8	32.7	-127.9	0.3	-5.6	47.1	-98.1	86.9	0.9053			
Week 36																	
Placebo		36	2156.9	98.2	36 (97.3%)	-72.5	39.3	-149.7	4.7								
Nera 18mg		45	2057.7	73.1	45 (90.0%)	-79.6	35.2	-148.8	-10.4	-7.1	50.8	-106.9	92.7	0.8889			
Week 44																	
Placebo		34	2104.1	103.8	34 (91.9%)	-95.2	41.8	-177.3	-13.1								
Nera 18mg		38	2048.9	75.7	38 (76.0%)	-104.8	38.1	-179.7	-29.9	-9.6	54.5	-116.6	97.4	0.8602			
Week 52																	
Placebo		35	2110.9	98.5	35 (94.6%)	-148.2	44.2	-235.1	-61.3								
Nera 18mg		42	2043.2	80.0	42 (84.0%)	-103.5	40.4	-182.9	-24.1	44.7	57.7	-68.6	158.0	0.4384			
Week 64																	
Placebo		35	2080.2	100.7	35 (94.6%)	-170.3	51.3	-271.0	-69.6								

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

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Table H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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		36	2110.8	80.4	36 (72.0%)	-111.9	47.9	-206.0	-17.7	58.4	67.6	-74.4	191.3	0.3877			
Week 76																	
Placebo		23	2078.4	111.7	23 (62.2%)												
Nera 18mg		23	2135.0	96.7	23 (46.0%)												
Week 88																	
Placebo		7	2098.3	212.9	7 (18.9%)												
Nera 18mg		5	2087.8	321.9	5 (10.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 6														0.4502			
Week 12														0.6958			
Week 18														0.9389			
Week 26														0.9874			
Week 36														0.7622			
Week 44														0.9865			
Week 52														0.8930			
Week 64														0.4985			
<=70%																	
Baseline																	
Placebo	109	109	2233.7	49.1	107 (100.0%)												
Nera 18mg	112	112	2337.3	45.8	111 (100.0%)												
Week 2																	
Placebo		103	2220.0	48.8	103 (96.3%)	-11.3	17.1	-44.8	22.2								
Nera 18mg		109	2373.7	46.6	109 (98.2%)	20.7	16.2	-11.2	52.6	32.0	21.8	-10.8	74.9	0.1423			
Week 6																	
Placebo		103	2223.5	52.5	103 (96.3%)	-23.6	17.8	-58.7	11.4								
Nera 18mg		108	2363.0	48.3	108 (97.3%)	20.6	17.1	-13.0	54.2	44.2	22.9	-0.8	89.3	0.0540			
Week 12																	
Placebo		100	2245.6	53.9	100 (93.5%)	-33.7	21.4	-75.8	8.4								
Nera 18mg		104	2352.4	51.1	104 (93.7%)	-11.3	20.6	-51.7	29.2	22.4	27.7	-32.0	76.7	0.4189			

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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 H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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 18																	
Placebo		97	2230.7	55.5	97 (90.7%)	-57.1	20.7	-97.7	-16.4								
Nera 18mg		105	2362.3	49.5	105 (94.6%)	-17.0	19.7	-55.7	21.8	40.1	26.6	-12.2	92.4	0.1324			
Week 26																	
Placebo		95	2208.2	55.5	95 (88.8%)	-83.0	23.2	-128.5	-37.4								
Nera 18mg		96	2351.4	51.5	96 (86.5%)	-32.9	22.4	-76.9	11.0	50.0	30.1	-9.1	109.1	0.0968			
Week 36																	
Placebo		89	2184.6	60.3	89 (83.2%)	-129.8	25.4	-179.6	-80.0								
Nera 18mg		91	2336.1	51.5	91 (82.0%)	-97.7	24.3	-145.5	-49.9	32.1	32.9	-32.6	96.8	0.3298			
Week 44																	
Placebo		87	2153.5	58.8	87 (81.3%)	-171.6	27.0	-224.7	-118.5								
Nera 18mg		83	2324.6	52.6	83 (74.8%)	-126.3	26.2	-177.8	-74.8	45.3	35.3	-24.1	114.6	0.2003			
Week 52																	
Placebo		82	2173.0	61.8	82 (76.6%)	-188.6	29.0	-245.6	-131.6								
Nera 18mg		86	2280.2	55.6	86 (77.5%)	-139.5	28.1	-194.6	-84.4	49.1	37.9	-25.4	123.6	0.1957			
Week 64																	
Placebo		78	2120.0	67.0	78 (72.9%)	-230.7	34.0	-297.6	-163.9								
Nera 18mg		74	2265.4	59.1	74 (66.7%)	-198.0	33.3	-263.5	-132.5	32.7	44.8	-55.2	120.7	0.4651			
Week 76																	
Placebo		55	2161.0	70.9	55 (51.4%)												
Nera 18mg		55	2322.9	65.8	55 (49.5%)												
Week 88																	
Placebo		15	2270.3	149.7	15 (14.0%)												
Nera 18mg		9	2213.4	197.9	9 (8.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	197	197	3226.1	47.9	197 (100.0%)												
Nera 18mg	193	193	3141.5	52.0	193 (100.0%)												
Week 2																	
Placebo		190	3246.9	48.9	190 (96.4%)	0.7	12.0	-22.9	24.4								
Nera 18mg		188	3145.4	53.8	188 (97.4%)	12.2	11.8	-11.1	35.4	11.4	16.3	-20.6	43.5	0.4842			
Week 6																	
Placebo		196	3192.1	47.7	196 (99.5%)	-29.9	12.5	-54.4	-5.4								

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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 H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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		192	3139.1	52.9	192 (99.5%)	3.2	12.4	-21.1	27.4	33.1	17.0	-0.3	66.4	0.0521			
Week 12																	
Placebo		192	3189.4	48.7	192 (97.5%)	-39.0	15.0	-68.4	-9.5								
Nera 18mg		188	3118.8	54.4	188 (97.4%)	-19.2	14.8	-48.4	9.9	19.7	20.4	-20.3	59.8	0.3337			
Week 18																	
Placebo		189	3170.7	48.6	189 (95.9%)	-46.1	14.4	-74.4	-17.7								
Nera 18mg		188	3124.1	53.6	188 (97.4%)	-5.4	14.2	-33.3	22.5	40.7	19.6	2.2	79.2	0.0385	0.21	0.00	0.41
Week 26																	
Placebo		184	3131.6	50.1	184 (93.4%)	-77.5	16.2	-109.2	-45.7								
Nera 18mg		182	3103.3	54.6	182 (94.3%)	-38.7	16.0	-70.1	-7.4	38.7	22.0	-4.4	81.9	0.0785			
Week 36																	
Placebo		178	3111.4	50.1	178 (90.4%)	-112.6	17.6	-147.1	-78.1								
Nera 18mg		183	3057.8	54.6	183 (94.8%)	-79.8	17.2	-113.6	-46.0	32.8	23.8	-13.9	79.5	0.1685			
Week 44																	
Placebo		174	3068.1	52.0	174 (88.3%)	-143.5	18.7	-180.2	-106.7								
Nera 18mg		171	3059.9	56.6	171 (88.6%)	-92.3	18.4	-128.4	-56.2	51.1	25.3	1.4	100.9	0.0441	0.21	-0.00	0.42
Week 52																	
Placebo		173	3046.1	53.4	173 (87.8%)	-183.9	19.9	-223.1	-144.8								
Nera 18mg		177	3053.0	54.7	177 (91.7%)	-103.3	19.5	-141.6	-65.0	80.6	26.9	27.7	133.6	0.0029	0.31	0.10	0.52
Week 64																	
Placebo		163	3001.2	56.1	163 (82.7%)	-209.3	23.3	-255.2	-163.5								
Nera 18mg		164	3045.8	57.6	164 (85.0%)	-128.4	22.9	-173.5	-83.4	80.9	31.6	18.8	143.0	0.0107	0.27	0.06	0.49
Week 76																	
Placebo		119	3003.4	70.1	119 (60.4%)												
Nera 18mg		111	3112.2	75.7	111 (57.5%)												
Week 88																	
Placebo		35	3039.4	130.5	35 (17.8%)												
Nera 18mg		27	3412.0	174.7	27 (14.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	2852.0	NC	1 (0.5%)												
Type of AF therapy																	
Test for homogeneity (H0)^																	
Week 6														0.0119			

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Table H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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														0.4779			
Week 18														0.7242			
Week 26														0.6920			
Week 36														0.8455			
Week 44														0.2258			
Week 52														0.3493			
Week 64														0.8669			
Nintedanib																	
Baseline																	
Placebo	173	173	2971.3		61.0 172 (100.0%)												
Nera 18mg	178	178	2863.6		60.3 177 (100.0%)												
Week 2																	
Placebo		164	2977.7		62.6 164 (95.3%)	-17.0	12.3	-41.1	7.2								
Nera 18mg		172	2895.9		61.4 172 (97.2%)	30.4	12.0	6.8	54.0	47.4	17.2	13.6	81.2	0.0061	0.30	0.09	0.51
Week 6																	
Placebo		169	2968.6		61.2 169 (98.3%)	-21.8	12.8	-47.0	3.4								
Nera 18mg		176	2891.8		60.5 176 (99.4%)	23.0	12.6	-1.6	47.7	44.8	18.0	9.6	80.1	0.0128	0.27	0.06	0.48
Week 12																	
Placebo		164	2965.5		62.1 164 (95.3%)	-36.9	15.5	-67.3	-6.4								
Nera 18mg		168	2876.2		62.4 168 (94.9%)	-11.4	15.3	-41.4	18.5	25.4	21.8	-17.3	68.2	0.2427			
Week 18																	
Placebo		162	2966.9		61.4 162 (94.2%)	-42.8	14.9	-72.1	-13.5								
Nera 18mg		167	2875.5		61.7 167 (94.4%)	-8.2	14.6	-37.0	20.5	34.6	20.9	-6.4	75.7	0.0982			
Week 26																	
Placebo		154	2936.6		63.1 154 (89.5%)	-76.2	16.8	-109.2	-43.1								
Nera 18mg		159	2879.1		62.7 159 (89.8%)	-30.8	16.5	-63.2	1.7	45.4	23.6	-0.9	91.7	0.0549			
Week 36																	
Placebo		151	2918.5		63.2 151 (87.8%)	-121.6	18.2	-157.4	-85.8								
Nera 18mg		155	2857.4		63.0 155 (87.6%)	-68.8	17.9	-104.0	-33.6	52.8	25.6	2.6	103.0	0.0392	0.24	0.01	0.46
Week 44																	
Placebo		147	2878.7		65.3 147 (85.5%)	-151.4	19.4	-189.6	-113.3								
Nera 18mg		139	2892.7		66.2 139 (78.5%)	-85.1	19.3	-123.0	-47.3	66.3	27.3	12.6	120.0	0.0157	0.29	0.05	0.52
Week 52																	
Placebo		148	2850.3		65.2 148 (86.0%)	-179.1	20.7	-219.8	-138.4								
Nera 18mg		149	2841.9		65.1 149 (84.2%)	-105.3	20.5	-145.5	-65.1	73.8	29.1	16.6	131.0	0.0115	0.29	0.07	0.52

Study: 1305-0014. 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, 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 H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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 64																	
Placebo		134	2829.1	69.1	134 (77.9%)	-216.5	24.5	-264.5	-168.4								
Nera 18mg		133	2851.0	68.3	133 (75.1%)	-132.7	24.2	-180.3	-85.1	83.8	34.4	16.2	151.3	0.0151	0.30	0.06	0.54
Week 76																	
Placebo		102	2831.5	83.0	102 (59.3%)												
Nera 18mg		90	2893.5	87.9	90 (50.8%)												
Week 88																	
Placebo		29	2877.5	152.2	29 (16.9%)												
Nera 18mg		22	3120.5	244.4	22 (12.4%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Pirfenidone																	
Baseline																	
Placebo	133	133	2744.2	63.9	132 (100.0%)												
Nera 18mg	127	127	2821.9	59.8	127 (100.0%)												
Week 2																	
Placebo		129	2769.1	66.7	129 (97.7%)	13.5	14.0	-13.9	40.9								
Nera 18mg		125	2815.8	60.7	125 (98.4%)	-5.5	14.2	-33.3	22.3	-18.9	19.8	-57.9	20.0	0.3399			
Week 6																	
Placebo		130	2715.2	63.6	130 (98.5%)	-35.5	14.6	-64.3	-6.8								
Nera 18mg		124	2814.3	61.7	124 (97.6%)	-10.2	14.9	-39.5	19.1	25.3	20.9	-15.7	66.2	0.2264			
Week 12																	
Placebo		128	2739.0	64.5	128 (97.0%)	-37.4	17.6	-71.9	-2.8								
Nera 18mg		124	2804.8	63.6	124 (97.6%)	-23.7	17.8	-58.7	11.4	13.7	25.0	-35.4	62.9	0.5833			
Week 18																	
Placebo		124	2701.7	65.8	124 (93.9%)	-58.7	17.0	-92.1	-25.3								
Nera 18mg		126	2818.7	62.3	126 (99.2%)	-11.5	17.0	-44.9	21.9	47.3	24.0	0.1	94.4	0.0496	0.25	-0.00	0.50
Week 26																	
Placebo		125	2670.0	65.6	125 (94.7%)	-83.4	18.9	-120.6	-46.2								
Nera 18mg		119	2796.4	64.7	119 (93.7%)	-45.0	19.2	-82.7	-7.3	38.4	26.9	-14.5	91.3	0.1543			
Week 36																	
Placebo		116	2651.4	68.9	116 (87.9%)	-114.1	20.7	-154.8	-73.4								
Nera 18mg		119	2766.9	63.9	119 (93.7%)	-108.4	20.6	-149.0	-67.9	5.7	29.2	-51.7	63.1	0.8451			
Week 44																	
Placebo		114	2614.5	68.2	114 (86.4%)	-154.9	22.0	-198.2	-111.6								

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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 H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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		115	2731.3	65.6	115 (90.6%)	-127.5	22.0	-170.7	-84.3	27.5	31.1	-33.6	88.5	0.3776			
Week 52																	
Placebo		107	2647.7	71.2	107 (81.1%)	-194.8	23.7	-241.4	-148.1								
Nera 18mg		114	2745.9	66.2	114 (89.8%)	-128.4	23.5	-174.6	-82.2	66.4	33.4	0.8	131.9	0.0472	0.27	0.00	0.53
Week 64																	
Placebo		107	2574.3	73.9	107 (81.1%)	-217.1	27.6	-271.4	-162.8								
Nera 18mg		105	2742.6	71.5	105 (82.7%)	-174.8	27.6	-229.1	-120.5	42.3	39.0	-34.4	119.0	0.2790			
Week 76																	
Placebo		72	2603.5	85.4	72 (54.5%)												
Nera 18mg		76	2799.9	87.4	76 (59.8%)												
Week 88																	
Placebo		21	2713.7	169.4	21 (15.9%)												
Nera 18mg		14	3099.7	186.8	14 (11.0%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	2852.0	NC	1 (0.8%)												
Region																	
Test for homogeneity (H0)^																	
Week 6														0.8962			
Week 12														0.7165			
Week 18														0.2413			
Week 26														0.8963			
Week 36														0.6916			
Week 44														0.1552			
Week 52														0.8964			
Week 64														0.9287			
Europe																	
Baseline																	
Placebo	136	136	3043.0	65.6	136 (100.0%)												
Nera 18mg	136	136	2995.0	66.0	136 (100.0%)												
Week 2																	
Placebo		133	3042.3	66.6	133 (97.8%)	-6.0	13.9	-33.2	21.3								
Nera 18mg		132	2993.7	68.8	132 (97.1%)	15.1	13.9	-12.1	42.3	21.0	19.5	-17.3	59.4	0.2820			

Study: 1305-0014. 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, 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 H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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 6																	
Placebo		136	3002.8	65.0	136 (100.0%)	-36.0	14.4	-64.4	-7.7								
Nera 18mg		135	3004.5	67.8	135 (99.3%)	8.7	14.4	-19.7	37.0	44.7	20.4	4.7	84.7	0.0286	0.27	0.03	0.50
Week 12																	
Placebo		130	3042.0	66.1	130 (95.6%)	-25.2	17.5	-59.5	9.1								
Nera 18mg		130	2986.7	70.3	130 (95.6%)	-30.7	17.4	-64.8	3.5	-5.5	24.6	-53.7	42.7	0.8231			
Week 18																	
Placebo		129	3025.6	66.8	129 (94.9%)	-48.3	16.8	-81.3	-15.3								
Nera 18mg		131	2998.7	68.9	131 (96.3%)	-13.0	16.7	-45.7	19.7	35.3	23.6	-10.9	81.6	0.1342			
Week 26																	
Placebo		124	2980.1	67.4	124 (91.2%)	-78.9	18.9	-116.0	-41.8								
Nera 18mg		123	2995.0	70.1	123 (90.4%)	-52.6	18.8	-89.6	-15.7	26.3	26.5	-25.8	78.4	0.3218			
Week 36																	
Placebo		122	3001.9	67.4	122 (89.7%)	-102.9	20.3	-142.8	-63.0								
Nera 18mg		124	2920.8	69.6	124 (91.2%)	-117.1	20.1	-156.5	-77.7	-14.2	28.4	-70.0	41.6	0.6175			
Week 44																	
Placebo		120	2934.3	68.9	120 (88.2%)	-161.9	21.7	-204.6	-119.2								
Nera 18mg		112	2962.7	72.5	112 (82.4%)	-125.9	21.7	-168.5	-83.2	36.0	30.5	-24.0	96.0	0.2386			
Week 52																	
Placebo		117	2928.7	68.3	117 (86.0%)	-187.9	23.3	-233.6	-142.1								
Nera 18mg		118	2951.8	70.6	118 (86.8%)	-131.4	23.1	-176.7	-86.0	56.5	32.6	-7.5	120.5	0.0836			
Week 64																	
Placebo		110	2910.8	72.9	110 (80.9%)	-216.0	27.3	-269.6	-162.4								
Nera 18mg		106	2960.0	75.1	106 (77.9%)	-181.1	27.3	-234.8	-127.4	34.9	38.3	-40.4	110.2	0.3632			
Week 76																	
Placebo		80	2948.5	84.6	80 (58.8%)												
Nera 18mg		72	3006.3	97.0	72 (52.9%)												
Week 88																	
Placebo		22	2868.9	168.7	22 (16.2%)												
Nera 18mg		18	3188.5	237.4	18 (13.2%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Asia																	
Baseline																	
Placebo	72	72	2555.5	82.9	71 (100.0%)												

Study: 1305-0014. 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 H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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	79	79	2581.3	70.8	79 (100.0%)												
Week 2																	
Placebo		69	2565.7	85.9	69 (97.2%)	-10.0	19.3	-48.0	28.0								
Nera 18mg		77	2613.8	73.8	77 (97.5%)	22.8	18.3	-13.2	58.8	32.8	26.4	-19.0	84.6	0.2142			
Week 6																	
Placebo		69	2568.5	83.1	69 (97.2%)	-23.4	20.3	-63.3	16.4								
Nera 18mg		78	2605.3	73.4	78 (98.7%)	14.3	19.2	-23.4	51.9	37.7	27.6	-16.5	92.0	0.1727			
Week 12																	
Placebo		69	2544.0	84.2	69 (97.2%)	-46.6	24.2	-94.2	1.0								
Nera 18mg		74	2606.8	73.0	74 (93.7%)	5.9	23.2	-39.6	51.4	52.5	33.2	-12.6	117.7	0.1140			
Week 18																	
Placebo		64	2555.9	84.8	64 (90.1%)	-41.6	23.7	-88.1	4.8								
Nera 18mg		75	2616.5	74.2	75 (94.9%)	17.6	22.2	-25.9	61.2	59.3	32.1	-3.8	122.3	0.0653			
Week 26																	
Placebo		63	2527.7	84.7	63 (88.7%)	-69.7	26.6	-121.9	-17.6								
Nera 18mg		73	2602.6	76.8	73 (92.4%)	-6.0	24.8	-54.8	42.8	63.8	36.0	-6.9	134.4	0.0769			
Week 36																	
Placebo		61	2483.8	88.7	61 (85.9%)	-117.3	28.5	-173.4	-61.3								
Nera 18mg		70	2623.9	77.3	70 (88.6%)	-16.2	26.8	-68.7	36.4	101.2	38.7	25.1	177.2	0.0092	0.45	0.10	0.80
Week 44																	
Placebo		59	2449.8	92.3	59 (83.1%)	-137.7	30.7	-198.0	-77.5								
Nera 18mg		68	2592.4	79.4	68 (86.1%)	-53.2	28.7	-109.5	3.1	84.5	41.6	2.9	166.1	0.0424	0.36	0.01	0.71
Week 52																	
Placebo		59	2421.3	92.6	59 (83.1%)	-175.1	32.8	-239.5	-110.6								
Nera 18mg		67	2568.6	80.8	67 (84.8%)	-64.5	30.7	-124.8	-4.2	110.6	44.4	23.3	197.9	0.0132	0.44	0.09	0.79
Week 64																	
Placebo		55	2346.7	101.6	55 (77.5%)	-237.2	38.5	-312.8	-161.6								
Nera 18mg		62	2539.0	88.1	62 (78.5%)	-93.6	36.1	-164.4	-22.7	143.7	52.2	41.1	246.2	0.0062	0.50	0.13	0.87
Week 76																	
Placebo		37	2414.5	116.2	37 (52.1%)												
Nera 18mg		49	2590.8	101.9	49 (62.0%)												
Week 88																	
Placebo		11	2747.5	254.5	11 (15.5%)												
Nera 18mg		7	2630.1	367.6	7 (8.9%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												

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Table H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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		0	NC	NC	0 (0.0%)												
Canada and USA																	
Baseline																	
Placebo	75	75	2876.5	94.9	74 (100.0%)												
Nera 18mg	56	56	2886.6	103.1	56 (100.0%)												
Week 2																	
Placebo		69	2917.2	101.0	69 (93.2%)	9.4	19.0	-27.9	46.8								
Nera 18mg		56	2893.9	98.2	56 (100.0%)	7.3	21.3	-34.6	49.2	-2.1	28.6	-58.3	54.0	0.9401			
Week 6																	
Placebo		72	2879.5	98.4	72 (97.3%)	-15.0	19.7	-53.6	23.6								
Nera 18mg		55	2885.2	97.9	55 (98.2%)	-2.1	22.5	-46.3	42.1	12.9	29.9	-45.8	71.6	0.6660			
Week 12																	
Placebo		70	2878.9	97.5	70 (94.6%)	-47.0	23.6	-93.4	-0.6								
Nera 18mg		56	2888.5	100.3	56 (100.0%)	1.8	26.7	-50.6	54.2	48.8	35.6	-21.2	118.8	0.1712			
Week 18																	
Placebo		70	2829.7	98.8	70 (94.6%)	-50.7	22.6	-95.2	-6.2								
Nera 18mg		56	2879.0	104.1	56 (100.0%)	-7.7	25.6	-57.9	42.5	43.0	34.1	-24.1	110.1	0.2086			
Week 26																	
Placebo		69	2799.0	101.0	69 (93.2%)	-95.4	25.4	-145.2	-45.6								
Nera 18mg		53	2853.8	109.3	53 (94.6%)	-15.4	28.8	-72.0	41.1	80.0	38.4	4.7	155.3	0.0374	0.38	0.02	0.74
Week 36																	
Placebo		64	2743.6	104.0	64 (86.5%)	-157.8	27.5	-211.8	-103.9								
Nera 18mg		54	2837.4	107.5	54 (96.4%)	-67.0	30.6	-127.1	-7.0	90.8	41.1	10.1	171.5	0.0276	0.41	0.04	0.77
Week 44																	
Placebo		60	2718.6	105.0	60 (81.1%)	-180.8	29.6	-238.9	-122.7								
Nera 18mg		48	2822.3	113.0	48 (85.7%)	-99.2	33.1	-164.1	-34.2	81.6	44.4	-5.6	168.8	0.0664			
Week 52																	
Placebo		60	2747.2	107.4	60 (81.1%)	-221.5	31.7	-283.8	-159.2								
Nera 18mg		52	2761.7	108.8	52 (92.9%)	-128.4	35.0	-197.1	-59.7	93.1	47.2	0.4	185.8	0.0491	0.37	-0.00	0.74
Week 64																	
Placebo		58	2669.0	105.4	58 (78.4%)	-229.4	37.0	-302.2	-156.6								
Nera 18mg		47	2801.0	113.8	47 (83.9%)	-137.2	41.3	-218.3	-56.2	92.2	55.4	-16.8	201.1	0.0971			
Week 76																	
Placebo		41	2592.4	137.8	41 (55.4%)												
Nera 18mg		34	2889.3	144.0	34 (60.7%)												
Week 88																	

Study: 1305-0014. 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, 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 H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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		14	2628.1	198.2	14 (18.9%)												
Nera 18mg		9	3352.6	348.0	9 (16.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		1	2852.0	NC	1 (1.8%)												
Rest of the World																	
Baseline																	
Placebo	23	23	2845.0	146.6	23 (100.0%)												
Nera 18mg	34	34	2800.0	132.6	33 (100.0%)												
Week 2																	
Placebo		22	2846.3	149.0	22 (95.7%)	-9.1	33.8	-75.5	57.2								
Nera 18mg		32	2861.8	134.5	32 (97.0%)	12.5	28.1	-42.6	67.7	21.7	43.9	-64.6	108.0	0.6222			
Week 6																	
Placebo		22	2806.2	152.5	22 (95.7%)	-32.2	35.4	-101.7	37.3								
Nera 18mg		32	2825.1	140.1	32 (97.0%)	19.8	29.4	-38.1	77.6	52.0	46.0	-38.4	142.4	0.2591			
Week 12																	
Placebo		23	2800.5	145.8	23 (100.0%)	-45.7	41.6	-127.5	36.1								
Nera 18mg		32	2751.7	146.7	32 (97.0%)	-41.9	35.0	-110.6	26.9	3.8	54.4	-103.0	110.7	0.9440			
Week 18																	
Placebo		23	2769.2	138.8	23 (100.0%)	-77.0	39.9	-155.3	1.4								
Nera 18mg		31	2744.2	126.1	31 (93.9%)	-60.2	33.9	-126.8	6.3	16.7	52.3	-86.0	119.5	0.7494			
Week 26																	
Placebo		23	2786.0	152.7	23 (100.0%)	-60.5	44.4	-147.6	26.7								
Nera 18mg		29	2790.2	127.6	29 (87.9%)	-80.8	38.5	-156.5	-5.1	-20.4	58.8	-135.8	95.1	0.7292			
Week 36																	
Placebo		20	2746.5	143.3	20 (87.0%)	-93.1	48.5	-188.3	2.2								
Nera 18mg		26	2811.0	139.5	26 (78.8%)	-155.7	42.2	-238.6	-72.8	-62.6	64.3	-188.9	63.6	0.3302			
Week 44																	
Placebo		22	2793.1	149.7	22 (95.7%)	-63.4	51.1	-163.7	36.9								
Nera 18mg		26	2792.6	144.2	26 (78.8%)	-138.3	45.4	-227.4	-49.2	-74.9	68.3	-209.1	59.3	0.2733			
Week 52																	
Placebo		19	2884.7	160.6	19 (82.6%)	-95.8	55.6	-205.0	13.3								
Nera 18mg		26	2787.0	151.8	26 (78.8%)	-142.4	48.7	-238.2	-46.7	-46.6	73.9	-191.8	98.6	0.5287			
Week 64																	
Placebo		18	2805.6	160.3	18 (78.3%)	-121.0	65.3	-249.3	7.3								
Nera 18mg		23	2796.8	151.3	23 (69.7%)	-184.3	57.6	-297.6	-71.1	-63.4	87.1	-234.5	107.7	0.4672			

Study: 1305-0014. 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, 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 H.1.1.1.2.1: 11 Adjusted mean (SE) of absolute change from baseline in FVC [mL] (MMRM) over the whole trial - 18mg - FAS (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		16	2797.5	181.3	16 (69.6%)												
Nera 18mg		11	2870.5	209.3	11 (33.3%)												
Week 88																	
Placebo		3	3434.3	578.7	3 (13.0%)												
Nera 18mg		2	3034.5	154.5	2 (6.1%)												
Week 100																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0014. 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, 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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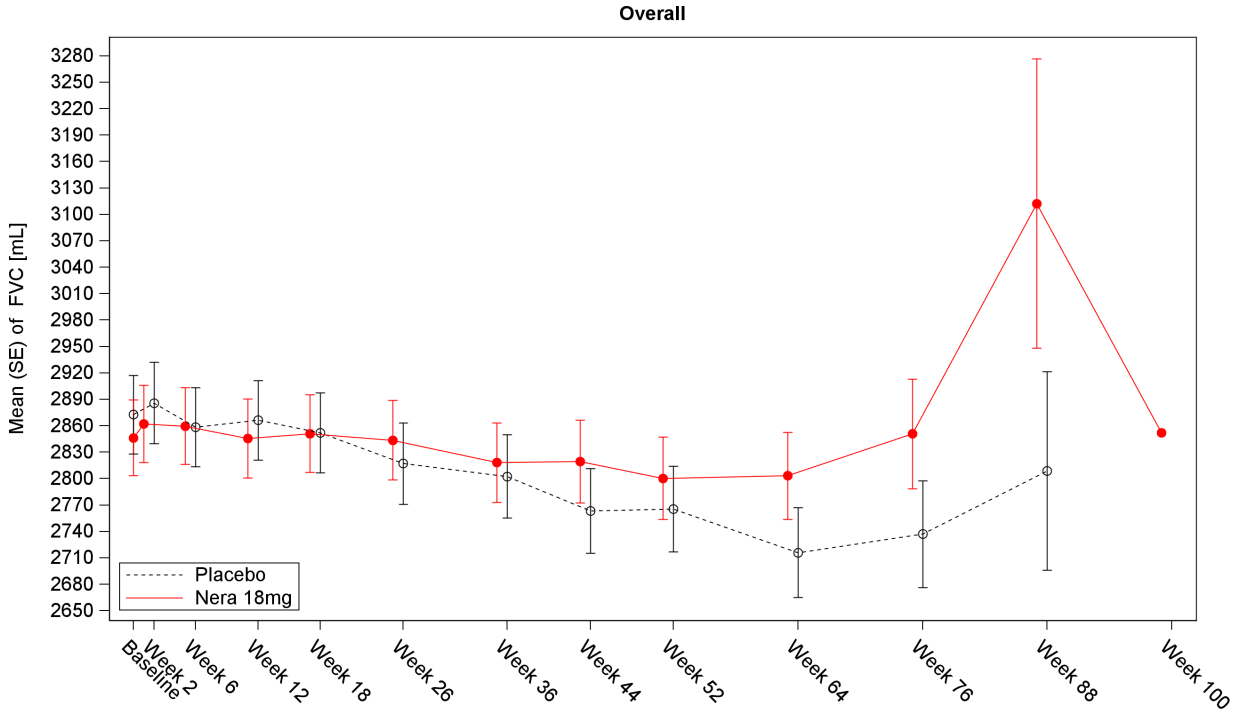

Number of patients

Placebo	306	293	299	292	286	279	267	261	255	241	174	50	0
Nera 18mg	305	297	300	292	293	278	274	254	263	238	166	36	1

Study: 1305-0014. Number of patients refers to the number of patients with observed data at visit.

Figure H.1.1.1.2.1: 11 Mean (SE) of FVC [mL]
over the whole trial - 18mg - FAS (AF background)

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Boehringer Ingelheim
BI Trial No.: x1305p3.hta

Figure H.1.1.1.2.1: 11

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H.1.1.2 Safety analysis

H.1.1.2.1 Safety analysis over the whole trial

H.1.1.2.1.1 Adverse events overall over the whole trial

Table H.1.1.2.1.1: 1 Proportion of patients with any adverse events over the whole trial - 18mg - TS (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	306	300	98.0	305	299	98.0	0.9954	1.00 (0.98, 1.02)	1.00 (0.32, 3.13)	-0.01 (-2.50, 2.48)	
Age											0.9229
<65 years	69	67	97.1	63	61	96.8	0.9264	1.00 (0.94, 1.06)	0.91 (0.12, 6.66)	-0.28 (-8.24, 7.16)	
>=65 years	237	233	98.3	242	238	98.3	0.9762	1.00 (0.98, 1.02)	1.02 (0.25, 4.13)	0.03 (-2.69, 2.80)	
Sex											0.8198
Male	269	264	98.1	255	250	98.0	0.9320	1.00 (0.98, 1.02)	0.95 (0.27, 3.31)	-0.10 (-2.86, 2.56)	
Female	37	36	97.3	50	49	98.0	0.8288	1.01 (0.94, 1.08)	1.36 (0.08, 22.50)	0.70 (-8.08, 11.95)	
Baseline FVC percent predicted											0.9699
<=70%	109	108	99.1	112	111	99.1	0.9846	1.00 (0.98, 1.03)	1.03 (0.06, 16.64)	0.02 (-4.04, 4.19)	
>70%	197	192	97.5	193	188	97.4	0.9738	1.00 (0.97, 1.03)	0.98 (0.28, 3.44)	-0.05 (-3.68, 3.53)	
Type of AF therapy											0.6205
Nintedanib	173	171	98.8	178	175	98.3	0.6757	0.99 (0.97, 1.02)	0.68 (0.11, 4.13)	-0.53 (-3.79, 2.63)	
Pirfenidone	133	129	97.0	127	124	97.6	0.7479	1.01 (0.97, 1.05)	1.28 (0.28, 5.84)	0.65 (-4.08, 5.38)	
Region											0.2537
Europe	136	132	97.1	136	134	98.5	0.4090	1.02 (0.98, 1.05)	2.03 (0.37, 11.27)	1.47 (-2.67, 5.98)	
Asia	72	70	97.2	79	78	98.7	0.5061	1.02 (0.97, 1.06)	2.23 (0.20, 25.11)	1.51 (-4.40, 8.39)	
Canada and USA	75	75	100.0	56	54	96.4	0.0991	0.96 (0.92, 1.01)	0.00 (NC, NC)	-3.57 (-12.12, 1.94)	
Rest of the World	23	23	100.0	34	33	97.1	0.4067	0.97 (0.92, 1.03)	0.00 (NC, NC)	-2.94 (-14.92, 11.57)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.1: 2 Proportion of patients with any adverse events (excluding disease-related events) over the whole trial - 18mg - TS (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	306	299	97.7	305	298	97.7	0.9951	1.00 (0.98, 1.02)	1.00 (0.35, 2.88)	-0.01 (-2.65, 2.63)	
Age											0.9220
<65 years	69	67	97.1	63	61	96.8	0.9264	1.00 (0.94, 1.06)	0.91 (0.12, 6.66)	-0.28 (-8.24, 7.16)	
>=65 years	237	232	97.9	242	237	97.9	0.9734	1.00 (0.97, 1.03)	1.02 (0.29, 3.58)	0.04 (-2.89, 3.02)	
Sex											0.8173
Male	269	263	97.8	255	249	97.6	0.9254	1.00 (0.97, 1.03)	0.95 (0.30, 2.97)	-0.12 (-3.06, 2.73)	
Female	37	36	97.3	50	49	98.0	0.8288	1.01 (0.94, 1.08)	1.36 (0.08, 22.50)	0.70 (-8.08, 11.95)	
Baseline FVC percent predicted											0.5634
<=70%	109	108	99.1	112	110	98.2	0.5771	0.99 (0.96, 1.02)	0.51 (0.05, 5.70)	-0.87 (-5.42, 3.43)	
>70%	197	191	97.0	193	188	97.4	0.7861	1.00 (0.97, 1.04)	1.18 (0.35, 3.94)	0.46 (-3.26, 4.20)	
Type of AF therapy											0.6428
Nintedanib	173	170	98.3	178	174	97.8	0.7310	0.99 (0.97, 1.02)	0.77 (0.17, 3.48)	-0.51 (-4.09, 3.00)	
Pirfenidone	133	129	97.0	127	124	97.6	0.7479	1.01 (0.97, 1.05)	1.28 (0.28, 5.84)	0.65 (-4.08, 5.38)	
Region											0.1251
Europe	136	131	96.3	136	134	98.5	0.2507	1.02 (0.98, 1.06)	2.56 (0.49, 13.41)	2.21 (-2.07, 6.97)	
Asia	72	70	97.2	79	78	98.7	0.5061	1.02 (0.97, 1.06)	2.23 (0.20, 25.11)	1.51 (-4.40, 8.39)	
Canada and USA	75	75	100.0	56	54	96.4	0.0991	0.96 (0.92, 1.01)	0.00 (NC, NC)	-3.57 (-12.12, 1.94)	
Rest of the World	23	23	100.0	34	32	94.1	0.2364	0.94 (0.87, 1.02)	0.00 (NC, NC)	-5.88 (-19.09, 9.05)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.1: 3 Proportion of patients with serious adverse events over the whole trial - 18mg - TS (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	306	133	43.5	305	133	43.6	0.9717	1.00 (0.84, 1.20)	1.01 (0.73, 1.38)	0.14 (-7.67, 7.96)	
Age											0.5270
<65 years	69	22	31.9	63	23	36.5	0.5756	1.15 (0.71, 1.84)	1.23 (0.60, 2.53)	4.62 (-11.29, 20.38)	
>=65 years	237	111	46.8	242	110	45.5	0.7618	0.97 (0.80, 1.18)	0.95 (0.66, 1.35)	-1.38 (-10.23, 7.49)	
Sex											0.3379
Male	269	124	46.1	255	116	45.5	0.8892	0.99 (0.82, 1.19)	0.98 (0.69, 1.38)	-0.61 (-9.07, 7.88)	
Female	37	9	24.3	50	17	34.0	0.3297	1.40 (0.70, 2.78)	1.60 (0.62, 4.15)	9.68 (-9.90, 27.34)	
Baseline FVC percent predicted											0.2757
<=70%	109	51	46.8	112	59	52.7	0.3813	1.13 (0.86, 1.47)	1.27 (0.75, 2.15)	5.89 (-7.19, 18.69)	
>70%	197	82	41.6	193	74	38.3	0.5083	0.92 (0.72, 1.18)	0.87 (0.58, 1.31)	-3.28 (-12.87, 6.40)	
Type of AF therapy											0.2161
Nintedanib	173	66	38.2	178	76	42.7	0.3856	1.12 (0.87, 1.44)	1.21 (0.79, 1.85)	4.55 (-5.68, 14.63)	
Pirfenidone	133	67	50.4	127	57	44.9	0.3753	0.89 (0.69, 1.15)	0.80 (0.49, 1.31)	-5.49 (-17.33, 6.57)	
Region											0.0540
Europe	136	48	35.3	136	64	47.1	0.0487	1.33 (1.00, 1.78)	1.63 (1.00, 2.65)	11.76 (0.08, 23.01)	
Asia	72	34	47.2	79	34	43.0	0.6057	0.91 (0.64, 1.30)	0.84 (0.44, 1.61)	-4.18 (-19.56, 11.43)	
Canada and USA	75	38	50.7	56	20	35.7	0.0883	0.70 (0.46, 1.07)	0.54 (0.27, 1.10)	-14.95 (-30.69, 2.19)	
Rest of the World	23	13	56.5	34	15	44.1	0.3581	0.78 (0.46, 1.31)	0.61 (0.21, 1.76)	-12.40 (-35.87, 13.26)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.1: 4 Proportion of patients with serious adverse events (excluding disease-related events) over the whole trial - 18mg - TS (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	306	129	42.2	305	124	40.7	0.7064	0.96 (0.80, 1.16)	0.94 (0.68, 1.30)	-1.50 (-9.25, 6.28)	
Age											0.5499
<65 years	69	22	31.9	63	22	34.9	0.7116	1.10 (0.68, 1.77)	1.15 (0.56, 2.37)	3.04 (-12.75, 18.78)	
>=65 years	237	107	45.1	242	102	42.1	0.5082	0.93 (0.76, 1.14)	0.89 (0.62, 1.27)	-3.00 (-11.78, 5.84)	
Sex											0.3774
Male	269	120	44.6	255	108	42.4	0.6025	0.95 (0.78, 1.15)	0.91 (0.65, 1.29)	-2.26 (-10.66, 6.20)	
Female	37	9	24.3	50	16	32.0	0.4341	1.32 (0.66, 2.64)	1.46 (0.56, 3.81)	7.68 (-11.71, 25.31)	
Baseline FVC percent predicted											0.4354
<=70%	109	50	45.9	112	54	48.2	0.7272	1.05 (0.79, 1.39)	1.10 (0.65, 1.86)	2.34 (-10.65, 15.22)	
>70%	197	79	40.1	193	70	36.3	0.4361	0.90 (0.70, 1.17)	0.85 (0.56, 1.28)	-3.83 (-13.33, 5.78)	
Type of AF therapy											0.3828
Nintedanib	173	64	37.0	178	69	38.8	0.7326	1.05 (0.80, 1.37)	1.08 (0.70, 1.66)	1.77 (-8.32, 11.79)	
Pirfenidone	133	65	48.9	127	55	43.3	0.3682	0.89 (0.68, 1.15)	0.80 (0.49, 1.30)	-5.57 (-17.38, 6.48)	
Region											0.0658
Europe	136	46	33.8	136	59	43.4	0.1054	1.28 (0.95, 1.74)	1.50 (0.92, 2.45)	9.56 (-1.99, 20.76)	
Asia	72	32	44.4	79	32	40.5	0.6248	0.91 (0.63, 1.32)	0.85 (0.45, 1.62)	-3.94 (-19.25, 11.57)	
Canada and USA	75	38	50.7	56	20	35.7	0.0883	0.70 (0.46, 1.07)	0.54 (0.27, 1.10)	-14.95 (-30.69, 2.19)	
Rest of the World	23	13	56.5	34	13	38.2	0.1739	0.68 (0.39, 1.18)	0.48 (0.16, 1.40)	-18.29 (-41.18, 7.56)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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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H.1.1.2.1.2 Adverse events by intensity over the whole trial

Table H.1.1.2.1.2: 1 Proportion of patients with any adverse events with CTCAE grade >=3 over the whole trial - 18mg - TS (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	306	106	34.6	305	117	38.4	0.3396	1.11 (0.90, 1.37)	1.17 (0.84, 1.63)	3.72 (-3.90, 11.28)	
Age											0.5501
<65 years	69	19	27.5	63	22	34.9	0.3598	1.27 (0.76, 2.11)	1.41 (0.67, 2.96)	7.38 (-8.26, 22.73)	
>=65 years	237	87	36.7	242	95	39.3	0.5658	1.07 (0.85, 1.34)	1.11 (0.77, 1.61)	2.55 (-6.11, 11.15)	
Sex											0.4303
Male	269	98	36.4	255	101	39.6	0.4539	1.09 (0.87, 1.35)	1.14 (0.80, 1.63)	3.18 (-5.10, 11.42)	
Female	37	8	21.6	50	16	32.0	0.2843	1.48 (0.71, 3.09)	1.71 (0.64, 4.56)	10.38 (-8.83, 27.57)	
Baseline FVC percent predicted											0.5757
<=70%	109	41	37.6	112	50	44.6	0.2885	1.19 (0.86, 1.63)	1.34 (0.78, 2.29)	7.03 (-5.88, 19.60)	
>70%	197	65	33.0	193	67	34.7	0.7197	1.05 (0.80, 1.39)	1.08 (0.71, 1.64)	1.72 (-7.62, 11.03)	
Type of AF therapy											0.1477
Nintedanib	173	57	32.9	178	74	41.6	0.0949	1.26 (0.96, 1.66)	1.45 (0.94, 2.24)	8.63 (-1.49, 18.48)	
Pirfenidone	133	49	36.8	127	43	33.9	0.6150	0.92 (0.66, 1.28)	0.88 (0.53, 1.46)	-2.98 (-14.39, 8.57)	
Region											0.0793
Europe	136	40	29.4	136	57	41.9	0.0314	1.43 (1.03, 1.98)	1.73 (1.05, 2.86)	12.50 (1.12, 23.44)	
Asia	72	25	34.7	79	31	39.2	0.5659	1.13 (0.74, 1.72)	1.21 (0.63, 2.36)	4.52 (-10.75, 19.38)	
Canada and USA	75	31	41.3	56	15	26.8	0.0844	0.65 (0.39, 1.08)	0.52 (0.25, 1.10)	-14.55 (-29.52, 1.99)	
Rest of the World	23	10	43.5	34	14	41.2	0.8629	0.95 (0.51, 1.75)	0.91 (0.31, 2.65)	-2.30 (-26.96, 22.07)	

Study: 1305-0014. 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 H.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 (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 p-value*	Odds ratio (95% CI)	Risk diff. p-value*	Risk diff. (95% CI)	Interaction p-value**
Overall	306	102	33.3	305	109	35.7	0.5320	1.07 (0.86, 1.33)	0.5320	1.11 (0.80, 1.55)	0.5320	2.40 (-5.11, 9.89)	
Age													0.5986
<65 years	69	19	27.5	63	21	33.3	0.4691	1.21 (0.72, 2.03)	0.4691	1.32 (0.63, 2.77)	0.4691	5.80 (-9.71, 21.12)	
>=65 years	237	83	35.0	242	88	36.4	0.7591	1.04 (0.82, 1.32)	0.7591	1.06 (0.73, 1.54)	0.7591	1.34 (-7.20, 9.85)	
Sex													0.4909
Male	269	94	34.9	255	94	36.9	0.6472	1.05 (0.84, 1.33)	0.6472	1.09 (0.76, 1.55)	0.6472	1.92 (-6.26, 10.08)	
Female	37	8	21.6	50	15	30.0	0.3810	1.39 (0.66, 2.92)	0.3810	1.55 (0.58, 4.18)	0.3810	8.38 (-10.63, 25.52)	
Baseline FVC percent predicted													0.7346
<=70%	109	40	36.7	112	46	41.1	0.5049	1.12 (0.80, 1.56)	0.5049	1.20 (0.70, 2.07)	0.5049	4.37 (-8.38, 16.91)	
>70%	197	62	31.5	193	63	32.6	0.8044	1.04 (0.78, 1.38)	0.8044	1.06 (0.69, 1.61)	0.8044	1.17 (-8.04, 10.36)	
Type of AF therapy													0.1678
Nintedanib	173	54	31.2	178	68	38.2	0.1693	1.22 (0.92, 1.63)	0.1693	1.36 (0.88, 2.12)	0.1693	6.99 (-2.96, 16.73)	
Pirfenidone	133	48	36.1	127	41	32.3	0.5179	0.89 (0.64, 1.25)	0.5179	0.84 (0.51, 1.41)	0.5179	-3.81 (-15.11, 7.68)	
Region													0.0794
Europe	136	39	28.7	136	54	39.7	0.0552	1.38 (0.99, 1.94)	0.0552	1.64 (0.99, 2.72)	0.0552	11.03 (-0.24, 21.92)	
Asia	72	22	30.6	79	28	35.4	0.5239	1.16 (0.73, 1.83)	0.5239	1.25 (0.63, 2.47)	0.5239	4.89 (-10.05, 19.37)	
Canada and USA	75	31	41.3	56	15	26.8	0.0844	0.65 (0.39, 1.08)	0.0844	0.52 (0.25, 1.10)	0.0844	-14.55 (-29.52, 1.99)	
Rest of the World	23	10	43.5	34	12	35.3	0.5335	0.81 (0.42, 1.56)	0.5335	0.71 (0.24, 2.10)	0.5335	-8.18 (-32.25, 16.32)	

Study: 1305-0014. 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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H.1.1.2.1.3 Adverse events leading to treatment discontinuation over the whole trial

Table H.1.1.2.1.3: 1 Proportion of patients with any adverse events leading to treatment discontinuation over the whole trial - 18mg - TS (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	306	42	13.7	305	56	18.4	0.1185	1.34 (0.93, 1.93)	1.41 (0.91, 2.19)	4.64 (-1.20, 10.46)	
Age											0.4162
<65 years	69	5	7.2	63	9	14.3	0.1895	1.97 (0.70, 5.57)	2.13 (0.67, 6.75)	7.04 (-3.81, 18.49)	
>=65 years	237	37	15.6	242	47	19.4	0.2730	1.24 (0.84, 1.84)	1.30 (0.81, 2.09)	3.81 (-3.03, 10.61)	
Sex											0.0302
Male	269	42	15.6	255	41	16.1	0.8841	1.03 (0.69, 1.53)	1.04 (0.65, 1.66)	0.47 (-5.80, 6.78)	
Female	37	0	0.0	50	15	30.0	0.0004	>10 (1.43, >99)	NC (NC, NC)	30.00 (15.61, 43.75)	
Baseline FVC percent predicted											0.5165
<=70%	109	17	15.6	112	20	17.9	0.6527	1.14 (0.63, 2.07)	1.18 (0.58, 2.39)	2.26 (-7.71, 12.14)	
>70%	197	25	12.7	193	36	18.7	0.1051	1.47 (0.92, 2.35)	1.58 (0.91, 2.75)	5.96 (-1.28, 13.22)	
Type of AF therapy											0.2732
Nintedanib	173	26	15.0	178	41	23.0	0.0564	1.53 (0.98, 2.39)	1.69 (0.98, 2.91)	8.00 (-0.25, 16.12)	
Pirfenidone	133	16	12.0	127	15	11.8	0.9566	0.98 (0.51, 1.90)	0.98 (0.46, 2.07)	-0.22 (-8.24, 7.90)	
Region											0.1008
Europe	136	13	9.6	136	29	21.3	0.0073	2.23 (1.21, 4.10)	2.56 (1.27, 5.18)	11.76 (3.17, 20.32)	
Asia	72	13	18.1	79	13	16.5	0.7948	0.91 (0.45, 1.83)	0.89 (0.38, 2.08)	-1.60 (-13.93, 10.47)	
Canada and USA	75	11	14.7	56	5	8.9	0.3211	0.61 (0.22, 1.65)	0.57 (0.19, 1.75)	-5.74 (-16.69, 6.35)	
Rest of the World	23	5	21.7	34	9	26.5	0.6839	1.22 (0.47, 3.17)	1.30 (0.37, 4.52)	4.73 (-18.67, 25.30)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	37	12.1	305	52	17.0	0.0824	1.41 (0.95, 2.08)	1.49 (0.95, 2.36)	4.96 (-0.66, 10.58)	
Age											0.2831
<65 years	69	4	5.8	63	9	14.3	0.1021	2.46 (0.80, 7.61)	2.71 (0.79, 9.28)	8.49 (-2.01, 19.74)	
>=65 years	237	33	13.9	242	43	17.8	0.2496	1.28 (0.84, 1.94)	1.34 (0.82, 2.19)	3.84 (-2.74, 10.39)	
Sex											0.0374
Male	269	37	13.8	255	38	14.9	0.7078	1.08 (0.71, 1.65)	1.10 (0.67, 1.79)	1.15 (-4.87, 7.22)	
Female	37	0	0.0	50	14	28.0	0.0007	>10 (1.33, >99)	NC (NC, NC)	28.00 (13.88, 41.67)	
Baseline FVC percent predicted											0.6512
<=70%	109	14	12.8	112	18	16.1	0.4955	1.25 (0.66, 2.39)	1.30 (0.61, 2.76)	3.23 (-6.22, 12.60)	
>70%	197	23	11.7	193	34	17.6	0.0968	1.51 (0.92, 2.46)	1.62 (0.91, 2.86)	5.94 (-1.11, 13.02)	
Type of AF therapy											0.0502
Nintedanib	173	21	12.1	178	40	22.5	0.0106	1.85 (1.14, 3.01)	2.10 (1.18, 3.73)	10.33 (2.40, 18.15)	
Pirfenidone	133	16	12.0	127	12	9.4	0.5021	0.79 (0.39, 1.59)	0.76 (0.35, 1.68)	-2.58 (-10.30, 5.19)	
Region											0.0660
Europe	136	10	7.4	136	27	19.9	0.0026	2.70 (1.36, 5.36)	3.12 (1.45, 6.74)	12.50 (4.38, 20.69)	
Asia	72	11	15.3	79	13	16.5	0.8433	1.08 (0.52, 2.25)	1.09 (0.46, 2.62)	1.18 (-10.83, 12.86)	
Canada and USA	75	11	14.7	56	5	8.9	0.3211	0.61 (0.22, 1.65)	0.57 (0.19, 1.75)	-5.74 (-16.69, 6.35)	
Rest of the World	23	5	21.7	34	7	20.6	0.9167	0.95 (0.34, 2.62)	0.93 (0.26, 3.40)	-1.15 (-23.77, 19.06)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)

Primary System Organ Class Preferred Term	Placebo N	 n	 %	Nera 18mg N	 n	 %
Overall	306	42	13.7	305	56	18.4
Gastrointestinal disorders		4	1.3		28	9.2
Diarrhoea		2	0.7		23	7.5
Nausea		2	0.7		4	1.3
Abdominal pain		0	0.0		2	0.7
Abdominal discomfort		0	0.0		1	0.3
Flatulence		1	0.3		0	0.0
Gastric dilatation		1	0.3		0	0.0
Gastrointestinal disorder		1	0.3		0	0.0
Gastrooesophageal reflux disease		1	0.3		0	0.0
Paraesthesia oral		0	0.0		1	0.3
General disorders and administration site conditions		11	3.6		9	3.0
Condition aggravated		7	2.3		6	2.0
Asthenia		0	0.0		3	1.0
Fatigue		3	1.0		0	0.0
Death		1	0.3		0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		13	4.2		7	2.3
Lung neoplasm malignant		2	0.7		1	0.3
Squamous cell carcinoma of skin		2	0.7		1	0.3
Lung adenocarcinoma		2	0.7		0	0.0
Prostate cancer		2	0.7		0	0.0
Acute leukaemia		0	0.0		1	0.3
Chronic myeloid leukaemia		1	0.3		0	0.0
Hodgkin’s disease		1	0.3		0	0.0
Lip squamous cell carcinoma		1	0.3		0	0.0
Lung cancer metastatic		0	0.0		1	0.3
Neuroendocrine carcinoma of the skin		1	0.3		0	0.0
Oesophageal neoplasm		0	0.0		1	0.3
Sarcomatoid carcinoma		0	0.0		1	0.3
Squamous cell carcinoma of lung		0	0.0		1	0.3
Transitional cell carcinoma		1	0.3		0	0.0
Respiratory, thoracic and mediastinal disorders		6	2.0		1	0.3
Dyspnoea		3	1.0		0	0.0
Cough		1	0.3		0	0.0
Hepatopulmonary syndrome		1	0.3		0	0.0
Pneumothorax		0	0.0		1	0.3
Respiratory failure		1	0.3		0	0.0

Study: 1305-0014. 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 H.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 (AF background)

Primary System Organ Class Preferred Term	Placebo N	 n	 %	Nera 18mg N	 n	 %
Infections and infestations		2	0.7		3	1.0
Bacterial infection		1	0.3		0	0.0
Herpes zoster		0	0.0		1	0.3
Pneumonia bacterial		0	0.0		1	0.3
Septic shock		0	0.0		1	0.3
Urinary tract infection		1	0.3		0	0.0
Nervous system disorders		3	1.0		2	0.7
Cerebral haemorrhage		1	0.3		0	0.0
Dizziness		1	0.3		0	0.0
Dysgeusia		0	0.0		1	0.3
Encephalopathy		1	0.3		0	0.0
Hypoaesthesia		0	0.0		1	0.3
Psychiatric disorders		0	0.0		5	1.6
Anxiety		0	0.0		3	1.0
Suicidal ideation		0	0.0		2	0.7
Vascular disorders		1	0.3		3	1.0
Vasculitis		0	0.0		3	1.0
Granulomatosis with polyangiitis		1	0.3		0	0.0
Cardiac disorders		1	0.3		2	0.7
Coronary artery disease		0	0.0		1	0.3
Heart failure with reduced ejection fraction		0	0.0		1	0.3
Palpitations		1	0.3		0	0.0
Metabolism and nutrition disorders		1	0.3		2	0.7
Abnormal loss of weight		0	0.0		1	0.3
Decreased appetite		0	0.0		1	0.3
Hyponatraemia		1	0.3		0	0.0
Hepatobiliary disorders		2	0.7		0	0.0
Hepatic function abnormal		1	0.3		0	0.0
Suspected drug-induced liver injury		1	0.3		0	0.0
Investigations		0	0.0		2	0.7
Weight decreased		0	0.0		2	0.7
Musculoskeletal and connective tissue disorders		1	0.3		1	0.3
Arthralgia		1	0.3		1	0.3
Myalgia		1	0.3		0	0.0

Study: 1305-0014. 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 H.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 (AF background)

Primary System Organ Class Preferred Term	Placebo N	 n	 %	Nera 18mg N	 n	 %
Blood and lymphatic system disorders		1	0.3		0	0.0
Anaemia		1	0.3		0	0.0
Injury, poisoning and procedural complications		1	0.3		0	0.0
Cervical vertebral fracture		1	0.3		0	0.0
Skin and subcutaneous tissue disorders		0	0.0		1	0.3
Rash		0	0.0		1	0.3

Study: 1305-0014. 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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H.1.1.2.1.4 Adverse events on SOC level over the whole trial

Table H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (AF 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	306	14	4.6	305	9	3.0	0.2915	0.64 (0.28, 1.47)	0.63 (0.27, 1.49)	-1.62 (-4.89, 1.52)	
Age											
<65 years	69	3	4.3	63	1	1.6					
>=65 years	237	11	4.6	242	8	3.3					
Sex											
Male	269	11	4.1	255	8	3.1					
Female	37	3	8.1	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	5	4.6	112	3	2.7					
>70%	197	9	4.6	193	6	3.1					
Type of AF therapy											
Nintedanib	173	7	4.0	178	6	3.4					
Pirfenidone	133	7	5.3	127	3	2.4					
Region											
Europe	136	6	4.4	136	3	2.2					
Asia	72	2	2.8	79	1	1.3					
Canada and USA	75	5	6.7	56	5	8.9					
Rest of the World	23	1	4.3	34	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	42	13.7	305	42	13.8	0.9871	1.00 (0.67, 1.49)	1.00 (0.63, 1.59)	0.05 (-5.45, 5.55)	
Age											
<65 years	69	11	15.9	63	4	6.3					
>=65 years	237	31	13.1	242	38	15.7					
Sex											
Male	269	40	14.9	255	37	14.5					
Female	37	2	5.4	50	5	10.0					
Baseline FVC percent predicted											
<=70%	109	19	17.4	112	16	14.3					
>70%	197	23	11.7	193	26	13.5					
Type of AF therapy											
Nintedanib	173	27	15.6	178	25	14.0					
Pirfenidone	133	15	11.3	127	17	13.4					
Region											
Europe	136	14	10.3	136	20	14.7					
Asia	72	10	13.9	79	7	8.9					
Canada and USA	75	13	17.3	56	9	16.1					
Rest of the World	23	5	21.7	34	6	17.6					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	14	4.6	305	16	5.2	0.7012	1.15 (0.57, 2.31)	1.15 (0.55, 2.41)	0.67 (-2.89, 4.27)	
Age											
<65 years	69	2	2.9	63	1	1.6					
>=65 years	237	12	5.1	242	15	6.2					
Sex											
Male	269	13	4.8	255	11	4.3					
Female	37	1	2.7	50	5	10.0					
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	6	5.4					
>70%	197	12	6.1	193	10	5.2					
Type of AF therapy											
Nintedanib	173	8	4.6	178	8	4.5					
Pirfenidone	133	6	4.5	127	8	6.3					
Region											
Europe	136	5	3.7	136	8	5.9					
Asia	72	1	1.4	79	3	3.8					
Canada and USA	75	7	9.3	56	2	3.6					
Rest of the World	23	1	4.3	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	23	7.5	305	18	5.9	0.4251	0.79 (0.43, 1.43)	0.77 (0.41, 1.46)	-1.61 (-5.72, 2.45)	
Age											
<65 years	69	4	5.8	63	5	7.9					
>=65 years	237	19	8.0	242	13	5.4					
Sex											
Male	269	21	7.8	255	17	6.7					
Female	37	2	5.4	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	12	11.0	112	6	5.4					
>70%	197	11	5.6	193	12	6.2					
Type of AF therapy											
Nintedanib	173	13	7.5	178	9	5.1					
Pirfenidone	133	10	7.5	127	9	7.1					
Region											
Europe	136	16	11.8	136	13	9.6					
Asia	72	4	5.6	79	2	2.5					
Canada and USA	75	1	1.3	56	1	1.8					
Rest of the World	23	2	8.7	34	2	5.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (AF background)
SOC: Gastrointestinal 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	306	139	45.4	305	194	63.6	<.0001	1.40 (1.21, 1.63)	2.10 (1.52, 2.90)	18.18 (10.31, 25.74)	
Age											0.6922
<65 years	69	30	43.5	63	36	57.1	0.1168	1.31 (0.93, 1.85)	1.73 (0.87, 3.45)	13.66 (-3.32, 29.58)	
>=65 years	237	109	46.0	242	158	65.3	<.0001	1.42 (1.20, 1.68)	2.21 (1.53, 3.19)	19.30 (10.42, 27.75)	
Sex											0.2622
Male	269	122	45.4	255	155	60.8	0.0004	1.34 (1.14, 1.58)	1.87 (1.32, 2.64)	15.43 (6.89, 23.66)	
Female	37	17	45.9	50	39	78.0	0.0020	1.70 (1.16, 2.48)	4.17 (1.64, 10.58)	32.05 (11.54, 49.60)	
Baseline FVC percent predicted											0.2668
<=70%	109	50	45.9	112	64	57.1	0.0937	1.25 (0.96, 1.61)	1.57 (0.93, 2.68)	11.27 (-1.87, 23.88)	
>70%	197	89	45.2	193	130	67.4	<.0001	1.49 (1.24, 1.79)	2.50 (1.66, 3.78)	22.18 (12.37, 31.39)	
Type of AF therapy											0.8073
Nintedanib	173	91	52.6	178	132	74.2	<.0001	1.41 (1.19, 1.66)	2.59 (1.65, 4.05)	21.56 (11.51, 31.02)	
Pirfenidone	133	48	36.1	127	62	48.8	0.0378	1.35 (1.01, 1.80)	1.69 (1.03, 2.77)	12.73 (0.72, 24.25)	
Region											0.5243
Europe	136	66	48.5	136	90	66.2	0.0033	1.36 (1.10, 1.68)	2.08 (1.27, 3.38)	17.65 (5.89, 28.73)	
Asia	72	23	31.9	79	45	57.0	0.0020	1.78 (1.21, 2.63)	2.82 (1.45, 5.49)	25.02 (9.15, 39.14)	
Canada and USA	75	39	52.0	56	36	64.3	0.1597	1.24 (0.92, 1.66)	1.66 (0.82, 3.38)	12.29 (-4.77, 28.11)	
Rest of the World	23	11	47.8	34	23	67.6	0.1345	1.41 (0.87, 2.30)	2.28 (0.77, 6.78)	19.82 (-5.70, 42.63)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	92	30.1	305	98	32.1	0.5812	1.07 (0.84, 1.35)	1.10 (0.78, 1.55)	2.07 (-5.26, 9.36)	
Age											
<65 years	69	17	24.6	63	14	22.2					
>=65 years	237	75	31.6	242	84	34.7					
Sex											
Male	269	86	32.0	255	82	32.2					
Female	37	6	16.2	50	16	32.0					
Baseline FVC percent predicted											
<=70%	109	36	33.0	112	40	35.7					
>70%	197	56	28.4	193	58	30.1					
Type of AF therapy											
Nintedanib	173	52	30.1	178	54	30.3					
Pirfenidone	133	40	30.1	127	44	34.6					
Region											
Europe	136	42	30.9	136	50	36.8					
Asia	72	20	27.8	79	14	17.7					
Canada and USA	75	29	38.7	56	23	41.1					
Rest of the World	23	1	4.3	34	11	32.4					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	16	5.2	305	10	3.3	0.2325	0.63 (0.29, 1.36)	0.61 (0.27, 1.38)	-1.95 (-5.38, 1.36)	
Age											
<65 years	69	4	5.8	63	2	3.2					
>=65 years	237	12	5.1	242	8	3.3					
Sex											
Male	269	14	5.2	255	7	2.7					
Female	37	2	5.4	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	1	0.9	112	3	2.7					
>70%	197	15	7.6	193	7	3.6					
Type of AF therapy											
Nintedanib	173	13	7.5	178	7	3.9					
Pirfenidone	133	3	2.3	127	3	2.4					
Region											
Europe	136	3	2.2	136	4	2.9					
Asia	72	8	11.1	79	4	5.1					
Canada and USA	75	3	4.0	56	1	1.8					
Rest of the World	23	2	8.7	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	208	68.0	305	202	66.2	0.6463	0.97 (0.87, 1.09)	0.92 (0.66, 1.30)	-1.74 (-9.15, 5.68)	
Age											
<65 years	69	50	72.5	63	46	73.0					
>=65 years	237	158	66.7	242	156	64.5					
Sex											
Male	269	178	66.2	255	165	64.7					
Female	37	30	81.1	50	37	74.0					
Baseline FVC percent predicted											
<=70%	109	73	67.0	112	69	61.6					
>70%	197	135	68.5	193	133	68.9					
Type of AF therapy											
Nintedanib	173	119	68.8	178	109	61.2					
Pirfenidone	133	89	66.9	127	93	73.2					
Region											
Europe	136	90	66.2	136	94	69.1					
Asia	72	48	66.7	79	51	64.6					
Canada and USA	75	52	69.3	56	37	66.1					
Rest of the World	23	18	78.3	34	20	58.8					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	43	14.1	305	47	15.4	0.6359	1.10 (0.75, 1.61)	1.11 (0.71, 1.74)	1.36 (-4.29, 7.01)	
Age											
<65 years	69	7	10.1	63	7	11.1					
>=65 years	237	36	15.2	242	40	16.5					
Sex											
Male	269	37	13.8	255	39	15.3					
Female	37	6	16.2	50	8	16.0					
Baseline FVC percent predicted											
<=70%	109	15	13.8	112	10	8.9					
>70%	197	28	14.2	193	37	19.2					
Type of AF therapy											
Nintedanib	173	23	13.3	178	35	19.7					
Pirfenidone	133	20	15.0	127	12	9.4					
Region											
Europe	136	18	13.2	136	19	14.0					
Asia	72	3	4.2	79	11	13.9					
Canada and USA	75	15	20.0	56	11	19.6					
Rest of the World	23	7	30.4	34	6	17.6					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	68	22.2	305	83	27.2	0.1527	1.22 (0.93, 1.62)	1.31 (0.90, 1.89)	4.99 (-1.85, 11.78)	
Age											
<65 years	69	10	14.5	63	12	19.0					
>=65 years	237	58	24.5	242	71	29.3					
Sex											
Male	269	59	21.9	255	71	27.8					
Female	37	9	24.3	50	12	24.0					
Baseline FVC percent predicted											
<=70%	109	23	21.1	112	31	27.7					
>70%	197	45	22.8	193	52	26.9					
Type of AF therapy											
Nintedanib	173	41	23.7	178	59	33.1					
Pirfenidone	133	27	20.3	127	24	18.9					
Region											
Europe	136	25	18.4	136	39	28.7					
Asia	72	14	19.4	79	23	29.1					
Canada and USA	75	22	29.3	56	15	26.8					
Rest of the World	23	7	30.4	34	6	17.6					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (AF background)
SOC: Metabolism and nutrition 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	306	59	19.3	305	49	16.1	0.2975	0.83 (0.59, 1.18)	0.80 (0.53, 1.22)	-3.22 (-9.27, 2.85)	
Age											
<65 years	69	10	14.5	63	5	7.9					
>=65 years	237	49	20.7	242	44	18.2					
Sex											
Male	269	47	17.5	255	42	16.5					
Female	37	12	32.4	50	7	14.0					
Baseline FVC percent predicted											
<=70%	109	26	23.9	112	22	19.6					
>70%	197	33	16.8	193	27	14.0					
Type of AF therapy											
Nintedanib	173	28	16.2	178	24	13.5					
Pirfenidone	133	31	23.3	127	25	19.7					
Region											
Europe	136	20	14.7	136	21	15.4					
Asia	72	20	27.8	79	18	22.8					
Canada and USA	75	15	20.0	56	7	12.5					
Rest of the World	23	4	17.4	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	70	22.9	305	85	27.9	0.1561	1.22 (0.93, 1.60)	1.30 (0.90, 1.88)	4.99 (-1.91, 11.84)	
Age											
<65 years	69	19	27.5	63	15	23.8					
>=65 years	237	51	21.5	242	70	28.9					
Sex											
Male	269	60	22.3	255	64	25.1					
Female	37	10	27.0	50	21	42.0					
Baseline FVC percent predicted											
<=70%	109	19	17.4	112	22	19.6					
>70%	197	51	25.9	193	63	32.6					
Type of AF therapy											
Nintedanib	173	38	22.0	178	45	25.3					
Pirfenidone	133	32	24.1	127	40	31.5					
Region											
Europe	136	35	25.7	136	41	30.1					
Asia	72	13	18.1	79	16	20.3					
Canada and USA	75	16	21.3	56	21	37.5					
Rest of the World	23	6	26.1	34	7	20.6					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	25	8.2	305	19	6.2	0.3536	0.76 (0.43, 1.36)	0.75 (0.40, 1.39)	-1.94 (-6.17, 2.24)	
Age											
<65 years	69	1	1.4	63	5	7.9					
>=65 years	237	24	10.1	242	14	5.8					
Sex											
Male	269	24	8.9	255	16	6.3					
Female	37	1	2.7	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	8	7.3	112	4	3.6					
>70%	197	17	8.6	193	15	7.8					
Type of AF therapy											
Nintedanib	173	14	8.1	178	9	5.1					
Pirfenidone	133	11	8.3	127	10	7.9					
Region											
Europe	136	7	5.1	136	8	5.9					
Asia	72	6	8.3	79	3	3.8					
Canada and USA	75	8	10.7	56	6	10.7					
Rest of the World	23	4	17.4	34	2	5.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	66	21.6	305	70	23.0	0.6813	1.06 (0.79, 1.43)	1.08 (0.74, 1.59)	1.38 (-5.21, 7.97)	
Age											
<65 years	69	14	20.3	63	10	15.9					
>=65 years	237	52	21.9	242	60	24.8					
Sex											
Male	269	60	22.3	255	59	23.1					
Female	37	6	16.2	50	11	22.0					
Baseline FVC percent predicted											
<=70%	109	20	18.3	112	31	27.7					
>70%	197	46	23.4	193	39	20.2					
Type of AF therapy											
Nintedanib	173	36	20.8	178	38	21.3					
Pirfenidone	133	30	22.6	127	32	25.2					
Region											
Europe	136	36	26.5	136	32	23.5					
Asia	72	5	6.9	79	12	15.2					
Canada and USA	75	20	26.7	56	15	26.8					
Rest of the World	23	5	21.7	34	11	32.4					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	63	20.6	305	61	20.0	0.8566	0.97 (0.71, 1.33)	0.96 (0.65, 1.43)	-0.59 (-6.97, 5.80)	
Age											
<65 years	69	11	15.9	63	11	17.5					
>=65 years	237	52	21.9	242	50	20.7					
Sex											
Male	269	52	19.3	255	46	18.0					
Female	37	11	29.7	50	15	30.0					
Baseline FVC percent predicted											
<=70%	109	25	22.9	112	25	22.3					
>70%	197	38	19.3	193	36	18.7					
Type of AF therapy											
Nintedanib	173	30	17.3	178	36	20.2					
Pirfenidone	133	33	24.8	127	25	19.7					
Region											
Europe	136	30	22.1	136	29	21.3					
Asia	72	17	23.6	79	15	19.0					
Canada and USA	75	12	16.0	56	13	23.2					
Rest of the World	23	4	17.4	34	4	11.8					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	22	7.2	305	24	7.9	0.7503	1.09 (0.63, 1.91)	1.10 (0.60, 2.01)	0.68 (-3.60, 4.98)	
Age											
<65 years	69	3	4.3	63	3	4.8					
>=65 years	237	19	8.0	242	21	8.7					
Sex											
Male	269	18	6.7	255	21	8.2					
Female	37	4	10.8	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	7	6.4	112	4	3.6					
>70%	197	15	7.6	193	20	10.4					
Type of AF therapy											
Nintedanib	173	14	8.1	178	18	10.1					
Pirfenidone	133	8	6.0	127	6	4.7					
Region											
Europe	136	9	6.6	136	12	8.8					
Asia	72	6	8.3	79	8	10.1					
Canada and USA	75	6	8.0	56	2	3.6					
Rest of the World	23	1	4.3	34	2	5.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	7	2.3	305	23	7.5	0.0027	3.30 (1.44, 7.57)	3.48 (1.47, 8.25)	5.25 (1.84, 8.96)	
Age											0.3960
<65 years	69	0	0.0	63	4	6.3	0.0540	9.84 (0.54, >99)	NC (NC, NC)	6.35 (-0.18, 15.22)	
>=65 years	237	7	3.0	242	19	7.9	0.0180	2.66 (1.14, 6.21)	2.80 (1.15, 6.79)	4.90 (0.80, 9.25)	
Sex											0.7247
Male	269	7	2.6	255	20	7.8	0.0067	3.01 (1.30, 7.01)	3.19 (1.32, 7.67)	5.24 (1.44, 9.42)	
Female	37	0	0.0	50	3	6.0	0.2115	5.22 (0.28, 98.00)	NC (NC, NC)	6.00 (-4.20, 16.22)	
Baseline FVC percent predicted											0.2646
<=70%	109	4	3.7	112	8	7.1	0.2546	1.95 (0.60, 6.28)	2.02 (0.59, 6.91)	3.47 (-2.94, 10.18)	
>70%	197	3	1.5	193	15	7.8	0.0033	5.10 (1.50, 17.35)	5.45 (1.55, 19.14)	6.25 (2.10, 11.01)	
Type of AF therapy											0.2416
Nintedanib	173	5	2.9	178	11	6.2	0.1396	2.14 (0.76, 6.03)	2.21 (0.75, 6.51)	3.29 (-1.28, 8.13)	
Pirfenidone	133	2	1.5	127	12	9.4	0.0046	6.28 (1.43, 27.52)	6.83 (1.50, 31.18)	7.95 (2.45, 14.38)	
Region											0.3475
Europe	136	1	0.7	136	10	7.4	0.0056	10.00 (1.30, 77.05)	>10 (1.35, 84.90)	6.62 (1.94, 12.30)	
Asia	72	2	2.8	79	4	5.1	0.4727	1.82 (0.34, 9.65)	1.87 (0.33, 10.51)	2.29 (-5.17, 9.80)	
Canada and USA	75	2	2.7	56	6	10.7	0.0570	4.02 (0.84, 19.17)	4.38 (0.85, 22.59)	8.05 (-0.64, 18.97)	
Rest of the World	23	2	8.7	34	3	8.8	0.9866	1.01 (0.18, 5.61)	1.02 (0.16, 6.61)	0.13 (-18.87, 15.60)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	148	48.4	305	128	42.0	0.1120	0.87 (0.73, 1.03)	0.77 (0.56, 1.06)	-6.40	(-14.17, 1.48)	
Age												
<65 years	69	35	50.7	63	22	34.9						
>=65 years	237	113	47.7	242	106	43.8						
Sex												
Male	269	136	50.6	255	106	41.6						
Female	37	12	32.4	50	22	44.0						
Baseline FVC percent predicted												
<=70%	109	66	60.6	112	49	43.8						
>70%	197	82	41.6	193	79	40.9						
Type of AF therapy												
Nintedanib	173	85	49.1	178	69	38.8						
Pirfenidone	133	63	47.4	127	59	46.5						
Region												
Europe	136	65	47.8	136	56	41.2						
Asia	72	25	34.7	79	28	35.4						
Canada and USA	75	43	57.3	56	29	51.8						
Rest of the World	23	15	65.2	34	15	44.1						

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	37	12.1	305	55	18.0	0.0401	1.49 (1.01, 2.19)	1.60 (1.02, 2.51)	5.94 (0.25, 11.63)	
Age											0.9428
<65 years	69	5	7.2	63	7	11.1	0.4404	1.53 (0.51, 4.59)	1.60 (0.48, 5.32)	3.86 (-6.43, 14.76)	
>=65 years	237	32	13.5	242	48	19.8	0.0632	1.47 (0.98, 2.21)	1.59 (0.97, 2.58)	6.33 (-0.37, 12.98)	
Sex											0.1937
Male	269	35	13.0	255	45	17.6	0.1403	1.36 (0.90, 2.04)	1.43 (0.89, 2.31)	4.64 (-1.55, 10.86)	
Female	37	2	5.4	50	10	20.0	0.0510	3.70 (0.86, 15.89)	4.38 (0.90, 21.34)	14.59 (-0.50, 28.21)	
Baseline FVC percent predicted											0.5549
<=70%	109	11	10.1	112	14	12.5	0.5720	1.24 (0.59, 2.61)	1.27 (0.55, 2.94)	2.41 (-6.21, 10.99)	
>70%	197	26	13.2	193	41	21.2	0.0352	1.61 (1.03, 2.52)	1.77 (1.04, 3.04)	8.05 (0.54, 15.53)	
Type of AF therapy											0.0499
Nintedanib	173	15	8.7	178	34	19.1	0.0048	2.20 (1.25, 3.90)	2.49 (1.30, 4.76)	10.43 (3.19, 17.66)	
Pirfenidone	133	22	16.5	127	21	16.5	0.9990	1.00 (0.58, 1.73)	1.00 (0.52, 1.92)	-0.01 (-9.07, 9.15)	
Region											0.1503
Europe	136	24	17.6	136	23	16.9	0.8726	0.96 (0.57, 1.61)	0.95 (0.51, 1.78)	-0.74 (-9.77, 8.31)	
Asia	72	5	6.9	79	14	17.7	0.0461	2.55 (0.97, 6.73)	2.89 (0.98, 8.47)	10.78 (0.01, 21.39)	
Canada and USA	75	4	5.3	56	9	16.1	0.0420	3.01 (0.98, 9.29)	3.40 (0.99, 11.68)	10.74 (0.15, 22.91)	
Rest of the World	23	4	17.4	34	9	26.5	0.4229	1.52 (0.53, 4.36)	1.71 (0.46, 6.40)	9.08 (-13.96, 28.71)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	30	9.8	305	27	8.9	0.6860	0.90 (0.55, 1.48)	0.89 (0.52, 1.54)	-0.95 (-5.65, 3.74)	
Age											
<65 years	69	6	8.7	63	3	4.8					
>=65 years	237	24	10.1	242	24	9.9					
Sex											
Male	269	28	10.4	255	23	9.0					
Female	37	2	5.4	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	8	7.3	112	5	4.5					
>70%	197	22	11.2	193	22	11.4					
Type of AF therapy											
Nintedanib	173	16	9.2	178	17	9.6					
Pirfenidone	133	14	10.5	127	10	7.9					
Region											
Europe	136	12	8.8	136	16	11.8					
Asia	72	8	11.1	79	6	7.6					
Canada and USA	75	8	10.7	56	1	1.8					
Rest of the World	23	2	8.7	34	4	11.8					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	20	6.5	305	18	5.9	0.7455	0.90 (0.49, 1.67)	0.90 (0.46, 1.73)	-0.63 (-4.60, 3.31)	
Age											
<65 years	69	7	10.1	63	3	4.8					
>=65 years	237	13	5.5	242	15	6.2					
Sex											
Male	269	20	7.4	255	15	5.9					
Female	37	0	0.0	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	10	9.2	112	8	7.1					
>70%	197	10	5.1	193	10	5.2					
Type of AF therapy											
Nintedanib	173	10	5.8	178	9	5.1					
Pirfenidone	133	10	7.5	127	9	7.1					
Region											
Europe	136	6	4.4	136	11	8.1					
Asia	72	4	5.6	79	2	2.5					
Canada and USA	75	7	9.3	56	4	7.1					
Rest of the World	23	3	13.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	9	2.9	305	12	3.9	0.5004	1.34 (0.57, 3.13)	1.35 (0.56, 3.26)	0.99 (-2.06, 4.13)	
Age											
<65 years	69	2	2.9	63	0	0.0					
>=65 years	237	7	3.0	242	12	5.0					
Sex											
Male	269	8	3.0	255	11	4.3					
Female	37	1	2.7	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	5	4.5					
>70%	197	7	3.6	193	7	3.6					
Type of AF therapy											
Nintedanib	173	6	3.5	178	9	5.1					
Pirfenidone	133	3	2.3	127	3	2.4					
Region											
Europe	136	2	1.5	136	3	2.2					
Asia	72	2	2.8	79	5	6.3					
Canada and USA	75	3	4.0	56	2	3.6					
Rest of the World	23	2	8.7	34	2	5.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	33	10.8	305	31	10.2	0.8023	0.94 (0.59, 1.50)	0.94 (0.56, 1.57)	-0.62 (-5.55, 4.30)	
Age											
<65 years	69	7	10.1	63	3	4.8					
>=65 years	237	26	11.0	242	28	11.6					
Sex											
Male	269	32	11.9	255	27	10.6					
Female	37	1	2.7	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	16	14.7	112	19	17.0					
>70%	197	17	8.6	193	12	6.2					
Type of AF therapy											
Nintedanib	173	19	11.0	178	19	10.7					
Pirfenidone	133	14	10.5	127	12	9.4					
Region											
Europe	136	15	11.0	136	13	9.6					
Asia	72	12	16.7	79	6	7.6					
Canada and USA	75	6	8.0	56	5	8.9					
Rest of the World	23	0	0.0	34	7	20.6					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	30	9.8	305	38	12.5	0.2968	1.27 (0.81, 2.00)	1.31 (0.79, 2.17)	2.66 (-2.38, 7.71)	
Age											
<65 years	69	4	5.8	63	6	9.5					
>=65 years	237	26	11.0	242	32	13.2					
Sex											
Male	269	28	10.4	255	33	12.9					
Female	37	2	5.4	50	5	10.0					
Baseline FVC percent predicted											
<=70%	109	16	14.7	112	19	17.0					
>70%	197	14	7.1	193	19	9.8					
Type of AF therapy											
Nintedanib	173	14	8.1	178	21	11.8					
Pirfenidone	133	16	12.0	127	17	13.4					
Region											
Europe	136	10	7.4	136	13	9.6					
Asia	72	10	13.9	79	16	20.3					
Canada and USA	75	8	10.7	56	5	8.9					
Rest of the World	23	2	8.7	34	4	11.8					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	22	7.2	305	14	4.6	0.1725	0.64 (0.33, 1.22)	0.62 (0.31, 1.24)	-2.60 (-6.51, 1.21)	
Age											
<65 years	69	1	1.4	63	4	6.3					
>=65 years	237	21	8.9	242	10	4.1					
Sex											
Male	269	22	8.2	255	12	4.7					
Female	37	0	0.0	50	2	4.0					
Baseline FVC percent predicted											
<=70%	109	6	5.5	112	4	3.6					
>70%	197	16	8.1	193	10	5.2					
Type of AF therapy											
Nintedanib	173	13	7.5	178	6	3.4					
Pirfenidone	133	9	6.8	127	8	6.3					
Region											
Europe	136	5	3.7	136	6	4.4					
Asia	72	6	8.3	79	2	2.5					
Canada and USA	75	7	9.3	56	4	7.1					
Rest of the World	23	4	17.4	34	2	5.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	10	3.3	305	9	3.0	0.8213	0.90 (0.37, 2.19)	0.90 (0.36, 2.25)	-0.32 (-3.30, 2.64)	
Age											
<65 years	69	1	1.4	63	2	3.2					
>=65 years	237	9	3.8	242	7	2.9					
Sex											
Male	269	10	3.7	255	9	3.5					
Female	37	0	0.0	50	0	0.0					
Baseline FVC percent predicted											
<=70%	109	4	3.7	112	4	3.6					
>70%	197	6	3.0	193	5	2.6					
Type of AF therapy											
Nintedanib	173	4	2.3	178	5	2.8					
Pirfenidone	133	6	4.5	127	4	3.1					
Region											
Europe	136	2	1.5	136	6	4.4					
Asia	72	0	0.0	79	1	1.3					
Canada and USA	75	7	9.3	56	1	1.8					
Rest of the World	23	1	4.3	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	44	14.4	305	38	12.5	0.4863	0.87 (0.58, 1.30)	0.85 (0.53, 1.35)	-1.92 (-7.37, 3.53)	
Age											
<65 years	69	11	15.9	63	5	7.9					
>=65 years	237	33	13.9	242	33	13.6					
Sex											
Male	269	40	14.9	255	32	12.5					
Female	37	4	10.8	50	6	12.0					
Baseline FVC percent predicted											
<=70%	109	21	19.3	112	21	18.8					
>70%	197	23	11.7	193	17	8.8					
Type of AF therapy											
Nintedanib	173	24	13.9	178	21	11.8					
Pirfenidone	133	20	15.0	127	17	13.4					
Region											
Europe	136	14	10.3	136	15	11.0					
Asia	72	12	16.7	79	10	12.7					
Canada and USA	75	16	21.3	56	7	12.5					
Rest of the World	23	2	8.7	34	6	17.6					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.1.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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 ratio p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff.	Risk diff. (95% CI)	Interaction p-value**
Overall	306	14	4.6	305	16	5.2	0.7012	1.15 (0.57, 2.31)	1.15 (0.55, 2.41)	0.67	(-2.89, 4.27)	
Age												
<65 years	69	6	8.7	63	4	6.3						
>=65 years	237	8	3.4	242	12	5.0						
Sex												
Male	269	14	5.2	255	14	5.5						
Female	37	0	0.0	50	2	4.0						
Baseline FVC percent predicted												
<=70%	109	7	6.4	112	8	7.1						
>70%	197	7	3.6	193	8	4.1						
Type of AF therapy												
Nintedanib	173	7	4.0	178	9	5.1						
Pirfenidone	133	7	5.3	127	7	5.5						
Region												
Europe	136	4	2.9	136	9	6.6						
Asia	72	2	2.8	79	2	2.5						
Canada and USA	75	5	6.7	56	4	7.1						
Rest of the World	23	3	13.0	34	1	2.9						

Study: 1305-0014. 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 H.1.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (AF background)
SOC: Gastrointestinal 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	306	10	3.3	305	20	6.6	0.0599	2.01 (0.96,	4.22)	2.08 (0.96,	4.51)	3.29	(-0.20, 6.96)	
Age														
<65 years	69	3	4.3	63	3	4.8								
>=65 years	237	7	3.0	242	17	7.0								
Sex														
Male	269	9	3.3	255	19	7.5								
Female	37	1	2.7	50	1	2.0								
Baseline FVC percent predicted														
<=70%	109	1	0.9	112	7	6.3								
>70%	197	9	4.6	193	13	6.7								
Type of AF therapy														
Nintedanib	173	7	4.0	178	17	9.6								
Pirfenidone	133	3	2.3	127	3	2.4								
Region														
Europe	136	3	2.2	136	11	8.1								
Asia	72	2	2.8	79	6	7.6								
Canada and USA	75	3	4.0	56	1	1.8								
Rest of the World	23	2	8.7	34	2	5.9								

Study: 1305-0014. 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 H.1.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	31	10.1	305	31	10.2	0.9892	1.00 (0.63, 1.61)	1.00 (0.59, 1.70)	0.03 (-4.83, 4.90)	
Age											
<65 years	69	7	10.1	63	3	4.8					
>=65 years	237	24	10.1	242	28	11.6					
Sex											
Male	269	30	11.2	255	27	10.6					
Female	37	1	2.7	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	15	13.8	112	18	16.1					
>70%	197	16	8.1	193	13	6.7					
Type of AF therapy											
Nintedanib	173	19	11.0	178	20	11.2					
Pirfenidone	133	12	9.0	127	11	8.7					
Region											
Europe	136	14	10.3	136	13	9.6					
Asia	72	11	15.3	79	6	7.6					
Canada and USA	75	6	8.0	56	5	8.9					
Rest of the World	23	0	0.0	34	7	20.6					

Study: 1305-0014. 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 H.1.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	32	10.5	305	33	10.8	0.8846	1.03 (0.65, 1.64)	1.04 (0.62, 1.74)	0.36 (-4.59, 5.32)	
Age											
<65 years	69	5	7.2	63	7	11.1					
>=65 years	237	27	11.4	242	26	10.7					
Sex											
Male	269	30	11.2	255	29	11.4					
Female	37	2	5.4	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	15	13.8	112	16	14.3					
>70%	197	17	8.6	193	17	8.8					
Type of AF therapy											
Nintedanib	173	14	8.1	178	20	11.2					
Pirfenidone	133	18	13.5	127	13	10.2					
Region											
Europe	136	10	7.4	136	13	9.6					
Asia	72	9	12.5	79	14	17.7					
Canada and USA	75	11	14.7	56	2	3.6					
Rest of the World	23	2	8.7	34	4	11.8					

Study: 1305-0014. 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 H.1.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (AF background)
SOC: Investigations

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	306	3	1.0	305	11	3.6	0.0301	3.68 (1.04, 13.06)	3.78 (1.04, 13.68)	2.63 (0.18, 5.44)	
Age											0.3494
<65 years	69	1	1.4	63	1	1.6	0.9483	1.10 (0.07, 17.14)	1.10 (0.07, 17.91)	0.14 (-6.31, 7.11)	
>=65 years	237	2	0.8	242	10	4.1	0.0213	4.90 (1.08, 22.11)	5.06 (1.10, 23.37)	3.29 (0.41, 6.65)	
Sex											0.7066
Male	269	3	1.1	255	8	3.1	0.1066	2.81 (0.75, 10.49)	2.87 (0.75, 10.95)	2.02 (-0.59, 5.04)	
Female	37	0	0.0	50	3	6.0	0.2115	5.22 (0.28, 98.00)	NC (NC, NC)	6.00 (-4.20, 16.22)	
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	6	5.4					
>70%	197	1	0.5	193	5	2.6					
Type of AF therapy											0.6101
Nintedanib	173	2	1.2	178	9	5.1	0.0360	4.37 (0.96, 19.95)	4.55 (0.97, 21.39)	3.90 (0.11, 8.25)	
Pirfenidone	133	1	0.8	127	2	1.6	0.5345	2.09 (0.19, 22.81)	2.11 (0.19, 23.58)	0.82 (-2.75, 4.86)	
Region											
Europe	136	1	0.7	136	6	4.4					
Asia	72	0	0.0	79	3	3.8					
Canada and USA	75	1	1.3	56	2	3.6					
Rest of the World	23	1	4.3	34	0	0.0					

Study: 1305-0014. 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 H.1.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	10	3.3	305	5	1.6	0.1934	0.50 (0.17, 1.45)	0.49 (0.17, 1.46)	-1.63 (-4.43, 0.98)	
Age											
<65 years	69	1	1.4	63	1	1.6					
>=65 years	237	9	3.8	242	4	1.7					
Sex											
Male	269	10	3.7	255	4	1.6					
Female	37	0	0.0	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	1	0.9					
>70%	197	8	4.1	193	4	2.1					
Type of AF therapy											
Nintedanib	173	5	2.9	178	2	1.1					
Pirfenidone	133	5	3.8	127	3	2.4					
Region											
Europe	136	2	1.5	136	2	1.5					
Asia	72	4	5.6	79	1	1.3					
Canada and USA	75	3	4.0	56	1	1.8					
Rest of the World	23	1	4.3	34	1	2.9					

Study: 1305-0014. 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 H.1.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	9	2.9	305	11	3.6	0.6440	1.23 (0.52, 2.92)	1.23 (0.50, 3.02)	0.67 (-2.34, 3.73)	
Age											
<65 years	69	2	2.9	63	2	3.2					
>=65 years	237	7	3.0	242	9	3.7					
Sex											
Male	269	9	3.3	255	11	4.3					
Female	37	0	0.0	50	0	0.0					
Baseline FVC percent predicted											
<=70%	109	4	3.7	112	6	5.4					
>70%	197	5	2.5	193	5	2.6					
Type of AF therapy											
Nintedanib	173	4	2.3	178	7	3.9					
Pirfenidone	133	5	3.8	127	4	3.1					
Region											
Europe	136	2	1.5	136	7	5.1					
Asia	72	0	0.0	79	1	1.3					
Canada and USA	75	7	9.3	56	2	3.6					
Rest of the World	23	0	0.0	34	1	2.9					

Study: 1305-0014. 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 H.1.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial - 18mg - TS (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	306	33	10.8	305	25	8.2	0.2752	0.76 (0.46, 1.25)	0.74 (0.43, 1.27)	-2.59 (-7.33, 2.12)	
Age											
<65 years	69	8	11.6	63	3	4.8					
>=65 years	237	25	10.5	242	22	9.1					
Sex											
Male	269	30	11.2	255	21	8.2					
Female	37	3	8.1	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	20	18.3	112	14	12.5					
>70%	197	13	6.6	193	11	5.7					
Type of AF therapy											
Nintedanib	173	20	11.6	178	14	7.9					
Pirfenidone	133	13	9.8	127	11	8.7					
Region											
Europe	136	11	8.1	136	11	8.1					
Asia	72	7	9.7	79	5	6.3					
Canada and USA	75	13	17.3	56	4	7.1					
Rest of the World	23	2	8.7	34	5	14.7					

Study: 1305-0014. 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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H.1.1.2.1.5 Adverse events on PT level over the whole trial

Table H.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 (AF background)
SOC: Gastrointestinal disorders
PT: Abdominal 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	306	9	2.9	305	14	4.6	0.2843	1.56 (0.69, 3.55)	1.59 (0.68, 3.73)	1.65 (-1.50, 4.92)	
Age											
<65 years	69	4	5.8	63	5	7.9					
>=65 years	237	5	2.1	242	9	3.7					
Sex											
Male	269	7	2.6	255	9	3.5					
Female	37	2	5.4	50	5	10.0					
Baseline FVC percent predicted											
<=70%	109	5	4.6	112	6	5.4					
>70%	197	4	2.0	193	8	4.1					
Type of AF therapy											
Nintedanib	173	7	4.0	178	10	5.6					
Pirfenidone	133	2	1.5	127	4	3.1					
Region											
Europe	136	5	3.7	136	11	8.1					
Asia	72	0	0.0	79	1	1.3					
Canada and USA	75	4	5.3	56	1	1.8					
Rest of the World	23	0	0.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF 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	306	16	5.2	305	9	3.0	0.1553	0.56 (0.25, 1.26)	0.55 (0.24, 1.27)	-2.28 (-5.67, 0.96)	
Age											
<65 years	69	3	4.3	63	0	0.0					
>=65 years	237	13	5.5	242	9	3.7					
Sex											
Male	269	14	5.2	255	7	2.7					
Female	37	2	5.4	50	2	4.0					
Baseline FVC percent predicted											
<=70%	109	8	7.3	112	3	2.7					
>70%	197	8	4.1	193	6	3.1					
Type of AF therapy											
Nintedanib	173	3	1.7	178	4	2.2					
Pirfenidone	133	13	9.8	127	5	3.9					
Region											
Europe	136	3	2.2	136	5	3.7					
Asia	72	4	5.6	79	2	2.5					
Canada and USA	75	7	9.3	56	1	1.8					
Rest of the World	23	2	8.7	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	66	21.6	305	142	46.6	<.0001	2.16 (1.69, 2.76)	3.17 (2.22, 4.51)	24.99 (17.58, 32.02)	
Age											0.5903
<65 years	69	13	18.8	63	22	34.9	0.0366	1.85 (1.02, 3.36)	2.31 (1.04, 5.12)	16.08 (0.97, 30.50)	
>=65 years	237	53	22.4	242	120	49.6	<.0001	2.22 (1.69, 2.90)	3.41 (2.30, 5.07)	27.22 (18.76, 35.13)	
Sex											0.2322
Male	269	60	22.3	255	115	45.1	<.0001	2.02 (1.56, 2.62)	2.86 (1.96, 4.18)	22.79 (14.77, 30.44)	
Female	37	6	16.2	50	27	54.0	0.0003	3.33 (1.53, 7.23)	6.07 (2.15, 17.09)	37.78 (17.59, 53.38)	
Baseline FVC percent predicted											0.0865
<=70%	109	25	22.9	112	41	36.6	0.0264	1.60 (1.05, 2.43)	1.94 (1.08, 3.50)	13.67 (1.60, 25.19)	
>70%	197	41	20.8	193	101	52.3	<.0001	2.51 (1.86, 3.41)	4.18 (2.68, 6.52)	31.52 (22.15, 40.12)	
Type of AF therapy											0.3740
Nintedanib	173	54	31.2	178	111	62.4	<.0001	2.00 (1.56, 2.56)	3.65 (2.35, 5.68)	31.15 (20.85, 40.50)	
Pirfenidone	133	12	9.0	127	31	24.4	0.0008	2.71 (1.45, 5.03)	3.26 (1.59, 6.68)	15.39 (6.37, 24.37)	
Region											0.3222
Europe	136	37	27.2	136	71	52.2	<.0001	1.92 (1.40, 2.64)	2.92 (1.76, 4.85)	25.00 (13.42, 35.65)	
Asia	72	6	8.3	79	29	36.7	<.0001	4.41 (1.94, 9.99)	6.38 (2.46, 16.54)	28.38 (15.30, 40.26)	
Canada and USA	75	18	24.0	56	27	48.2	0.0039	2.01 (1.24, 3.27)	2.95 (1.40, 6.21)	24.21 (7.67, 39.42)	
Rest of the World	23	5	21.7	34	15	44.1	0.0824	2.03 (0.86, 4.81)	2.84 (0.86, 9.44)	22.38 (-2.89, 42.77)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Gastrointestinal disorders
PT: Flatulence

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	306	10	3.3	305	9	3.0	0.8213	0.90 (0.37, 2.19)	0.90 (0.36, 2.25)	-0.32 (-3.30, 2.64)	
Age											
<65 years	69	3	4.3	63	2	3.2					
>=65 years	237	7	3.0	242	7	2.9					
Sex											
Male	269	9	3.3	255	8	3.1					
Female	37	1	2.7	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	5	4.6	112	6	5.4					
>70%	197	5	2.5	193	3	1.6					
Type of AF therapy											
Nintedanib	173	8	4.6	178	4	2.2					
Pirfenidone	133	2	1.5	127	5	3.9					
Region											
Europe	136	5	3.7	136	5	3.7					
Asia	72	0	0.0	79	0	0.0					
Canada and USA	75	4	5.3	56	3	5.4					
Rest of the World	23	1	4.3	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Gastrointestinal disorders
PT: Nausea

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	306	25	8.2	305	30	9.8	0.4718	1.20 (0.73, 2.00)	1.23 (0.70, 2.14)	1.67 (-2.94, 6.30)	
Age											
<65 years	69	8	11.6	63	3	4.8					
>=65 years	237	17	7.2	242	27	11.2					
Sex											
Male	269	21	7.8	255	21	8.2					
Female	37	4	10.8	50	9	18.0					
Baseline FVC percent predicted											
<=70%	109	11	10.1	112	8	7.1					
>70%	197	14	7.1	193	22	11.4					
Type of AF therapy											
Nintedanib	173	15	8.7	178	18	10.1					
Pirfenidone	133	10	7.5	127	12	9.4					
Region											
Europe	136	8	5.9	136	19	14.0					
Asia	72	3	4.2	79	4	5.1					
Canada and USA	75	10	13.3	56	4	7.1					
Rest of the World	23	4	17.4	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF 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	306	17	5.6	305	18	5.9	0.8540	1.06 (0.56, 2.02)	1.07 (0.54, 2.11)	0.35 (-3.47, 4.18)	
Age											
<65 years	69	4	5.8	63	5	7.9					
>=65 years	237	13	5.5	242	13	5.4					
Sex											
Male	269	11	4.1	255	10	3.9					
Female	37	6	16.2	50	8	16.0					
Baseline FVC percent predicted											
<=70%	109	6	5.5	112	2	1.8					
>70%	197	11	5.6	193	16	8.3					
Type of AF therapy											
Nintedanib	173	13	7.5	178	16	9.0					
Pirfenidone	133	4	3.0	127	2	1.6					
Region											
Europe	136	10	7.4	136	13	9.6					
Asia	72	1	1.4	79	1	1.3					
Canada and USA	75	6	8.0	56	3	5.4					
Rest of the World	23	0	0.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: General disorders and administration site conditions
PT: Asthenia

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	306	8	2.6	305	16	5.2	0.0941	2.01 (0.87, 4.62)	2.06 (0.87, 4.89)	2.63 (-0.53, 5.99)	
Age											
<65 years	69	1	1.4	63	1	1.6					
>=65 years	237	7	3.0	242	15	6.2					
Sex											
Male	269	6	2.2	255	9	3.5					
Female	37	2	5.4	50	7	14.0					
Baseline FVC percent predicted											
<=70%	109	4	3.7	112	6	5.4					
>70%	197	4	2.0	193	10	5.2					
Type of AF therapy											
Nintedanib	173	3	1.7	178	12	6.7					
Pirfenidone	133	5	3.8	127	4	3.1					
Region											
Europe	136	5	3.7	136	11	8.1					
Asia	72	2	2.8	79	1	1.3					
Canada and USA	75	1	1.3	56	3	5.4					
Rest of the World	23	0	0.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF 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	306	6	2.0	305	11	3.6	0.2162	1.84 (0.69, 4.91)	1.87 (0.68, 5.12)	1.65 (-1.10, 4.58)	
Age											
<65 years	69	3	4.3	63	1	1.6					
>=65 years	237	3	1.3	242	10	4.1					
Sex											
Male	269	6	2.2	255	10	3.9					
Female	37	0	0.0	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	2	1.8					
>70%	197	4	2.0	193	9	4.7					
Type of AF therapy											
Nintedanib	173	3	1.7	178	4	2.2					
Pirfenidone	133	3	2.3	127	7	5.5					
Region											
Europe	136	4	2.9	136	1	0.7					
Asia	72	1	1.4	79	3	3.8					
Canada and USA	75	1	1.3	56	6	10.7					
Rest of the World	23	0	0.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF 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	306	39	12.7	305	39	12.8	0.9877	1.00 (0.66, 1.52)	1.00 (0.62, 1.61)	0.04 (-5.30, 5.38)	
Age											
<65 years	69	6	8.7	63	5	7.9					
>=65 years	237	33	13.9	242	34	14.0					
Sex											
Male	269	38	14.1	255	36	14.1					
Female	37	1	2.7	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	19	17.4	112	24	21.4					
>70%	197	20	10.2	193	15	7.8					
Type of AF therapy											
Nintedanib	173	23	13.3	178	23	12.9					
Pirfenidone	133	16	12.0	127	16	12.6					
Region											
Europe	136	17	12.5	136	20	14.7					
Asia	72	12	16.7	79	7	8.9					
Canada and USA	75	10	13.3	56	5	8.9					
Rest of the World	23	0	0.0	34	7	20.6					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	21	6.9	305	23	7.5	0.7457	1.10 (0.62, 1.94)	1.11 (0.60, 2.05)	0.68 (-3.52, 4.90)	
Age											
<65 years	69	5	7.2	63	2	3.2					
>=65 years	237	16	6.8	242	21	8.7					
Sex											
Male	269	18	6.7	255	20	7.8					
Female	37	3	8.1	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	7	6.4	112	6	5.4					
>70%	197	14	7.1	193	17	8.8					
Type of AF therapy											
Nintedanib	173	11	6.4	178	12	6.7					
Pirfenidone	133	10	7.5	127	11	8.7					
Region											
Europe	136	9	6.6	136	9	6.6					
Asia	72	3	4.2	79	1	1.3					
Canada and USA	75	9	12.0	56	10	17.9					
Rest of the World	23	0	0.0	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	30	9.8	305	32	10.5	0.7783	1.07 (0.67, 1.72)	1.08 (0.64, 1.82)	0.69 (-4.17, 5.55)	
Age											
<65 years	69	8	11.6	63	7	11.1					
>=65 years	237	22	9.3	242	25	10.3					
Sex											
Male	269	28	10.4	255	29	11.4					
Female	37	2	5.4	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	13	11.9	112	16	14.3					
>70%	197	17	8.6	193	16	8.3					
Type of AF therapy											
Nintedanib	173	13	7.5	178	19	10.7					
Pirfenidone	133	17	12.8	127	13	10.2					
Region											
Europe	136	18	13.2	136	23	16.9					
Asia	72	6	8.3	79	2	2.5					
Canada and USA	75	5	6.7	56	6	10.7					
Rest of the World	23	1	4.3	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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 Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	54	17.6	305	44	14.4	0.2780	0.82 (0.57, 1.18)	0.79 (0.51, 1.21)	-3.22 (-9.05, 2.62)	
Age											
<65 years	69	15	21.7	63	6	9.5					
>=65 years	237	39	16.5	242	38	15.7					
Sex											
Male	269	48	17.8	255	34	13.3					
Female	37	6	16.2	50	10	20.0					
Baseline FVC percent predicted											
<=70%	109	19	17.4	112	15	13.4					
>70%	197	35	17.8	193	29	15.0					
Type of AF therapy											
Nintedanib	173	30	17.3	178	22	12.4					
Pirfenidone	133	24	18.0	127	22	17.3					
Region											
Europe	136	20	14.7	136	19	14.0					
Asia	72	9	12.5	79	12	15.2					
Canada and USA	75	19	25.3	56	10	17.9					
Rest of the World	23	6	26.1	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Infections and infestations
PT: Gastroenteritis

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	306	10	3.3	305	4	1.3	0.1061	0.40 (0.13, 1.27)	0.39 (0.12, 1.27)	-1.96 (-4.72, 0.54)	
Age											
<65 years	69	1	1.4	63	1	1.6					
>=65 years	237	9	3.8	242	3	1.2					
Sex											
Male	269	9	3.3	255	4	1.6					
Female	37	1	2.7	50	0	0.0					
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	0	0.0					
>70%	197	8	4.1	193	4	2.1					
Type of AF therapy											
Nintedanib	173	6	3.5	178	3	1.7					
Pirfenidone	133	4	3.0	127	1	0.8					
Region											
Europe	136	6	4.4	136	2	1.5					
Asia	72	1	1.4	79	2	2.5					
Canada and USA	75	1	1.3	56	0	0.0					
Rest of the World	23	2	8.7	34	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	10	3.3	305	14	4.6	0.4002	1.40 (0.63, 3.11)	1.42 (0.62, 3.26)	1.32 (-1.90, 4.64)	
Age											
<65 years	69	5	7.2	63	5	7.9					
>=65 years	237	5	2.1	242	9	3.7					
Sex											
Male	269	9	3.3	255	13	5.1					
Female	37	1	2.7	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	5	4.6	112	4	3.6					
>70%	197	5	2.5	193	10	5.2					
Type of AF therapy											
Nintedanib	173	6	3.5	178	8	4.5					
Pirfenidone	133	4	3.0	127	6	4.7					
Region											
Europe	136	7	5.1	136	6	4.4					
Asia	72	1	1.4	79	4	5.1					
Canada and USA	75	1	1.3	56	1	1.8					
Rest of the World	23	1	4.3	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Infections and infestations
PT: Nasopharyngitis

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	306	39	12.7	305	36	11.8	0.7228	0.93 (0.61, 1.42)	0.92 (0.56, 1.49)	-0.94 (-6.20, 4.31)	
Age											
<65 years	69	11	15.9	63	12	19.0					
>=65 years	237	28	11.8	242	24	9.9					
Sex											
Male	269	34	12.6	255	32	12.5					
Female	37	5	13.5	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	14	12.8	112	11	9.8					
>70%	197	25	12.7	193	25	13.0					
Type of AF therapy											
Nintedanib	173	23	13.3	178	21	11.8					
Pirfenidone	133	16	12.0	127	15	11.8					
Region											
Europe	136	26	19.1	136	21	15.4					
Asia	72	5	6.9	79	13	16.5					
Canada and USA	75	8	10.7	56	2	3.6					
Rest of the World	23	0	0.0	34	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	26	8.5	305	28	9.2	0.7660	1.08 (0.65, 1.80)	1.09 (0.62, 1.90)	0.68 (-3.90, 5.28)	
Age											
<65 years	69	5	7.2	63	6	9.5					
>=65 years	237	21	8.9	242	22	9.1					
Sex											
Male	269	21	7.8	255	26	10.2					
Female	37	5	13.5	50	2	4.0					
Baseline FVC percent predicted											
<=70%	109	13	11.9	112	12	10.7					
>70%	197	13	6.6	193	16	8.3					
Type of AF therapy											
Nintedanib	173	11	6.4	178	12	6.7					
Pirfenidone	133	15	11.3	127	16	12.6					
Region											
Europe	136	7	5.1	136	9	6.6					
Asia	72	10	13.9	79	12	15.2					
Canada and USA	75	9	12.0	56	5	8.9					
Rest of the World	23	0	0.0	34	2	5.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Infections and infestations
PT: Respiratory tract infection

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	306	9	2.9	305	20	6.6	0.0356	2.23 (1.03, 4.82)	2.32 (1.04, 5.17)	3.62	(0.20, 7.24)		
Age													0.6254
<65 years	69	3	4.3	63	8	12.7	0.0829	2.92 (0.81, 10.53)	3.20 (0.81, 12.65)	8.35	(-1.47, 19.14)		
>=65 years	237	6	2.5	242	12	5.0	0.1626	1.96 (0.75, 5.13)	2.01 (0.74, 5.44)	2.43	(-1.14, 6.19)		
Sex													0.4051
Male	269	9	3.3	255	16	6.3	0.1159	1.88 (0.84, 4.17)	1.93 (0.84, 4.46)	2.93	(-0.81, 6.93)		
Female	37	0	0.0	50	4	8.0	0.1281	6.71 (0.37, >99)	NC (NC, NC)	8.00	(-2.58, 18.84)		
Baseline FVC percent predicted													0.1576
<=70%	109	4	3.7	112	4	3.6	0.9688	0.97 (0.25, 3.79)	0.97 (0.24, 3.99)	-0.10	(-5.91, 5.61)		
>70%	197	5	2.5	193	16	8.3	0.0119	3.27 (1.22, 8.74)	3.47 (1.25, 9.67)	5.75	(1.23, 10.72)		
Type of AF therapy													0.2798
Nintedanib	173	2	1.2	178	9	5.1	0.0360	4.37 (0.96, 19.95)	4.55 (0.97, 21.39)	3.90	(0.11, 8.25)		
Pirfenidone	133	7	5.3	127	11	8.7	0.2806	1.65 (0.66, 4.11)	1.71 (0.64, 4.55)	3.40	(-3.02, 10.14)		
Region													0.9162
Europe	136	7	5.1	136	15	11.0	0.0752	2.14 (0.90, 5.09)	2.28 (0.90, 5.79)	5.88	(-0.74, 12.78)		
Asia	72	1	1.4	79	1	1.3	0.9473	0.91 (0.06, 14.30)	0.91 (0.06, 14.83)	-0.12	(-6.28, 5.55)		
Canada and USA	75	0	0.0	56	1	1.8	0.3547	4.00 (0.17, 96.39)	NC (NC, NC)	1.79	(-3.30, 9.45)		
Rest of the World	23	1	4.3	34	3	8.8	0.5163	2.03 (0.22, 18.32)	2.13 (0.21, 21.84)	4.48	(-13.14, 19.06)		

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Infections and infestations
PT: Rhinitis

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	306	12	3.9	305	8	2.6	0.3671	0.67 (0.28, 1.61)	0.66 (0.27, 1.64)	-1.30 (-4.39, 1.68)	
Age											
<65 years	69	3	4.3	63	1	1.6					
>=65 years	237	9	3.8	242	7	2.9					
Sex											
Male	269	11	4.1	255	6	2.4					
Female	37	1	2.7	50	2	4.0					
Baseline FVC percent predicted											
<=70%	109	7	6.4	112	3	2.7					
>70%	197	5	2.5	193	5	2.6					
Type of AF therapy											
Nintedanib	173	6	3.5	178	1	0.6					
Pirfenidone	133	6	4.5	127	7	5.5					
Region											
Europe	136	6	4.4	136	4	2.9					
Asia	72	3	4.2	79	4	5.1					
Canada and USA	75	3	4.0	56	0	0.0					
Rest of the World	23	0	0.0	34	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Infections and infestations
PT: Sinusitis

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	306	8	2.6	305	10	3.3	0.6273	1.25 (0.50, 3.13)	1.26 (0.49, 3.24)	0.66 (-2.21, 3.61)	
Age											
<65 years	69	3	4.3	63	5	7.9					
>=65 years	237	5	2.1	242	5	2.1					
Sex											
Male	269	7	2.6	255	6	2.4					
Female	37	1	2.7	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	4	3.6					
>70%	197	6	3.0	193	6	3.1					
Type of AF therapy											
Nintedanib	173	3	1.7	178	7	3.9					
Pirfenidone	133	5	3.8	127	3	2.4					
Region											
Europe	136	3	2.2	136	2	1.5					
Asia	72	1	1.4	79	2	2.5					
Canada and USA	75	3	4.0	56	5	8.9					
Rest of the World	23	1	4.3	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	38	12.4	305	41	13.4	0.7059	1.08 (0.72, 1.63)	1.10 (0.68, 1.76)	1.02 (-4.34, 6.39)	
Age											
<65 years	69	8	11.6	63	6	9.5					
>=65 years	237	30	12.7	242	35	14.5					
Sex											
Male	269	30	11.2	255	32	12.5					
Female	37	8	21.6	50	9	18.0					
Baseline FVC percent predicted											
<=70%	109	15	13.8	112	8	7.1					
>70%	197	23	11.7	193	33	17.1					
Type of AF therapy											
Nintedanib	173	16	9.2	178	26	14.6					
Pirfenidone	133	22	16.5	127	15	11.8					
Region											
Europe	136	9	6.6	136	10	7.4					
Asia	72	16	22.2	79	14	17.7					
Canada and USA	75	11	14.7	56	9	16.1					
Rest of the World	23	2	8.7	34	8	23.5					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	13	4.2	305	10	3.3	0.5289	0.77 (0.34, 1.73)	0.76 (0.33, 1.77)	-0.97 (-4.21, 2.21)	
Age											
<65 years	69	2	2.9	63	1	1.6					
>=65 years	237	11	4.6	242	9	3.7					
Sex											
Male	269	8	3.0	255	7	2.7					
Female	37	5	13.5	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	3	2.8	112	2	1.8					
>70%	197	10	5.1	193	8	4.1					
Type of AF therapy											
Nintedanib	173	9	5.2	178	5	2.8					
Pirfenidone	133	4	3.0	127	5	3.9					
Region											
Europe	136	6	4.4	136	6	4.4					
Asia	72	1	1.4	79	1	1.3					
Canada and USA	75	4	5.3	56	2	3.6					
Rest of the World	23	2	8.7	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	32	10.5	305	42	13.8	0.2095	1.32 (0.86, 2.03)	1.37 (0.84, 2.23)	3.31 (-1.90, 8.55)	
Age											
<65 years	69	5	7.2	63	5	7.9					
>=65 years	237	27	11.4	242	37	15.3					
Sex											
Male	269	29	10.8	255	36	14.1					
Female	37	3	8.1	50	6	12.0					
Baseline FVC percent predicted											
<=70%	109	16	14.7	112	16	14.3					
>70%	197	16	8.1	193	26	13.5					
Type of AF therapy											
Nintedanib	173	24	13.9	178	31	17.4					
Pirfenidone	133	8	6.0	127	11	8.7					
Region											
Europe	136	7	5.1	136	18	13.2					
Asia	72	9	12.5	79	13	16.5					
Canada and USA	75	14	18.7	56	6	10.7					
Rest of the World	23	2	8.7	34	5	14.7					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF 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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	26	8.5	305	33	10.8	0.3310	1.27 (0.78, 2.08)	1.31 (0.76, 2.24)	2.32 (-2.42, 7.10)	
Age											
<65 years	69	3	4.3	63	5	7.9					
>=65 years	237	23	9.7	242	28	11.6					
Sex											
Male	269	21	7.8	255	28	11.0					
Female	37	5	13.5	50	5	10.0					
Baseline FVC percent predicted											
<=70%	109	13	11.9	112	16	14.3					
>70%	197	13	6.6	193	17	8.8					
Type of AF therapy											
Nintedanib	173	8	4.6	178	15	8.4					
Pirfenidone	133	18	13.5	127	18	14.2					
Region											
Europe	136	5	3.7	136	12	8.8					
Asia	72	12	16.7	79	14	17.7					
Canada and USA	75	7	9.3	56	5	8.9					
Rest of the World	23	2	8.7	34	2	5.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	17	5.6	305	12	3.9	0.3460	0.71 (0.34, 1.46)	0.70 (0.33, 1.48)	-1.62 (-5.20, 1.87)	
Age											
<65 years	69	6	8.7	63	1	1.6					
>=65 years	237	11	4.6	242	11	4.5					
Sex											
Male	269	15	5.6	255	8	3.1					
Female	37	2	5.4	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	8	7.3	112	4	3.6					
>70%	197	9	4.6	193	8	4.1					
Type of AF therapy											
Nintedanib	173	11	6.4	178	5	2.8					
Pirfenidone	133	6	4.5	127	7	5.5					
Region											
Europe	136	5	3.7	136	5	3.7					
Asia	72	5	6.9	79	0	0.0					
Canada and USA	75	4	5.3	56	6	10.7					
Rest of the World	23	3	13.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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 Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	13	4.2	305	24	7.9	0.0607	1.85 (0.96, 3.57)	1.92 (0.96, 3.86)	3.62 (-0.21, 7.60)	
Age											
<65 years	69	3	4.3	63	4	6.3					
>=65 years	237	10	4.2	242	20	8.3					
Sex											
Male	269	11	4.1	255	16	6.3					
Female	37	2	5.4	50	8	16.0					
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	6	5.4					
>70%	197	11	5.6	193	18	9.3					
Type of AF therapy											
Nintedanib	173	8	4.6	178	13	7.3					
Pirfenidone	133	5	3.8	127	11	8.7					
Region											
Europe	136	3	2.2	136	8	5.9					
Asia	72	4	5.6	79	6	7.6					
Canada and USA	75	4	5.3	56	7	12.5					
Rest of the World	23	2	8.7	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Musculoskeletal and connective tissue disorders
PT: Pain in extremity

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	306	4	1.3	305	10	3.3	0.1034	2.51 (0.80, 7.91)	2.56 (0.79, 8.25)	1.97 (-0.53, 4.74)	
Age											
<65 years	69	0	0.0	63	1	1.6					
>=65 years	237	4	1.7	242	9	3.7					
Sex											
Male	269	4	1.5	255	7	2.7					
Female	37	0	0.0	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	1	0.9	112	4	3.6					
>70%	197	3	1.5	193	6	3.1					
Type of AF therapy											
Nintedanib	173	3	1.7	178	7	3.9					
Pirfenidone	133	1	0.8	127	3	2.4					
Region											
Europe	136	4	2.9	136	6	4.4					
Asia	72	0	0.0	79	0	0.0					
Canada and USA	75	0	0.0	56	4	7.1					
Rest of the World	23	0	0.0	34	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	18	5.9	305	18	5.9	0.9919	1.00 (0.53, 1.89)	1.00 (0.51, 1.97)	0.02 (-3.85, 3.89)	
Age											
<65 years	69	3	4.3	63	1	1.6					
>=65 years	237	15	6.3	242	17	7.0					
Sex											
Male	269	18	6.7	255	16	6.3					
Female	37	0	0.0	50	2	4.0					
Baseline FVC percent predicted											
<=70%	109	3	2.8	112	5	4.5					
>70%	197	15	7.6	193	13	6.7					
Type of AF therapy											
Nintedanib	173	13	7.5	178	14	7.9					
Pirfenidone	133	5	3.8	127	4	3.1					
Region											
Europe	136	9	6.6	136	7	5.1					
Asia	72	1	1.4	79	6	7.6					
Canada and USA	75	7	9.3	56	5	8.9					
Rest of the World	23	1	4.3	34	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	18	5.9	305	25	8.2	0.2634	1.39 (0.78, 2.50)	1.43 (0.76, 2.68)	2.31 (-1.82, 6.52)	
Age											
<65 years	69	9	13.0	63	3	4.8					
>=65 years	237	9	3.8	242	22	9.1					
Sex											
Male	269	16	5.9	255	19	7.5					
Female	37	2	5.4	50	6	12.0					
Baseline FVC percent predicted											
<=70%	109	6	5.5	112	12	10.7					
>70%	197	12	6.1	193	13	6.7					
Type of AF therapy											
Nintedanib	173	10	5.8	178	12	6.7					
Pirfenidone	133	8	6.0	127	13	10.2					
Region											
Europe	136	11	8.1	136	11	8.1					
Asia	72	2	2.8	79	3	3.8					
Canada and USA	75	4	5.3	56	7	12.5					
Rest of the World	23	1	4.3	34	4	11.8					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	30	9.8	305	28	9.2	0.7926	0.94 (0.57, 1.53)	0.93 (0.54, 1.60)	-0.62 (-5.35, 4.10)	
Age											
<65 years	69	4	5.8	63	6	9.5					
>=65 years	237	26	11.0	242	22	9.1					
Sex											
Male	269	24	8.9	255	18	7.1					
Female	37	6	16.2	50	10	20.0					
Baseline FVC percent predicted											
<=70%	109	15	13.8	112	9	8.0					
>70%	197	15	7.6	193	19	9.8					
Type of AF therapy											
Nintedanib	173	16	9.2	178	14	7.9					
Pirfenidone	133	14	10.5	127	14	11.0					
Region											
Europe	136	17	12.5	136	12	8.8					
Asia	72	5	6.9	79	6	7.6					
Canada and USA	75	5	6.7	56	7	12.5					
Rest of the World	23	3	13.0	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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 ratio p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	31	10.1	305	30	9.8	0.9033	0.97 (0.60, 1.56)	0.97 (0.57, 1.64)	-0.29 (-5.12, 4.53)	
Age											
<65 years	69	8	11.6	63	5	7.9					
>=65 years	237	23	9.7	242	25	10.3					
Sex											
Male	269	24	8.9	255	25	9.8					
Female	37	7	18.9	50	5	10.0					
Baseline FVC percent predicted											
<=70%	109	14	12.8	112	14	12.5					
>70%	197	17	8.6	193	16	8.3					
Type of AF therapy											
Nintedanib	173	12	6.9	178	16	9.0					
Pirfenidone	133	19	14.3	127	14	11.0					
Region											
Europe	136	12	8.8	136	16	11.8					
Asia	72	10	13.9	79	6	7.6					
Canada and USA	75	8	10.7	56	5	8.9					
Rest of the World	23	1	4.3	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	12	3.9	305	9	3.0	0.5102	0.75 (0.32, 1.76)	0.74 (0.31, 1.79)	-0.97 (-4.10, 2.08)	
Age											
<65 years	69	2	2.9	63	1	1.6					
>=65 years	237	10	4.2	242	8	3.3					
Sex											
Male	269	11	4.1	255	8	3.1					
Female	37	1	2.7	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	4	3.7	112	5	4.5					
>70%	197	8	4.1	193	4	2.1					
Type of AF therapy											
Nintedanib	173	6	3.5	178	5	2.8					
Pirfenidone	133	6	4.5	127	4	3.1					
Region											
Europe	136	6	4.4	136	3	2.2					
Asia	72	4	5.6	79	3	3.8					
Canada and USA	75	1	1.3	56	2	3.6					
Rest of the World	23	1	4.3	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	70	22.9	305	63	20.7	0.5061	0.90 (0.67, 1.22)	0.88 (0.60, 1.29)	-2.22 (-8.75, 4.33)	
Age											
<65 years	69	16	23.2	63	11	17.5					
>=65 years	237	54	22.8	242	52	21.5					
Sex											
Male	269	67	24.9	255	51	20.0					
Female	37	3	8.1	50	12	24.0					
Baseline FVC percent predicted											
<=70%	109	31	28.4	112	20	17.9					
>70%	197	39	19.8	193	43	22.3					
Type of AF therapy											
Nintedanib	173	34	19.7	178	32	18.0					
Pirfenidone	133	36	27.1	127	31	24.4					
Region											
Europe	136	32	23.5	136	34	25.0					
Asia	72	10	13.9	79	12	15.2					
Canada and USA	75	20	26.7	56	12	21.4					
Rest of the World	23	8	34.8	34	5	14.7					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	50	16.3	305	36	11.8	0.1069	0.72 (0.49, 1.08)	0.69 (0.43, 1.09)	-4.54 (-10.08, 1.00)	
Age											
<65 years	69	7	10.1	63	3	4.8					
>=65 years	237	43	18.1	242	33	13.6					
Sex											
Male	269	46	17.1	255	31	12.2					
Female	37	4	10.8	50	5	10.0					
Baseline FVC percent predicted											
<=70%	109	29	26.6	112	15	13.4					
>70%	197	21	10.7	193	21	10.9					
Type of AF therapy											
Nintedanib	173	29	16.8	178	19	10.7					
Pirfenidone	133	21	15.8	127	17	13.4					
Region											
Europe	136	27	19.9	136	18	13.2					
Asia	72	3	4.2	79	6	7.6					
Canada and USA	75	15	20.0	56	11	19.6					
Rest of the World	23	5	21.7	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Epistaxis

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	306	6	2.0	305	10	3.3	0.3077	1.67 (0.62, 4.54)	1.69 (0.61, 4.72)	1.32 (-1.38, 4.17)	
Age											
<65 years	69	0	0.0	63	3	4.8					
>=65 years	237	6	2.5	242	7	2.9					
Sex											
Male	269	6	2.2	255	8	3.1					
Female	37	0	0.0	50	2	4.0					
Baseline FVC percent predicted											
<=70%	109	3	2.8	112	6	5.4					
>70%	197	3	1.5	193	4	2.1					
Type of AF therapy											
Nintedanib	173	5	2.9	178	4	2.2					
Pirfenidone	133	1	0.8	127	6	4.7					
Region											
Europe	136	3	2.2	136	5	3.7					
Asia	72	1	1.4	79	2	2.5					
Canada and USA	75	1	1.3	56	0	0.0					
Rest of the World	23	1	4.3	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Oropharyngeal 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	306	10	3.3	305	5	1.6	0.1934	0.50 (0.17, 1.45)	0.49 (0.17, 1.46)	-1.63 (-4.43, 0.98)	
Age											
<65 years	69	5	7.2	63	1	1.6					
>=65 years	237	5	2.1	242	4	1.7					
Sex											
Male	269	8	3.0	255	5	2.0					
Female	37	2	5.4	50	0	0.0					
Baseline FVC percent predicted											
<=70%	109	3	2.8	112	1	0.9					
>70%	197	7	3.6	193	4	2.1					
Type of AF therapy											
Nintedanib	173	4	2.3	178	2	1.1					
Pirfenidone	133	6	4.5	127	3	2.4					
Region											
Europe	136	5	3.7	136	3	2.2					
Asia	72	2	2.8	79	1	1.3					
Canada and USA	75	3	4.0	56	1	1.8					
Rest of the World	23	0	0.0	34	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Productive 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	306	9	2.9	305	14	4.6	0.2843	1.56 (0.69, 3.55)	1.59 (0.68, 3.73)	1.65 (-1.50, 4.92)	
Age											
<65 years	69	1	1.4	63	4	6.3					
>=65 years	237	8	3.4	242	10	4.1					
Sex											
Male	269	7	2.6	255	13	5.1					
Female	37	2	5.4	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	3	2.7					
>70%	197	7	3.6	193	11	5.7					
Type of AF therapy											
Nintedanib	173	6	3.5	178	9	5.1					
Pirfenidone	133	3	2.3	127	5	3.9					
Region											
Europe	136	4	2.9	136	7	5.1					
Asia	72	1	1.4	79	3	3.8					
Canada and USA	75	4	5.3	56	3	5.4					
Rest of the World	23	0	0.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pulmonary 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	306	11	3.6	305	12	3.9	0.8254	1.09 (0.49, 2.44)	1.10 (0.48, 2.53)	0.34 (-2.86, 3.57)	
Age											
<65 years	69	2	2.9	63	1	1.6					
>=65 years	237	9	3.8	242	11	4.5					
Sex											
Male	269	8	3.0	255	12	4.7					
Female	37	3	8.1	50	0	0.0					
Baseline FVC percent predicted											
<=70%	109	5	4.6	112	6	5.4					
>70%	197	6	3.0	193	6	3.1					
Type of AF therapy											
Nintedanib	173	6	3.5	178	6	3.4					
Pirfenidone	133	5	3.8	127	6	4.7					
Region											
Europe	136	2	1.5	136	6	4.4					
Asia	72	5	6.9	79	3	3.8					
Canada and USA	75	4	5.3	56	2	3.6					
Rest of the World	23	0	0.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Rhinorrhoea

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	306	8	2.6	305	13	4.3	0.2636	1.63 (0.69,	3.88)	1.66 (0.68,	4.06)	1.65 (-1.37, 4.81)	
Age													
<65 years	69	2	2.9	63	2	3.2							
>=65 years	237	6	2.5	242	11	4.5							
Sex													
Male	269	7	2.6	255	10	3.9							
Female	37	1	2.7	50	3	6.0							
Baseline FVC percent predicted													
<=70%	109	3	2.8	112	6	5.4							
>70%	197	5	2.5	193	7	3.6							
Type of AF therapy													
Nintedanib	173	3	1.7	178	6	3.4							
Pirfenidone	133	5	3.8	127	7	5.5							
Region													
Europe	136	5	3.7	136	8	5.9							
Asia	72	1	1.4	79	2	2.5							
Canada and USA	75	2	2.7	56	2	3.6							
Rest of the World	23	0	0.0	34	1	2.9							

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	10	3.3	305	10	3.3	0.9941	1.00 (0.42, 2.38)	1.00 (0.41, 2.45)	0.01 (-3.02, 3.05)	
Age											
<65 years	69	4	5.8	63	1	1.6					
>=65 years	237	6	2.5	242	9	3.7					
Sex											
Male	269	8	3.0	255	7	2.7					
Female	37	2	5.4	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	3	2.8	112	3	2.7					
>70%	197	7	3.6	193	7	3.6					
Type of AF therapy											
Nintedanib	173	8	4.6	178	6	3.4					
Pirfenidone	133	2	1.5	127	4	3.1					
Region											
Europe	136	2	1.5	136	7	5.1					
Asia	72	5	6.9	79	1	1.3					
Canada and USA	75	1	1.3	56	0	0.0					
Rest of the World	23	2	8.7	34	2	5.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	27	8.8	305	26	8.5	0.8956	0.97 (0.58, 1.62)	0.96 (0.55, 1.69)	-0.30	(-4.85, 4.25)	
Age												
<65 years	69	5	7.2	63	2	3.2						
>=65 years	237	22	9.3	242	24	9.9						
Sex												
Male	269	26	9.7	255	23	9.0						
Female	37	1	2.7	50	3	6.0						
Baseline FVC percent predicted												
<=70%	109	13	11.9	112	16	14.3						
>70%	197	14	7.1	193	10	5.2						
Type of AF therapy												
Nintedanib	173	15	8.7	178	17	9.6						
Pirfenidone	133	12	9.0	127	9	7.1						
Region												
Europe	136	12	8.8	136	11	8.1						
Asia	72	12	16.7	79	6	7.6						
Canada and USA	75	3	4.0	56	2	3.6						
Rest of the World	23	0	0.0	34	7	20.6						

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	16	5.2	305	14	4.6	0.7149	0.88 (0.44, 1.77)	0.87 (0.42, 1.82)	-0.64 (-4.24, 2.93)	
Age											
<65 years	69	2	2.9	63	1	1.6					
>=65 years	237	14	5.9	242	13	5.4					
Sex											
Male	269	14	5.2	255	14	5.5					
Female	37	2	5.4	50	0	0.0					
Baseline FVC percent predicted											
<=70%	109	9	8.3	112	7	6.3					
>70%	197	7	3.6	193	7	3.6					
Type of AF therapy											
Nintedanib	173	5	2.9	178	7	3.9					
Pirfenidone	133	11	8.3	127	7	5.5					
Region											
Europe	136	5	3.7	136	3	2.2					
Asia	72	6	8.3	79	9	11.4					
Canada and USA	75	5	6.7	56	2	3.6					
Rest of the World	23	0	0.0	34	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pulmonary 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	306	11	3.6	305	12	3.9	0.8254	1.09 (0.49, 2.44)	1.10 (0.48, 2.53)	0.34 (-2.86, 3.57)	
Age											
<65 years	69	2	2.9	63	1	1.6					
>=65 years	237	9	3.8	242	11	4.5					
Sex											
Male	269	8	3.0	255	12	4.7					
Female	37	3	8.1	50	0	0.0					
Baseline FVC percent predicted											
<=70%	109	5	4.6	112	6	5.4					
>70%	197	6	3.0	193	6	3.1					
Type of AF therapy											
Nintedanib	173	6	3.5	178	6	3.4					
Pirfenidone	133	5	3.8	127	6	4.7					
Region											
Europe	136	2	1.5	136	6	4.4					
Asia	72	5	6.9	79	3	3.8					
Canada and USA	75	4	5.3	56	2	3.6					
Rest of the World	23	0	0.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	2	0.7	305	10	3.3	0.0194	5.02 (1.11, 22.71)	5.15 (1.12, 23.71)	2.63	(0.37,	5.32)	
Age													
<65 years	69	1	1.4	63	2	3.2							
>=65 years	237	1	0.4	242	8	3.3							
Sex													0.3587
Male	269	2	0.7	255	10	3.9	0.0151	5.27 (1.17, 23.84)	5.45 (1.18, 25.12)	3.18	(0.56,	6.37)	
Female	37	0	0.0	50	0	0.0	0.8820	0.75 (0.02, 36.71)	NC (NC, NC)	0.00	(NC,	NC)	
Baseline FVC percent predicted													0.9191
<=70%	109	0	0.0	112	2	1.8	0.2546	4.87 (0.24, >99)	NC (NC, NC)	1.79	(-1.86,	6.28)	
>70%	197	2	1.0	193	8	4.1	0.0506	4.08 (0.88, 18.98)	4.22 (0.88, 20.11)	3.13	(-0.18,	7.02)	
Type of AF therapy													0.4729
Nintedanib	173	2	1.2	178	10	5.6	0.0215	4.86 (1.08, 21.86)	5.09 (1.10, 23.57)	4.46	(0.56,	8.95)	
Pirfenidone	133	0	0.0	127	0	0.0	0.9817	1.05 (0.02, 52.37)	NC (NC, NC)	0.00	(NC,	NC)	
Region													
Europe	136	1	0.7	136	8	5.9							
Asia	72	0	0.0	79	2	2.5							
Canada and USA	75	1	1.3	56	0	0.0							
Rest of the World	23	0	0.0	34	0	0.0							

Study: 1305-0014. 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 H.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 (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 (95% CI) p-value*	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	25	8.2	305	25	8.2	0.9904 1.00 (0.59, 1.71)	1.00 (0.56, 1.79)	0.03 (-4.41, 4.47)	
Age										
<65 years	69	5	7.2	63	2	3.2				
>=65 years	237	20	8.4	242	23	9.5				
Sex										
Male	269	24	8.9	255	22	8.6				
Female	37	1	2.7	50	3	6.0				
Baseline FVC percent predicted										
<=70%	109	12	11.0	112	15	13.4				
>70%	197	13	6.6	193	10	5.2				
Type of AF therapy										
Nintedanib	173	15	8.7	178	17	9.6				
Pirfenidone	133	10	7.5	127	8	6.3				
Region										
Europe	136	11	8.1	136	10	7.4				
Asia	72	11	15.3	79	6	7.6				
Canada and USA	75	3	4.0	56	2	3.6				
Rest of the World	23	0	0.0	34	7	20.6				

Study: 1305-0014. 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 H.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 (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 ratio p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	15	4.9	305	12	3.9	0.5607	0.80 (0.38, 1.69)	0.79 (0.37, 1.73)	-0.97 (-4.42, 2.43)	
Age											
<65 years	69	2	2.9	63	2	3.2					
>=65 years	237	13	5.5	242	10	4.1					
Sex											
Male	269	13	4.8	255	12	4.7					
Female	37	2	5.4	50	0	0.0					
Baseline FVC percent predicted											
<=70%	109	8	7.3	112	7	6.3					
>70%	197	7	3.6	193	5	2.6					
Type of AF therapy											
Nintedanib	173	5	2.9	178	7	3.9					
Pirfenidone	133	10	7.5	127	5	3.9					
Region											
Europe	136	4	2.9	136	3	2.2					
Asia	72	6	8.3	79	8	10.1					
Canada and USA	75	5	6.7	56	1	1.8					
Rest of the World	23	0	0.0	34	0	0.0					

Study: 1305-0014. 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 H.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 (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	306	10	3.3	305	6	2.0	0.3141	0.60 (0.22, 1.64)	0.59 (0.21, 1.66)	-1.30 (-4.15, 1.40)	
Age											
<65 years	69	3	4.3	63	0	0.0					
>=65 years	237	7	3.0	242	6	2.5					
Sex											
Male	269	9	3.3	255	6	2.4					
Female	37	1	2.7	50	0	0.0					
Baseline FVC percent predicted											
<=70%	109	10	9.2	112	2	1.8					
>70%	197	0	0.0	193	4	2.1					
Type of AF therapy											
Nintedanib	173	4	2.3	178	3	1.7					
Pirfenidone	133	6	4.5	127	3	2.4					
Region											
Europe	136	6	4.4	136	3	2.2					
Asia	72	1	1.4	79	2	2.5					
Canada and USA	75	3	4.0	56	1	1.8					
Rest of the World	23	0	0.0	34	0	0.0					

Study: 1305-0014. 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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H.1.1.2.1.6 C-SSRS

Table H.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (AF background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Number of patients (N, %)		306	100.0	305	100.0
Baseline	No Ideation	306	100.0	303	99.3
	Type 1-3	0	0.0	2	0.7
	Wish to be Dead	0	0.0	2	0.7
	Non-Specific Suicidal Thought	0	0.0	1	0.3
	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	306	100.0	302	99.0
	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 2	No Ideation	300	98.0	301	98.7
	Type 1-3	0	0.0	1	0.3
	Wish to be Dead	0	0.0	0	0.0
	Non-Specific Suicidal Thought	0	0.0	1	0.3
	Suicidal Ideation-No Intent	0	0.0	0	0.0
	Type 4-5	0	0.0	1	0.3
	Ideation with Intent, No Plan	0	0.0	1	0.3
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	300	98.0	302	99.0
	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: 1305-0014
A subject may appear in more than one category.

anav4\tlf\t-cssrs-ipf.sas 23JUN2026

Table H.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (AF background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Week 6	No Ideation	298	97.4	297	97.4
	Type 1-3	2	0.7	4	1.3
	Wish to be Dead	2	0.7	4	1.3
	Non-Specific Suicidal Thought	1	0.3	1	0.3
	Suicidal Ideation-No Intent	1	0.3	0	0.0
	Type 4-5	0	0.0	1	0.3
	Ideation with Intent, No Plan	0	0.0	1	0.3
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	299	97.7	301	98.7
	Type 6-9	1	0.3	0	0.0
	Preparatory Acts/Behavior	1	0.3	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	290	94.8	292	95.7
	Type 1-3	1	0.3	2	0.7
	Wish to be Dead	0	0.0	2	0.7
	Non-Specific Suicidal Thought	1	0.3	0	0.0
	Suicidal Ideation-No Intent	1	0.3	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	291	95.1	294	96.4
	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: 1305-0014
A subject may appear in more than one category.

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Table H.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (AF background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Week 18	No Ideation	286	93.5	292	95.7
	Type 1-3	1	0.3	2	0.7
	Wish to be Dead	1	0.3	2	0.7
	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	287	93.8	294	96.4
	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 26	No Ideation	278	90.8	285	93.4
	Type 1-3	1	0.3	0	0.0
	Wish to be Dead	1	0.3	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	279	91.2	285	93.4
	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: 1305-0014
A subject may appear in more than one category.

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Table H.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (AF background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Week 36	No Ideation	270	88.2	273	89.5
	Type 1-3	1	0.3	2	0.7
	Wish to be Dead	1	0.3	2	0.7
	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	271	88.6	275	90.2
	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
Week 44	No Ideation	265	86.6	261	85.6
	Type 1-3	1	0.3	2	0.7
	Wish to be Dead	1	0.3	2	0.7
	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	266	86.9	263	86.2
	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: 1305-0014
A subject may appear in more than one category.

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Table H.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (AF background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Week 52	No Ideation	260	85.0	259	84.9
	Type 1-3	0	0.0	1	0.3
	Wish to be Dead	0	0.0	1	0.3
	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	260	85.0	260	85.2
	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
Week 64	No Ideation	240	78.4	239	78.4
	Type 1-3	1	0.3	0	0.0
	Wish to be Dead	1	0.3	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	241	78.8	239	78.4
	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: 1305-0014
A subject may appear in more than one category.

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Table H.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (AF background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Week 76	No Ideation	179	58.5	173	56.7
	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	179	58.5	173	56.7
	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
Week 88	No Ideation	51	16.7	38	12.5
	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	51	16.7	38	12.5
	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

Study: 1305-0014
A subject may appear in more than one category.

anav4\tlf\t-cssrs-ipf.sas 23JUN2026

Table H.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (AF background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Week 100	No Ideation	0	0.0	1	0.3
	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	0	0.0	1	0.3
	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

Study: 1305-0014
A subject may appear in more than one category.

anav4\tlf\t-cssrs-ipf.sas 23JUN2026

Table H.1.1.2.1.6: 1 Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (AF background)

		Placebo N	Placebo %	Nera 18mg N	Nera 18mg %
Worst Ideation/Behavior over the whole trial	No Ideation	298	97.4	299	98.0
	Type 1-3	7	2.3	4	1.3
	Wish to be Dead	6	2.0	4	1.3
	Non-Specific Suicidal Thought	0	0.0	0	0.0
	Suicidal Ideation-No Intent	1	0.3	0	0.0
	Type 4-5	0	0.0	2	0.7
	Ideation with Intent, No Plan	0	0.0	2	0.7
	Ideation with Plan/Intent	0	0.0	0	0.0
	No Behavior	305	99.7	305	100.0
	Type 6-9	1	0.3	0	0.0
	Preparatory Acts/Behavior	1	0.3	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: 1305-0014
A subject may appear in more than one category.

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Table H.1.1.2.1.6: 2 Shift table of Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (AF background)

			Baseline					
			No Ideation		Type 1-3		Type 4-5	
Visit	Treatment	Suicidal ideation type	n	%	n	%	n	%
Week 2	Placebo	No Ideation	300	98.0	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
	Nera 18mg	No Ideation	300	98.4	1	0.3	0	0.0
		Type 1-3	0	0.0	1	0.3	0	0.0
		Type 4-5	0	0.0	1	0.3	0	0.0
Week 6	Placebo	No Ideation	298	97.4	0	0.0	0	0.0
		Type 1-3	2	0.7	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	296	97.0	1	0.3	0	0.0
		Type 1-3	3	1.0	1	0.3	0	0.0
		Type 4-5	1	0.3	0	0.0	0	0.0
Week 12	Placebo	No Ideation	290	94.8	0	0.0	0	0.0
		Type 1-3	1	0.3	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	291	95.4	1	0.3	0	0.0
		Type 1-3	2	0.7	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
Week 18	Placebo	No Ideation	286	93.5	0	0.0	0	0.0
		Type 1-3	1	0.3	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	290	95.1	2	0.7	0	0.0
		Type 1-3	2	0.7	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0

Study: 1305-0014
Patients without a baseline C-SSRS assessment are excluded from analysis.

anav4\tlf\t-cssrs-shift-ipf.sas 23JUN2026

Table H.1.1.2.1.6: 2 Shift table of Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (AF background)

			Baseline					
			No Ideation		Type 1-3		Type 4-5	
Visit	Treatment	Suicidal ideation type	n	%	n	%	n	%
Week 26	Placebo	No Ideation	278	90.8	0	0.0	0	0.0
		Type 1-3	1	0.3	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	284	93.1	1	0.3	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	270	88.2	0	0.0	0	0.0
		Type 1-3	1	0.3	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	272	89.2	1	0.3	0	0.0
		Type 1-3	2	0.7	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
Week 44	Placebo	No Ideation	265	86.6	0	0.0	0	0.0
		Type 1-3	1	0.3	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	260	85.2	1	0.3	0	0.0
		Type 1-3	2	0.7	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
Week 52	Placebo	No Ideation	260	85.0	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
	Nera 18mg	No Ideation	258	84.6	1	0.3	0	0.0
		Type 1-3	1	0.3	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0

Study: 1305-0014
Patients without a baseline C-SSRS assessment are excluded from analysis.

anav4\tlf\t-cssrs-shift-ipf.sas 23JUN2026

Table H.1.1.2.1.6: 2 Shift table of Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (AF background)

			Baseline					
			No Ideation		Type 1-3		Type 4-5	
Visit	Treatment	Suicidal ideation type	n	%	n	%	n	%
Week 64	Placebo	No Ideation	240	78.4	0	0.0	0	0.0
		Type 1-3	1	0.3	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	238	78.0	1	0.3	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	179	58.5	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	173	56.7	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 88	Placebo	No Ideation	51	16.7	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
	Nera 18mg	No Ideation	38	12.5	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 100	Placebo	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
	Nera 18mg	No Ideation	1	0.3	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: 1305-0014
Patients without a baseline C-SSRS assessment are excluded from analysis.

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Table H.1.1.2.1.6: 2 Shift table of Columbia Suicidal Severity Rating Scale (C-SSRS) over the whole trial - 18mg - TS (AF background)

			Baseline					
			No Ideation		Type 1-3		Type 4-5	
Visit	Treatment	Suicidal ideation type	n	%	n	%	n	%
Worst value over the whole trial	Placebo	No Ideation	298	97.4	0	0.0	0	0.0
		Type 1-3	8	2.6	0	0.0	0	0.0
		Type 4-5	0	0.0	0	0.0	0	0.0
	Nera 18mg	No Ideation	298	97.7	1	0.3	0	0.0
		Type 1-3	4	1.3	0	0.0	0	0.0
		Type 4-5	1	0.3	1	0.3	0	0.0

Study: 1305-0014
Patients without a baseline C-SSRS assessment are excluded from analysis.

anav4\tlf\t-cssrs-shift-ipf.sas 23JUN2026

H.1.1.2.1.7 HADS

Table H.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 (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
Overall																	
Baseline																	
Placebo	306	306	3.0	0.2	296 (100.0%)												
Nera 18mg	305	305	3.3	0.2	298 (100.0%)												
Week 12																	
Placebo		291	2.9	0.2	291 (98.3%)	-0.1	0.1	-0.4	0.2								
Nera 18mg		290	3.1	0.2	290 (97.3%)	-0.1	0.1	-0.4	0.1	-0.0	0.2	-0.4	0.3	0.8219			
Week 26																	
Placebo		274	2.9	0.2	274 (92.6%)	-0.1	0.1	-0.4	0.2								
Nera 18mg		273	3.1	0.2	273 (91.6%)	-0.1	0.1	-0.3	0.2	0.0	0.2	-0.4	0.4	0.8609			
Week 36																	
Placebo		268	3.1	0.2	268 (90.5%)	0.2	0.1	-0.1	0.5								
Nera 18mg		270	3.2	0.2	270 (90.6%)	0.0	0.1	-0.2	0.3	-0.2	0.2	-0.5	0.2	0.4045			
Week 44																	
Placebo		268	3.2	0.2	268 (90.5%)	0.3	0.1	0.0	0.6								
Nera 18mg		254	3.3	0.2	254 (85.2%)	0.1	0.1	-0.2	0.4	-0.2	0.2	-0.6	0.2	0.4017			
Week 52																	
Placebo		257	3.0	0.2	257 (86.8%)	0.2	0.1	-0.1	0.5								
Nera 18mg		259	3.3	0.2	259 (86.9%)	0.1	0.1	-0.2	0.4	-0.1	0.2	-0.5	0.3	0.7289			
Week 64																	
Placebo		207	3.1	0.2	207 (69.9%)	0.3	0.2	-0.0	0.6								
Nera 18mg		199	3.3	0.2	199 (66.8%)	0.1	0.2	-0.2	0.4	-0.2	0.2	-0.7	0.2	0.3525			
Week 76																	
Placebo		73	2.8	0.3	73 (24.7%)												
Nera 18mg		62	3.0	0.4	62 (20.8%)												
Week 88																	
Placebo		9	1.6	0.6	9 (3.0%)												
Nera 18mg		9	3.9	1.3	9 (3.0%)												
Age																	
Test for homogeneity (H0)^																	
Week 12														0.6604			
Week 26														0.6975			
Week 36														0.4162			
Week 44														0.8016			

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

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Table H.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 (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 52														0.1361			
Week 64														0.4651			
<65 years																	
Baseline																	
Placebo	69	69	3.1	0.4	68 (100.0%)												
Nera 18mg	63	63	3.1	0.3	62 (100.0%)												
Week 12																	
Placebo		65	3.3	0.4	65 (95.6%)	0.1	0.3	-0.4	0.7								
Nera 18mg		61	3.0	0.4	61 (98.4%)	-0.1	0.3	-0.6	0.5	-0.2	0.4	-1.0	0.6	0.6260			
Week 26																	
Placebo		64	3.2	0.4	64 (94.1%)	-0.0	0.3	-0.6	0.6								
Nera 18mg		61	3.0	0.4	61 (98.4%)	-0.1	0.3	-0.7	0.5	-0.1	0.4	-0.9	0.7	0.7972			
Week 36																	
Placebo		66	3.6	0.4	66 (97.1%)	0.4	0.3	-0.1	1.0								
Nera 18mg		59	2.9	0.4	59 (95.2%)	-0.0	0.3	-0.6	0.5	-0.4	0.4	-1.2	0.3	0.2701			
Week 44																	
Placebo		64	3.6	0.4	64 (94.1%)	0.4	0.3	-0.2	1.0								
Nera 18mg		54	3.1	0.4	54 (87.1%)	0.2	0.3	-0.5	0.8	-0.3	0.4	-1.1	0.6	0.5397			
Week 52																	
Placebo		63	3.0	0.4	63 (92.6%)	-0.2	0.3	-0.8	0.4								
Nera 18mg		55	3.4	0.5	55 (88.7%)	0.3	0.3	-0.3	0.9	0.5	0.4	-0.4	1.3	0.2613			
Week 64																	
Placebo		50	3.3	0.4	50 (73.5%)	0.3	0.3	-0.3	1.0								
Nera 18mg		39	3.7	0.6	39 (62.9%)	0.5	0.4	-0.3	1.2	0.1	0.5	-0.9	1.1	0.8206			
Week 76																	
Placebo		17	3.2	0.8	17 (25.0%)												
Nera 18mg		12	3.8	1.2	12 (19.4%)												
Week 88																	
Placebo		4	0.5	0.5	4 (5.9%)												
Nera 18mg		3	1.7	1.7	3 (4.8%)												
>=65 years																	
Baseline																	
Placebo	237	237	3.0	0.2	228 (100.0%)												
Nera 18mg	242	242	3.4	0.2	236 (100.0%)												
Week 12																	

Study: 1305-0014. 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, 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 H.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 (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		226	2.8	0.2	226 (99.1%)	-0.2	0.1	-0.5	0.1								
Nera 18mg		229	3.1	0.2	229 (97.0%)	-0.2	0.1	-0.4	0.1	0.0	0.2	-0.4	0.4	0.9856			
Week 26																	
Placebo		210	2.8	0.2	210 (92.1%)	-0.1	0.2	-0.4	0.2								
Nera 18mg		212	3.2	0.2	212 (89.8%)	-0.0	0.2	-0.4	0.3	0.1	0.2	-0.4	0.5	0.7322			
Week 36																	
Placebo		202	2.9	0.2	202 (88.6%)	0.1	0.2	-0.2	0.4								
Nera 18mg		211	3.3	0.2	211 (89.4%)	0.1	0.2	-0.2	0.4	-0.1	0.2	-0.5	0.4	0.7466			
Week 44																	
Placebo		204	3.1	0.2	204 (89.5%)	0.3	0.2	-0.1	0.6								
Nera 18mg		200	3.3	0.2	200 (84.7%)	0.1	0.2	-0.2	0.4	-0.1	0.2	-0.6	0.3	0.5448			
Week 52																	
Placebo		194	3.0	0.2	194 (85.1%)	0.3	0.2	0.0	0.7								
Nera 18mg		204	3.3	0.2	204 (86.4%)	0.1	0.2	-0.2	0.4	-0.2	0.2	-0.7	0.2	0.2903			
Week 64																	
Placebo		157	3.0	0.2	157 (68.9%)	0.3	0.2	-0.1	0.7								
Nera 18mg		160	3.2	0.2	160 (67.8%)	-0.0	0.2	-0.4	0.4	-0.3	0.3	-0.8	0.2	0.2604			
Week 76																	
Placebo		56	2.6	0.4	56 (24.6%)												
Nera 18mg		50	2.9	0.4	50 (21.2%)												
Week 88																	
Placebo		5	2.4	0.9	5 (2.2%)												
Nera 18mg		6	5.0	1.7	6 (2.5%)												
Sex																	
Test for homogeneity (H0)^																	
Week 12														0.3719			
Week 26														0.3374			
Week 36														0.6029			
Week 44														0.3902			
Week 52														0.4660			
Week 64														0.2141			
Male																	
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 H.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 (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	269	269	2.9	0.2	259 (100.0%)												
Nera 18mg	255	255	3.3	0.2	248 (100.0%)												
Week 12																	
Placebo		255	2.7	0.2	255 (98.5%)	-0.2	0.1	-0.5	0.1								
Nera 18mg		242	2.8	0.2	242 (97.6%)	-0.3	0.1	-0.6	-0.1	-0.1	0.2	-0.5	0.2	0.4538			
Week 26																	
Placebo		238	2.7	0.2	238 (91.9%)	-0.2	0.1	-0.5	0.1								
Nera 18mg		231	2.9	0.2	231 (93.1%)	-0.2	0.2	-0.5	0.0	-0.1	0.2	-0.5	0.3	0.7337			
Week 36																	
Placebo		232	2.9	0.2	232 (89.6%)	0.2	0.1	-0.1	0.4								
Nera 18mg		227	3.1	0.2	227 (91.5%)	-0.1	0.1	-0.4	0.2	-0.2	0.2	-0.6	0.2	0.2887			
Week 44																	
Placebo		232	3.1	0.2	232 (89.6%)	0.3	0.2	-0.0	0.6								
Nera 18mg		215	3.1	0.2	215 (86.7%)	-0.0	0.2	-0.3	0.3	-0.3	0.2	-0.7	0.2	0.2334			
Week 52																	
Placebo		222	2.9	0.2	222 (85.7%)	0.2	0.2	-0.1	0.5								
Nera 18mg		219	3.2	0.2	219 (88.3%)	0.0	0.2	-0.3	0.3	-0.2	0.2	-0.6	0.3	0.4935			
Week 64																	
Placebo		176	2.8	0.2	176 (68.0%)	0.1	0.2	-0.2	0.5								
Nera 18mg		170	3.2	0.2	170 (68.5%)	0.0	0.2	-0.3	0.4	-0.1	0.3	-0.6	0.4	0.6682			
Week 76																	
Placebo		64	2.5	0.3	64 (24.7%)												
Nera 18mg		52	2.9	0.5	52 (21.0%)												
Week 88																	
Placebo		8	1.4	0.7	8 (3.1%)												
Nera 18mg		9	3.9	1.3	9 (3.6%)												
Female																	
Baseline																	
Placebo	37	37	3.9	0.5	37 (100.0%)												
Nera 18mg	50	50	3.6	0.4	50 (100.0%)												
Week 12																	
Placebo		36	4.2	0.6	36 (97.3%)	0.6	0.4	-0.2	1.3								
Nera 18mg		48	4.4	0.5	48 (96.0%)	0.9	0.3	0.3	1.5	0.3	0.5	-0.6	1.3	0.5100			
Week 26																	
Placebo		36	3.9	0.6	36 (97.3%)	0.4	0.4	-0.3	1.2								
Nera 18mg		42	4.2	0.6	42 (84.0%)	0.9	0.3	0.2	1.6	0.5	0.5	-0.6	1.5	0.3691			

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

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Table H.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 (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 36																	
Placebo		36	4.1	0.5	36 (97.3%)	0.5	0.4	-0.2	1.2								
Nera 18mg		43	3.9	0.5	43 (86.0%)	0.6	0.3	-0.1	1.2	0.1	0.5	-0.9	1.0	0.9003			
Week 44																	
Placebo		36	4.1	0.4	36 (97.3%)	0.6	0.4	-0.2	1.4								
Nera 18mg		39	4.1	0.6	39 (78.0%)	0.8	0.4	0.1	1.5	0.2	0.5	-0.8	1.3	0.6599			
Week 52																	
Placebo		35	4.0	0.5	35 (94.6%)	0.4	0.4	-0.4	1.1								
Nera 18mg		40	4.2	0.6	40 (80.0%)	0.6	0.4	-0.1	1.3	0.3	0.5	-0.8	1.3	0.6122			
Week 64																	
Placebo		31	5.0	0.6	31 (83.8%)	1.3	0.4	0.4	2.1								
Nera 18mg		29	3.8	0.7	29 (58.0%)	0.3	0.4	-0.5	1.2	-0.9	0.6	-2.2	0.3	0.1276			
Week 76																	
Placebo		9	4.7	1.0	9 (24.3%)												
Nera 18mg		10	3.8	1.1	10 (20.0%)												
Week 88																	
Placebo		1	3.0	NC	1 (2.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 12														0.4282			
Week 26														0.7607			
Week 36														0.8664			
Week 44														0.9232			
Week 52														0.6305			
Week 64														0.6585			
<=70%																	
Baseline																	
Placebo	109	109	2.9	0.3	101 (100.0%)												
Nera 18mg	112	112	3.8	0.3	106 (100.0%)												
Week 12																	
Placebo		100	3.1	0.3	100 (99.0%)	0.1	0.2	-0.3	0.5								
Nera 18mg		101	3.4	0.3	101 (95.3%)	-0.1	0.2	-0.6	0.3	-0.2	0.3	-0.9	0.4	0.4330			

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Table H.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 (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		92	3.1	0.3	92 (91.1%)	0.3	0.2	-0.2	0.7								
Nera 18mg		94	3.7	0.3	94 (88.7%)	0.2	0.2	-0.2	0.7	-0.1	0.3	-0.7	0.6	0.8763			
Week 36																	
Placebo		88	3.4	0.3	88 (87.1%)	0.5	0.2	0.1	1.0								
Nera 18mg		89	3.8	0.3	89 (84.0%)	0.3	0.2	-0.1	0.8	-0.2	0.3	-0.9	0.4	0.5339			
Week 44																	
Placebo		90	3.3	0.3	90 (89.1%)	0.5	0.3	-0.0	1.0								
Nera 18mg		83	3.6	0.3	83 (78.3%)	0.3	0.3	-0.2	0.8	-0.2	0.4	-0.9	0.5	0.5684			
Week 52																	
Placebo		86	3.3	0.4	86 (85.1%)	0.5	0.2	0.1	1.0								
Nera 18mg		85	3.8	0.3	85 (80.2%)	0.3	0.2	-0.2	0.8	-0.2	0.4	-0.9	0.5	0.5496			
Week 64																	
Placebo		70	3.3	0.4	70 (69.3%)	0.6	0.3	0.0	1.1								
Nera 18mg		64	3.7	0.4	64 (60.4%)	0.2	0.3	-0.4	0.8	-0.4	0.4	-1.2	0.4	0.3658			
Week 76																	
Placebo		22	3.1	0.7	22 (21.8%)												
Nera 18mg		18	4.0	0.8	18 (17.0%)												
Week 88																	
Placebo		3	0.3	0.3	3 (3.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	197	197	3.1	0.2	195 (100.0%)												
Nera 18mg	193	193	3.0	0.2	192 (100.0%)												
Week 12																	
Placebo		191	2.8	0.2	191 (97.9%)	-0.2	0.2	-0.5	0.1								
Nera 18mg		189	2.9	0.2	189 (98.4%)	-0.1	0.2	-0.5	0.2	0.1	0.2	-0.4	0.5	0.7881			
Week 26																	
Placebo		182	2.8	0.2	182 (93.3%)	-0.3	0.2	-0.6	0.1								
Nera 18mg		179	2.9	0.2	179 (93.2%)	-0.2	0.2	-0.5	0.1	0.1	0.2	-0.4	0.5	0.7602			
Week 36																	
Placebo		180	3.0	0.2	180 (92.3%)	0.0	0.2	-0.3	0.3								
Nera 18mg		181	3.0	0.2	181 (94.3%)	-0.1	0.2	-0.4	0.2	-0.1	0.2	-0.6	0.3	0.5559			
Week 44																	
Placebo		178	3.1	0.2	178 (91.3%)	0.2	0.2	-0.1	0.6								

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Table H.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 (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		171	3.1	0.2	171 (89.1%)	0.1	0.2	-0.3	0.4	-0.2	0.3	-0.7	0.3	0.5224			
Week 52																	
Placebo		171	2.8	0.2	171 (87.7%)	0.0	0.2	-0.3	0.4								
Nera 18mg		174	3.1	0.2	174 (90.6%)	0.0	0.2	-0.3	0.4	-0.0	0.2	-0.5	0.5	0.9896			
Week 64																	
Placebo		137	3.0	0.2	137 (70.3%)	0.2	0.2	-0.2	0.6								
Nera 18mg		135	3.1	0.3	135 (70.3%)	0.0	0.2	-0.4	0.4	-0.2	0.3	-0.7	0.4	0.6039			
Week 76																	
Placebo		51	2.6	0.4	51 (26.2%)												
Nera 18mg		44	2.7	0.5	44 (22.9%)												
Week 88																	
Placebo		6	2.2	0.8	6 (3.1%)												
Nera 18mg		9	3.9	1.3	9 (4.7%)												
Type of AF therapy																	
Test for homogeneity (H0)^																	
Week 12														0.3053			
Week 26														0.4313			
Week 36														0.5048			
Week 44														0.5990			
Week 52														0.8173			
Week 64														0.1688			
Nintedanib																	
Baseline																	
Placebo	173	173	2.9	0.2	167 (100.0%)												
Nera 18mg	178	178	3.2	0.2	172 (100.0%)												
Week 12																	
Placebo		164	2.9	0.2	164 (98.2%)	-0.0	0.2	-0.4	0.3								
Nera 18mg		165	2.9	0.2	165 (95.9%)	-0.2	0.2	-0.6	0.1	-0.2	0.2	-0.7	0.3	0.3976			
Week 26																	
Placebo		153	2.7	0.2	153 (91.6%)	-0.2	0.2	-0.6	0.1								
Nera 18mg		154	3.0	0.2	154 (89.5%)	-0.1	0.2	-0.4	0.3	0.2	0.3	-0.3	0.7	0.5057			
Week 36																	
Placebo		152	3.0	0.2	152 (91.0%)	0.2	0.2	-0.2	0.5								

Study: 1305-0014. 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 H.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 (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		150	3.2	0.2	150 (87.2%)	0.1	0.2	-0.2	0.5	-0.0	0.3	-0.5	0.5	0.8635			
Week 44																	
Placebo		150	3.1	0.3	150 (89.8%)	0.2	0.2	-0.2	0.6								
Nera 18mg		141	3.1	0.3	141 (82.0%)	0.1	0.2	-0.3	0.5	-0.1	0.3	-0.6	0.5	0.7861			
Week 52																	
Placebo		146	2.8	0.2	146 (87.4%)	0.1	0.2	-0.3	0.5								
Nera 18mg		146	3.0	0.2	146 (84.9%)	-0.0	0.2	-0.4	0.3	-0.1	0.3	-0.6	0.4	0.6857			
Week 64																	
Placebo		116	2.7	0.3	116 (69.5%)	0.0	0.2	-0.4	0.5								
Nera 18mg		112	3.3	0.3	112 (65.1%)	0.1	0.2	-0.3	0.6	0.1	0.3	-0.5	0.7	0.8208			
Week 76																	
Placebo		41	2.6	0.5	41 (24.6%)												
Nera 18mg		34	3.9	0.6	34 (19.8%)												
Week 88																	
Placebo		6	1.3	0.8	6 (3.6%)												
Nera 18mg		4	2.8	1.4	4 (2.3%)												
Pirfenidone																	
Baseline																	
Placebo	133	133	3.1	0.2	129 (100.0%)												
Nera 18mg	127	127	3.4	0.3	126 (100.0%)												
Week 12																	
Placebo		127	2.9	0.3	127 (98.4%)	-0.2	0.2	-0.6	0.2								
Nera 18mg		125	3.3	0.3	125 (99.2%)	-0.0	0.2	-0.4	0.4	0.2	0.3	-0.4	0.7	0.5340			
Week 26																	
Placebo		121	3.1	0.3	121 (93.8%)	0.1	0.2	-0.3	0.5								
Nera 18mg		119	3.3	0.3	119 (94.4%)	-0.1	0.2	-0.5	0.4	-0.1	0.3	-0.7	0.4	0.6438			
Week 36																	
Placebo		116	3.2	0.3	116 (89.9%)	0.2	0.2	-0.2	0.6								
Nera 18mg		120	3.3	0.3	120 (95.2%)	-0.1	0.2	-0.5	0.3	-0.3	0.3	-0.9	0.3	0.2993			
Week 44																	
Placebo		118	3.4	0.3	118 (91.5%)	0.4	0.2	0.0	0.9								
Nera 18mg		113	3.4	0.3	113 (89.7%)	0.1	0.2	-0.3	0.6	-0.3	0.3	-0.9	0.3	0.3470			
Week 52																	
Placebo		111	3.2	0.3	111 (86.0%)	0.4	0.2	-0.1	0.8								
Nera 18mg		113	3.7	0.3	113 (89.7%)	0.3	0.2	-0.1	0.8	-0.0	0.3	-0.6	0.6	0.9621			
Week 64																	

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

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Table H.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 (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 95% CI value	lower	upper
Placebo		91	3.6	0.3	91 (70.5%)	0.7	0.3	0.2	1.1								
Nera 18mg		87	3.4	0.3	87 (69.0%)	0.1	0.3	-0.4	0.6	-0.6	0.4	-1.3	0.1	0.1031			
Week 76																	
Placebo		32	3.0	0.5	32 (24.8%)												
Nera 18mg		28	2.0	0.5	28 (22.2%)												
Week 88																	
Placebo		3	2.0	1.0	3 (2.3%)												
Nera 18mg		5	4.8	2.1	5 (4.0%)												
Region																	
Test for homogeneity (H0)^																	
Week 12														0.0869			
Week 26														0.5031			
Week 36														0.0076			
Week 44														0.0861			
Week 52														0.1667			
Week 64														0.0076			
Europe																	
Baseline																	
Placebo	136	136	3.2	0.2	134 (100.0%)												
Nera 18mg	136	136	3.5	0.3	133 (100.0%)												
Week 12																	
Placebo		130	2.8	0.2	130 (97.0%)	-0.3	0.2	-0.6	0.1								
Nera 18mg		125	3.3	0.3	125 (94.0%)	-0.0	0.2	-0.4	0.4	0.2	0.3	-0.3	0.8	0.3969			
Week 26																	
Placebo		122	2.9	0.3	122 (91.0%)	-0.1	0.2	-0.5	0.3								
Nera 18mg		122	3.2	0.3	122 (91.7%)	0.0	0.2	-0.4	0.4	0.2	0.3	-0.4	0.7	0.6020			
Week 36																	
Placebo		120	2.9	0.2	120 (89.6%)	0.0	0.2	-0.4	0.4								
Nera 18mg		120	3.6	0.3	120 (90.2%)	0.4	0.2	0.0	0.8	0.4	0.3	-0.2	1.0	0.1574			
Week 44																	
Placebo		122	3.2	0.3	122 (91.0%)	0.2	0.2	-0.2	0.6								
Nera 18mg		113	3.5	0.3	113 (85.0%)	0.4	0.2	-0.0	0.9	0.2	0.3	-0.4	0.8	0.4556			
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 H.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 (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		117	3.0	0.2	117 (87.3%)	0.2	0.2	-0.2	0.6								
Nera 18mg		115	3.7	0.3	115 (86.5%)	0.4	0.2	-0.0	0.8	0.2	0.3	-0.4	0.8	0.5569			
Week 64																	
Placebo		96	3.0	0.3	96 (71.6%)	0.1	0.2	-0.4	0.6								
Nera 18mg		87	3.8	0.3	87 (65.4%)	0.5	0.3	-0.0	1.0	0.4	0.4	-0.3	1.1	0.3059			
Week 76																	
Placebo		30	2.6	0.5	30 (22.4%)												
Nera 18mg		27	3.3	0.7	27 (20.3%)												
Week 88																	
Placebo		3	0.7	0.7	3 (2.2%)												
Nera 18mg		5	2.0	1.0	5 (3.8%)												
Asia																	
Baseline																	
Placebo	72	72	2.0	0.3	68 (100.0%)												
Nera 18mg	79	79	2.8	0.3	76 (100.0%)												
Week 12																	
Placebo		67	2.0	0.3	67 (98.5%)	-0.2	0.3	-0.8	0.3								
Nera 18mg		76	2.5	0.3	76 (100.0%)	-0.5	0.3	-1.0	0.0	-0.2	0.4	-1.0	0.5	0.5105			
Week 26																	
Placebo		63	2.2	0.3	63 (92.6%)	-0.1	0.3	-0.7	0.5								
Nera 18mg		71	2.7	0.4	71 (93.4%)	-0.3	0.3	-0.8	0.3	-0.1	0.4	-0.9	0.7	0.7327			
Week 36																	
Placebo		62	3.0	0.4	62 (91.2%)	0.7	0.3	0.1	1.3								
Nera 18mg		71	2.4	0.3	71 (93.4%)	-0.5	0.3	-1.0	0.0	-1.2	0.4	-1.9	-0.4	0.0022	-0.53	-0.88	-0.19
Week 44																	
Placebo		60	2.9	0.5	60 (88.2%)	0.6	0.3	0.0	1.2								
Nera 18mg		66	2.7	0.3	66 (86.8%)	-0.2	0.3	-0.8	0.3	-0.9	0.4	-1.7	-0.0	0.0451	-0.36	-0.71	-0.01
Week 52																	
Placebo		57	2.4	0.4	57 (83.8%)	0.4	0.3	-0.2	1.0								
Nera 18mg		66	2.9	0.4	66 (86.8%)	0.0	0.3	-0.6	0.6	-0.4	0.4	-1.2	0.4	0.3666			
Week 64																	
Placebo		47	2.8	0.5	47 (69.1%)	0.5	0.4	-0.2	1.2								
Nera 18mg		56	2.7	0.4	56 (73.7%)	-0.2	0.3	-0.9	0.4	-0.7	0.5	-1.7	0.2	0.1335			
Week 76																	
Placebo		15	2.9	0.8	15 (22.1%)												
Nera 18mg		16	2.4	0.6	16 (21.1%)												

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

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Table H.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 (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 88																	
Placebo		1	0.0	NC	1 (1.5%)												
Nera 18mg		1	6.0	NC	1 (1.3%)												
Canada and USA																	
Baseline																	
Placebo	75	75	3.8	0.3	71 (100.0%)												
Nera 18mg	56	56	3.8	0.3	56 (100.0%)												
Week 12																	
Placebo		71	3.7	0.4	71 (100.0%)	0.1	0.3	-0.5	0.6								
Nera 18mg		56	3.9	0.5	56 (100.0%)	0.3	0.3	-0.3	0.9	0.3	0.4	-0.5	1.0	0.5077			
Week 26																	
Placebo		67	3.4	0.4	67 (94.4%)	-0.0	0.3	-0.6	0.5								
Nera 18mg		52	4.0	0.4	52 (92.9%)	0.3	0.3	-0.3	0.9	0.3	0.4	-0.5	1.2	0.4576			
Week 36																	
Placebo		65	3.3	0.4	65 (91.5%)	-0.1	0.3	-0.6	0.4								
Nera 18mg		53	3.7	0.4	53 (94.6%)	0.0	0.3	-0.6	0.6	0.1	0.4	-0.7	0.9	0.7559			
Week 44																	
Placebo		64	3.5	0.3	64 (90.1%)	0.1	0.3	-0.5	0.7								
Nera 18mg		50	3.5	0.4	50 (89.3%)	-0.0	0.3	-0.7	0.6	-0.1	0.4	-1.0	0.7	0.7646			
Week 52																	
Placebo		64	3.3	0.4	64 (90.1%)	-0.1	0.3	-0.7	0.4								
Nera 18mg		52	3.4	0.4	52 (92.9%)	-0.1	0.3	-0.8	0.5	0.0	0.4	-0.8	0.9	0.9555			
Week 64																	
Placebo		49	3.2	0.4	49 (69.0%)	0.1	0.3	-0.6	0.8								
Nera 18mg		41	3.3	0.5	41 (73.2%)	-0.1	0.4	-0.9	0.6	-0.2	0.5	-1.2	0.8	0.6390			
Week 76																	
Placebo		20	2.6	0.6	20 (28.2%)												
Nera 18mg		12	2.8	0.8	12 (21.4%)												
Week 88																	
Placebo		2	3.0	2.0	2 (2.8%)												
Nera 18mg		1	6.0	NC	1 (1.8%)												
Rest of the World																	
Baseline																	
Placebo	23	23	2.7	0.7	23 (100.0%)												
Nera 18mg	34	34	3.1	0.4	33 (100.0%)												
Week 12																	

Study: 1305-0014. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Table H.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 (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		23	3.5	0.7	23 (100.0%)	0.7	0.5	-0.2	1.6								
Nera 18mg		33	2.5	0.5	33 (100.0%)	-0.6	0.4	-1.3	0.2	-1.3	0.6	-2.5	-0.1	0.0310	-0.58	-1.11	-0.04
Week 26																	
Placebo		22	2.9	0.6	22 (95.7%)	-0.0	0.5	-1.0	1.0								
Nera 18mg		28	2.4	0.6	28 (84.8%)	-0.6	0.4	-1.4	0.3	-0.6	0.7	-1.8	0.7	0.3997			
Week 36																	
Placebo		21	3.7	0.7	21 (91.3%)	0.7	0.5	-0.2	1.7								
Nera 18mg		26	2.8	0.6	26 (78.8%)	-0.2	0.4	-1.0	0.6	-1.0	0.6	-2.2	0.3	0.1357			
Week 44																	
Placebo		22	3.5	0.7	22 (95.7%)	0.6	0.5	-0.4	1.6								
Nera 18mg		25	3.1	0.6	25 (75.8%)	0.1	0.5	-0.9	1.0	-0.6	0.7	-1.9	0.8	0.4065			
Week 52																	
Placebo		19	3.5	0.9	19 (82.6%)	0.7	0.5	-0.3	1.7								
Nera 18mg		26	2.8	0.6	26 (78.8%)	-0.2	0.5	-1.1	0.7	-0.9	0.7	-2.3	0.5	0.1933			
Week 64																	
Placebo		15	4.4	0.9	15 (65.2%)	1.7	0.6	0.5	2.9								
Nera 18mg		15	2.9	1.0	15 (45.5%)	-0.3	0.6	-1.4	0.8	-2.0	0.8	-3.7	-0.4	0.0161	-0.86	-1.59	-0.13
Week 76																	
Placebo		8	3.5	1.2	8 (34.8%)												
Nera 18mg		7	4.3	2.0	7 (21.2%)												
Week 88																	
Placebo		3	2.0	1.0	3 (13.0%)												
Nera 18mg		2	6.5	5.5	2 (6.1%)												

Study: 1305-0014. 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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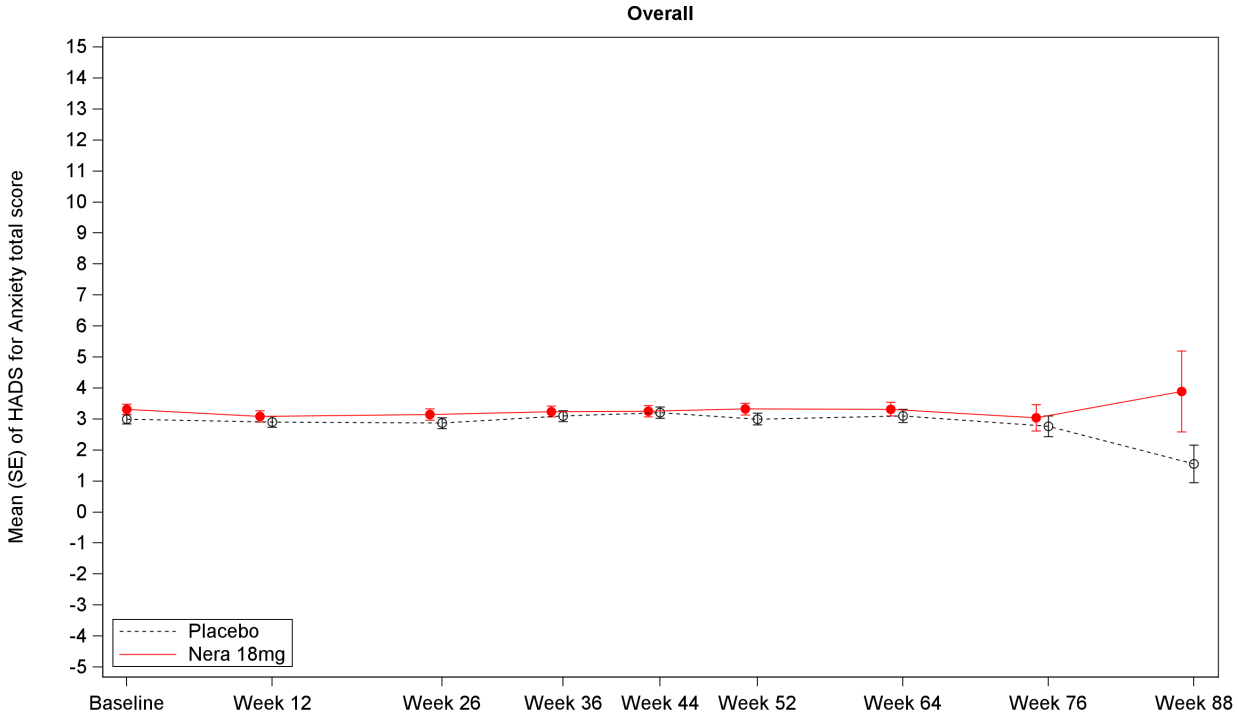

Number of patients

Placebo	306	291	274	268	268	257	207	73	9
Nera 18mg	305	290	273	270	254	259	199	62	9

Study: 1305-0014. Number of patients refers to the number of patients with observed data at visit.

Figure H.1.1.2.1.7: 1 Mean (SE) of HADS for Anxiety total score over the whole trial - 18mg - TS (AF background)

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Table H.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 (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	306	306	3.0	0.1	296 (100.0%)												
Nera 18mg	305	305	3.2	0.2	298 (100.0%)												
Week 12																	
Placebo		291	3.1	0.2	291 (98.3%)	0.1	0.1	-0.2	0.3								
Nera 18mg		290	3.4	0.2	290 (97.3%)	0.3	0.1	0.1	0.5	0.2	0.2	-0.1	0.6	0.1640			
Week 26																	
Placebo		274	3.1	0.2	274 (92.6%)	0.1	0.1	-0.2	0.3								
Nera 18mg		273	3.3	0.2	273 (91.6%)	0.2	0.1	-0.1	0.5	0.1	0.2	-0.2	0.5	0.4677			
Week 36																	
Placebo		268	3.2	0.2	268 (90.5%)	0.3	0.1	0.0	0.6								
Nera 18mg		270	3.7	0.2	270 (90.6%)	0.6	0.1	0.3	0.8	0.3	0.2	-0.1	0.6	0.1786			
Week 44																	
Placebo		268	3.4	0.2	268 (90.5%)	0.5	0.1	0.2	0.8								
Nera 18mg		254	3.7	0.2	254 (85.2%)	0.6	0.1	0.3	0.9	0.1	0.2	-0.4	0.5	0.8095			
Week 52																	
Placebo		257	3.4	0.2	257 (86.8%)	0.6	0.2	0.3	1.0								
Nera 18mg		259	3.7	0.2	259 (86.9%)	0.6	0.2	0.3	0.9	-0.0	0.2	-0.5	0.4	0.8787			
Week 64																	
Placebo		207	3.4	0.2	207 (69.9%)	0.8	0.2	0.4	1.1								
Nera 18mg		199	3.9	0.2	199 (66.8%)	0.8	0.2	0.5	1.1	0.0	0.2	-0.5	0.5	0.9298			
Week 76																	
Placebo		73	3.0	0.3	73 (24.7%)												
Nera 18mg		62	4.0	0.5	62 (20.8%)												
Week 88																	
Placebo		9	2.4	0.9	9 (3.0%)												
Nera 18mg		9	3.3	1.3	9 (3.0%)												
Age																	
Test for homogeneity (H0)^																	
Week 12														0.9399			
Week 26														0.3027			
Week 36														0.8271			
Week 44														0.7122			

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

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Table H.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 (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 52														0.3536			
Week 64														0.5213			
<65 years																	
Baseline																	
Placebo	69	69	2.9	0.3	68 (100.0%)												
Nera 18mg	63	63	3.5	0.4	62 (100.0%)												
Week 12																	
Placebo		65	3.0	0.4	65 (95.6%)	0.0	0.3	-0.5	0.5								
Nera 18mg		61	3.5	0.4	61 (98.4%)	0.2	0.3	-0.3	0.8	0.2	0.4	-0.5	0.9	0.5676			
Week 26																	
Placebo		64	2.7	0.3	64 (94.1%)	-0.3	0.3	-0.8	0.2								
Nera 18mg		61	2.9	0.3	61 (98.4%)	-0.5	0.3	-1.1	0.0	-0.2	0.4	-1.0	0.5	0.5589			
Week 36																	
Placebo		66	3.1	0.4	66 (97.1%)	0.1	0.3	-0.5	0.6								
Nera 18mg		59	3.5	0.3	59 (95.2%)	0.3	0.3	-0.3	0.8	0.2	0.4	-0.6	1.0	0.6651			
Week 44																	
Placebo		64	2.9	0.4	64 (94.1%)	0.0	0.3	-0.6	0.6								
Nera 18mg		54	3.2	0.4	54 (87.1%)	-0.1	0.3	-0.7	0.5	-0.1	0.4	-1.0	0.7	0.8046			
Week 52																	
Placebo		63	3.3	0.4	63 (92.6%)	0.4	0.3	-0.3	1.0								
Nera 18mg		55	3.4	0.4	55 (88.7%)	-0.0	0.3	-0.7	0.6	-0.4	0.5	-1.4	0.5	0.3624			
Week 64																	
Placebo		50	3.0	0.5	50 (73.5%)	0.3	0.3	-0.4	1.0								
Nera 18mg		39	3.9	0.6	39 (62.9%)	0.6	0.4	-0.2	1.4	0.3	0.5	-0.7	1.3	0.5509			
Week 76																	
Placebo		17	2.8	0.7	17 (25.0%)												
Nera 18mg		12	4.7	1.2	12 (19.4%)												
Week 88																	
Placebo		4	1.0	0.4	4 (5.9%)												
Nera 18mg		3	2.0	1.5	3 (4.8%)												
>=65 years																	
Baseline																	
Placebo	237	237	3.0	0.2	228 (100.0%)												
Nera 18mg	242	242	3.2	0.2	236 (100.0%)												
Week 12																	

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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, 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 H.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 (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		226	3.1	0.2	226 (99.1%)	0.1	0.1	-0.2	0.3								
Nera 18mg		229	3.4	0.2	229 (97.0%)	0.3	0.1	0.1	0.6	0.2	0.2	-0.1	0.6	0.2124			
Week 26																	
Placebo		210	3.2	0.2	210 (92.1%)	0.2	0.1	-0.1	0.5								
Nera 18mg		212	3.5	0.2	212 (89.8%)	0.4	0.1	0.1	0.7	0.2	0.2	-0.2	0.6	0.2771			
Week 36																	
Placebo		202	3.3	0.2	202 (88.6%)	0.4	0.2	0.1	0.7								
Nera 18mg		211	3.8	0.2	211 (89.4%)	0.6	0.2	0.3	0.9	0.3	0.2	-0.2	0.7	0.2099			
Week 44																	
Placebo		204	3.6	0.2	204 (89.5%)	0.7	0.2	0.4	1.0								
Nera 18mg		200	3.8	0.2	200 (84.7%)	0.8	0.2	0.4	1.1	0.1	0.2	-0.4	0.5	0.7502			
Week 52																	
Placebo		194	3.4	0.2	194 (85.1%)	0.7	0.2	0.3	1.1								
Nera 18mg		204	3.8	0.2	204 (86.4%)	0.8	0.2	0.4	1.1	0.1	0.3	-0.4	0.6	0.7909			
Week 64																	
Placebo		157	3.6	0.2	157 (68.9%)	0.9	0.2	0.6	1.3								
Nera 18mg		160	3.9	0.3	160 (67.8%)	0.9	0.2	0.5	1.2	-0.1	0.3	-0.6	0.5	0.8074			
Week 76																	
Placebo		56	3.1	0.4	56 (24.6%)												
Nera 18mg		50	3.8	0.5	50 (21.2%)												
Week 88																	
Placebo		5	3.6	1.4	5 (2.2%)												
Nera 18mg		6	4.0	1.8	6 (2.5%)												
Sex																	
Test for homogeneity (H0)^																	
Week 12														0.2360			
Week 26														0.6844			
Week 36														0.6953			
Week 44														0.7371			
Week 52														0.1899			
Week 64														0.0422			
Male																	
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 H.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 (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	269	269	3.0	0.2	259 (100.0%)												
Nera 18mg	255	255	3.2	0.2	248 (100.0%)												
Week 12																	
Placebo		255	3.0	0.2	255 (98.5%)	-0.1	0.1	-0.3	0.2								
Nera 18mg		242	3.4	0.2	242 (97.6%)	0.2	0.1	-0.0	0.5	0.3	0.2	-0.1	0.6	0.1139			
Week 26																	
Placebo		238	3.0	0.2	238 (91.9%)	0.0	0.1	-0.3	0.3								
Nera 18mg		231	3.3	0.2	231 (93.1%)	0.2	0.1	-0.1	0.4	0.2	0.2	-0.2	0.5	0.4409			
Week 36																	
Placebo		232	3.2	0.2	232 (89.6%)	0.3	0.1	0.0	0.6								
Nera 18mg		227	3.7	0.2	227 (91.5%)	0.6	0.1	0.3	0.9	0.3	0.2	-0.1	0.7	0.1692			
Week 44																	
Placebo		232	3.4	0.2	232 (89.6%)	0.5	0.2	0.2	0.9								
Nera 18mg		215	3.6	0.2	215 (86.7%)	0.6	0.2	0.2	0.9	0.0	0.2	-0.4	0.5	0.9534			
Week 52																	
Placebo		222	3.3	0.2	222 (85.7%)	0.6	0.2	0.3	1.0								
Nera 18mg		219	3.6	0.2	219 (88.3%)	0.5	0.2	0.1	0.8	-0.2	0.2	-0.7	0.3	0.4856			
Week 64																	
Placebo		176	3.2	0.2	176 (68.0%)	0.7	0.2	0.3	1.0								
Nera 18mg		170	4.0	0.3	170 (68.5%)	0.9	0.2	0.5	1.2	0.2	0.3	-0.3	0.7	0.4084			
Week 76																	
Placebo		64	2.9	0.4	64 (24.7%)												
Nera 18mg		52	3.8	0.5	52 (21.0%)												
Week 88																	
Placebo		8	2.3	1.0	8 (3.1%)												
Nera 18mg		9	3.3	1.3	9 (3.6%)												
Female																	
Baseline																	
Placebo	37	37	3.2	0.5	37 (100.0%)												
Nera 18mg	50	50	3.3	0.4	50 (100.0%)												
Week 12																	
Placebo		36	4.1	0.6	36 (97.3%)	0.9	0.3	0.3	1.6								
Nera 18mg		48	3.8	0.5	48 (96.0%)	0.7	0.3	0.1	1.2	-0.3	0.4	-1.2	0.6	0.5256			
Week 26																	
Placebo		36	3.4	0.5	36 (97.3%)	0.4	0.4	-0.3	1.1								
Nera 18mg		42	3.5	0.5	42 (84.0%)	0.4	0.3	-0.3	1.0	-0.1	0.5	-1.0	0.9	0.9007			

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

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Table H.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 (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 36																	
Placebo		36	3.3	0.5	36 (97.3%)	0.3	0.4	-0.4	1.0								
Nera 18mg		43	3.5	0.4	43 (86.0%)	0.4	0.3	-0.3	1.0	0.1	0.5	-0.9	1.1	0.8867			
Week 44																	
Placebo		36	3.5	0.5	36 (97.3%)	0.5	0.4	-0.3	1.3								
Nera 18mg		39	3.9	0.6	39 (78.0%)	0.7	0.4	-0.0	1.4	0.2	0.5	-0.9	1.3	0.6989			
Week 52																	
Placebo		35	3.7	0.5	35 (94.6%)	0.7	0.4	-0.2	1.6								
Nera 18mg		40	4.8	0.7	40 (80.0%)	1.4	0.4	0.6	2.2	0.7	0.6	-0.5	1.8	0.2581			
Week 64																	
Placebo		31	4.6	0.7	31 (83.8%)	1.5	0.5	0.6	2.4								
Nera 18mg		29	3.6	0.7	29 (58.0%)	0.3	0.4	-0.5	1.2	-1.2	0.6	-2.4	0.1	0.0633			
Week 76																	
Placebo		9	3.9	1.1	9 (24.3%)												
Nera 18mg		10	5.0	1.5	10 (20.0%)												
Week 88																	
Placebo		1	4.0	NC	1 (2.7%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 12														0.0108			
Week 26														0.7191			
Week 36														0.9138			
Week 44														0.8815			
Week 52														0.8801			
Week 64														0.9677			
<=70%																	
Baseline																	
Placebo	109	109	3.1	0.3	101 (100.0%)												
Nera 18mg	112	112	3.6	0.3	106 (100.0%)												
Week 12																	
Placebo		100	3.1	0.3	100 (99.0%)	-0.1	0.2	-0.5	0.3								
Nera 18mg		101	4.1	0.3	101 (95.3%)	0.8	0.2	0.4	1.2	0.8	0.3	0.3	1.4	0.0041	0.40	0.13	0.68

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Table H.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 (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 26																	
Placebo		92	3.4	0.3	92 (91.1%)	0.3	0.2	-0.1	0.8								
Nera 18mg		94	3.8	0.3	94 (88.7%)	0.5	0.2	0.1	1.0	0.2	0.3	-0.4	0.8	0.4889			
Week 36																	
Placebo		88	3.6	0.3	88 (87.1%)	0.5	0.2	0.0	1.0								
Nera 18mg		89	4.0	0.3	89 (84.0%)	0.8	0.2	0.3	1.2	0.3	0.3	-0.4	0.9	0.4003			
Week 44																	
Placebo		90	4.0	0.3	90 (89.1%)	0.9	0.3	0.4	1.4								
Nera 18mg		83	4.1	0.3	83 (78.3%)	0.9	0.3	0.4	1.4	0.0	0.4	-0.7	0.7	0.9970			
Week 52																	
Placebo		86	4.0	0.4	86 (85.1%)	1.1	0.3	0.5	1.6								
Nera 18mg		85	4.3	0.3	85 (80.2%)	1.0	0.3	0.4	1.5	-0.1	0.4	-0.9	0.7	0.8219			
Week 64																	
Placebo		70	3.9	0.4	70 (69.3%)	1.2	0.3	0.6	1.8								
Nera 18mg		64	4.6	0.4	64 (60.4%)	1.2	0.3	0.6	1.8	0.0	0.4	-0.8	0.8	0.9892			
Week 76																	
Placebo		22	4.1	0.8	22 (21.8%)												
Nera 18mg		18	4.9	0.9	18 (17.0%)												
Week 88																	
Placebo		3	1.0	0.6	3 (3.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												
>70%																	
Baseline																	
Placebo	197	197	2.9	0.2	195 (100.0%)												
Nera 18mg	193	193	3.0	0.2	192 (100.0%)												
Week 12																	
Placebo		191	3.1	0.2	191 (97.9%)	0.1	0.1	-0.2	0.4								
Nera 18mg		189	3.1	0.2	189 (98.4%)	0.0	0.1	-0.2	0.3	-0.1	0.2	-0.5	0.3	0.7007			
Week 26																	
Placebo		182	2.9	0.2	182 (93.3%)	-0.1	0.2	-0.4	0.3								
Nera 18mg		179	3.1	0.2	179 (93.2%)	0.0	0.2	-0.3	0.3	0.1	0.2	-0.4	0.5	0.7300			
Week 36																	
Placebo		180	3.0	0.2	180 (92.3%)	0.2	0.2	-0.1	0.5								
Nera 18mg		181	3.5	0.2	181 (94.3%)	0.4	0.2	0.1	0.8	0.2	0.2	-0.2	0.7	0.3188			
Week 44																	
Placebo		178	3.2	0.2	178 (91.3%)	0.3	0.2	-0.0	0.7								

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Table H.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 (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		171	3.4	0.2	171 (89.1%)	0.4	0.2	0.0	0.8	0.1	0.3	-0.4	0.6	0.7929			
Week 52																	
Placebo		171	3.1	0.2	171 (87.7%)	0.4	0.2	0.0	0.8								
Nera 18mg		174	3.5	0.3	174 (90.6%)	0.4	0.2	0.0	0.8	-0.0	0.3	-0.6	0.5	0.9549			
Week 64																	
Placebo		137	3.2	0.3	137 (70.3%)	0.6	0.2	0.1	1.0								
Nera 18mg		135	3.6	0.3	135 (70.3%)	0.6	0.2	0.2	1.0	0.0	0.3	-0.6	0.6	0.9289			
Week 76																	
Placebo		51	2.6	0.4	51 (26.2%)												
Nera 18mg		44	3.6	0.5	44 (22.9%)												
Week 88																	
Placebo		6	3.2	1.2	6 (3.1%)												
Nera 18mg		9	3.3	1.3	9 (4.7%)												
Type of AF therapy																	
Test for homogeneity (H0)^																	
Week 12														0.5281			
Week 26														0.7370			
Week 36														0.2612			
Week 44														0.5204			
Week 52														0.9989			
Week 64														0.0113			
Nintedanib																	
Baseline																	
Placebo	173	173	2.9	0.2	167 (100.0%)												
Nera 18mg	178	178	3.3	0.2	172 (100.0%)												
Week 12																	
Placebo		164	3.1	0.2	164 (98.2%)	0.1	0.2	-0.2	0.4								
Nera 18mg		165	3.4	0.2	165 (95.9%)	0.3	0.2	-0.0	0.6	0.1	0.2	-0.3	0.6	0.5254			
Week 26																	
Placebo		153	2.8	0.2	153 (91.6%)	-0.1	0.2	-0.4	0.3								
Nera 18mg		154	3.1	0.2	154 (89.5%)	0.0	0.2	-0.3	0.3	0.1	0.2	-0.4	0.6	0.7365			
Week 36																	
Placebo		152	2.9	0.2	152 (91.0%)	0.1	0.2	-0.2	0.5								

Study: 1305-0014. 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 H.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 (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		150	3.7	0.2	150 (87.2%)	0.6	0.2	0.2	0.9	0.4	0.3	-0.1	0.9	0.0777			
Week 44																	
Placebo		150	3.2	0.3	150 (89.8%)	0.4	0.2	0.0	0.8								
Nera 18mg		141	3.6	0.3	141 (82.0%)	0.6	0.2	0.2	1.0	0.2	0.3	-0.4	0.7	0.5389			
Week 52																	
Placebo		146	3.1	0.2	146 (87.4%)	0.5	0.2	0.1	1.0								
Nera 18mg		146	3.6	0.3	146 (84.9%)	0.5	0.2	0.1	0.9	-0.0	0.3	-0.6	0.6	0.9165			
Week 64																	
Placebo		116	3.0	0.2	116 (69.5%)	0.4	0.2	-0.0	0.9								
Nera 18mg		112	4.1	0.4	112 (65.1%)	1.0	0.2	0.5	1.4	0.6	0.3	-0.1	1.2	0.0787			
Week 76																	
Placebo		41	3.1	0.4	41 (24.6%)												
Nera 18mg		34	4.8	0.7	34 (19.8%)												
Week 88																	
Placebo		6	2.3	1.4	6 (3.6%)												
Nera 18mg		4	3.3	2.0	4 (2.3%)												
Pirfenidone																	
Baseline																	
Placebo	133	133	3.2	0.2	129 (100.0%)												
Nera 18mg	127	127	3.2	0.3	126 (100.0%)												
Week 12																	
Placebo		127	3.1	0.3	127 (98.4%)	-0.0	0.2	-0.4	0.3								
Nera 18mg		125	3.5	0.3	125 (99.2%)	0.3	0.2	-0.0	0.7	0.4	0.3	-0.1	0.9	0.1641			
Week 26																	
Placebo		121	3.4	0.3	121 (93.8%)	0.3	0.2	-0.1	0.6								
Nera 18mg		119	3.6	0.3	119 (94.4%)	0.5	0.2	0.1	0.8	0.2	0.3	-0.3	0.7	0.4575			
Week 36																	
Placebo		116	3.6	0.3	116 (89.9%)	0.5	0.2	0.1	0.9								
Nera 18mg		120	3.7	0.3	120 (95.2%)	0.6	0.2	0.2	1.0	0.0	0.3	-0.6	0.6	0.9541			
Week 44																	
Placebo		118	3.8	0.3	118 (91.5%)	0.7	0.2	0.3	1.1								
Nera 18mg		113	3.8	0.3	113 (89.7%)	0.6	0.2	0.2	1.1	-0.1	0.3	-0.7	0.5	0.7531			
Week 52																	
Placebo		111	3.7	0.3	111 (86.0%)	0.7	0.2	0.3	1.2								
Nera 18mg		113	3.9	0.3	113 (89.7%)	0.7	0.2	0.2	1.2	-0.0	0.3	-0.7	0.6	0.9253			
Week 64																	

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Table H.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 (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		91	4.1	0.4	91 (70.5%)	1.2	0.3	0.7	1.7								
Nera 18mg		87	3.6	0.3	87 (69.0%)	0.6	0.3	0.0	1.1	-0.7	0.4	-1.4	0.0	0.0669			
Week 76																	
Placebo		32	2.9	0.6	32 (24.8%)												
Nera 18mg		28	2.9	0.5	28 (22.2%)												
Week 88																	
Placebo		3	2.7	0.7	3 (2.3%)												
Nera 18mg		5	3.4	1.9	5 (4.0%)												
Region																	
Test for homogeneity (H0)^																	
Week 12														0.4224			
Week 26														0.2613			
Week 36														0.0101			
Week 44														0.3987			
Week 52														0.0665			
Week 64														0.0131			
Europe																	
Baseline																	
Placebo	136	136	3.1	0.2	134 (100.0%)												
Nera 18mg	136	136	3.4	0.3	133 (100.0%)												
Week 12																	
Placebo		130	3.2	0.3	130 (97.0%)	0.1	0.2	-0.2	0.5								
Nera 18mg		125	3.7	0.3	125 (94.0%)	0.5	0.2	0.2	0.9	0.4	0.3	-0.1	0.9	0.1102			
Week 26																	
Placebo		122	3.1	0.2	122 (91.0%)	0.1	0.2	-0.3	0.5								
Nera 18mg		122	3.6	0.3	122 (91.7%)	0.4	0.2	0.0	0.8	0.3	0.3	-0.2	0.9	0.2390			
Week 36																	
Placebo		120	3.0	0.2	120 (89.6%)	0.1	0.2	-0.3	0.5								
Nera 18mg		120	4.1	0.3	120 (90.2%)	0.9	0.2	0.5	1.3	0.8	0.3	0.3	1.4	0.0043	0.37	0.11	0.62
Week 44																	
Placebo		122	3.5	0.3	122 (91.0%)	0.6	0.2	0.1	1.0								
Nera 18mg		113	4.0	0.3	113 (85.0%)	0.8	0.2	0.4	1.3	0.3	0.3	-0.4	0.9	0.4028			
Week 52																	

Study: 1305-0014. 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 H.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 (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		117	3.3	0.3	117 (87.3%)	0.5	0.2	0.0	1.0								
Nera 18mg		115	4.3	0.3	115 (86.5%)	0.9	0.2	0.5	1.4	0.4	0.3	-0.2	1.1	0.1871			
Week 64																	
Placebo		96	3.2	0.3	96 (71.6%)	0.6	0.2	0.1	1.0								
Nera 18mg		87	4.5	0.4	87 (65.4%)	1.2	0.3	0.7	1.7	0.6	0.4	-0.1	1.3	0.0746			
Week 76																	
Placebo		30	3.0	0.6	30 (22.4%)												
Nera 18mg		27	4.5	0.8	27 (20.3%)												
Week 88																	
Placebo		3	1.7	0.3	3 (2.2%)												
Nera 18mg		5	1.8	1.0	5 (3.8%)												
Asia																	
Baseline																	
Placebo	72	72	3.0	0.3	68 (100.0%)												
Nera 18mg	79	79	3.3	0.3	76 (100.0%)												
Week 12																	
Placebo		67	2.6	0.3	67 (98.5%)	-0.4	0.2	-0.9	0.1								
Nera 18mg		76	3.2	0.3	76 (100.0%)	-0.1	0.2	-0.5	0.4	0.4	0.3	-0.3	1.0	0.2911			
Week 26																	
Placebo		63	2.8	0.4	63 (92.6%)	-0.3	0.3	-0.8	0.2								
Nera 18mg		71	3.1	0.4	71 (93.4%)	-0.1	0.3	-0.6	0.4	0.2	0.4	-0.5	0.9	0.6172			
Week 36																	
Placebo		62	3.5	0.4	62 (91.2%)	0.4	0.3	-0.1	1.0								
Nera 18mg		71	3.3	0.4	71 (93.4%)	0.1	0.3	-0.4	0.6	-0.3	0.4	-1.1	0.4	0.3737			
Week 44																	
Placebo		60	3.5	0.5	60 (88.2%)	0.5	0.3	-0.2	1.1								
Nera 18mg		66	3.4	0.3	66 (86.8%)	0.2	0.3	-0.4	0.8	-0.2	0.4	-1.1	0.6	0.5719			
Week 52																	
Placebo		57	3.5	0.5	57 (83.8%)	0.8	0.3	0.1	1.5								
Nera 18mg		66	3.3	0.4	66 (86.8%)	0.1	0.3	-0.5	0.8	-0.6	0.5	-1.6	0.3	0.1691			
Week 64																	
Placebo		47	4.1	0.6	47 (69.1%)	1.2	0.4	0.5	1.9								
Nera 18mg		56	3.9	0.4	56 (73.7%)	0.6	0.3	-0.1	1.2	-0.6	0.5	-1.6	0.3	0.1840			
Week 76																	
Placebo		15	3.0	0.9	15 (22.1%)												
Nera 18mg		16	3.4	0.8	16 (21.1%)												

Study: 1305-0014. 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, 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 H.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 (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 88																	
Placebo		1	0.0	NC	1 (1.5%)												
Nera 18mg		1	9.0	NC	1 (1.3%)												
Canada and USA																	
Baseline																	
Placebo	75	75	2.8	0.2	71 (100.0%)												
Nera 18mg	56	56	2.9	0.4	56 (100.0%)												
Week 12																	
Placebo		71	3.3	0.3	71 (100.0%)	0.4	0.2	-0.1	0.9								
Nera 18mg		56	3.3	0.4	56 (100.0%)	0.3	0.3	-0.2	0.9	-0.1	0.4	-0.8	0.6	0.8197			
Week 26																	
Placebo		67	3.1	0.3	67 (94.4%)	0.3	0.3	-0.2	0.8								
Nera 18mg		52	3.5	0.4	52 (92.9%)	0.4	0.3	-0.2	1.0	0.1	0.4	-0.7	0.9	0.8131			
Week 36																	
Placebo		65	3.1	0.3	65 (91.5%)	0.4	0.3	-0.2	0.9								
Nera 18mg		53	3.4	0.4	53 (94.6%)	0.4	0.3	-0.2	1.0	0.0	0.4	-0.8	0.8	0.9310			
Week 44																	
Placebo		64	3.2	0.3	64 (90.1%)	0.5	0.3	-0.1	1.1								
Nera 18mg		50	3.4	0.4	50 (89.3%)	0.6	0.3	-0.1	1.3	0.1	0.4	-0.8	1.0	0.8739			
Week 52																	
Placebo		64	3.3	0.4	64 (90.1%)	0.7	0.3	0.1	1.3								
Nera 18mg		52	3.3	0.4	52 (92.9%)	0.6	0.4	-0.1	1.3	-0.1	0.5	-1.1	0.8	0.8081			
Week 64																	
Placebo		49	3.0	0.4	49 (69.0%)	0.6	0.3	-0.0	1.3								
Nera 18mg		41	3.1	0.5	41 (73.2%)	0.5	0.4	-0.3	1.2	-0.1	0.5	-1.2	0.9	0.7757			
Week 76																	
Placebo		20	2.7	0.5	20 (28.2%)												
Nera 18mg		12	3.1	0.8	12 (21.4%)												
Week 88																	
Placebo		2	5.0	4.0	2 (2.8%)												
Nera 18mg		1	1.0	NC	1 (1.8%)												
Rest of the World																	
Baseline																	
Placebo	23	23	3.0	0.6	23 (100.0%)												
Nera 18mg	34	34	2.9	0.5	33 (100.0%)												
Week 12																	

Study: 1305-0014. N: Number of patients in analysis set, n1: Number of patients with observed data at visit, ^: Interaction p-value.
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Table H.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 (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		23	3.1	0.6	23 (100.0%)	0.1	0.4	-0.7	1.0								
Nera 18mg		33	3.2	0.5	33 (100.0%)	0.2	0.4	-0.5	0.9	0.1	0.6	-1.0	1.2	0.8771			
Week 26																	
Placebo		22	3.4	0.6	22 (95.7%)	0.3	0.5	-0.6	1.2								
Nera 18mg		28	2.6	0.4	28 (84.8%)	-0.3	0.4	-1.1	0.5	-0.6	0.6	-1.8	0.6	0.3152			
Week 36																	
Placebo		21	4.0	0.8	21 (91.3%)	0.9	0.5	-0.1	1.8								
Nera 18mg		26	3.4	0.6	26 (78.8%)	0.5	0.4	-0.3	1.4	-0.4	0.6	-1.6	0.9	0.5760			
Week 44																	
Placebo		22	3.5	0.7	22 (95.7%)	0.5	0.5	-0.5	1.5								
Nera 18mg		25	3.3	0.6	25 (75.8%)	0.4	0.5	-0.6	1.3	-0.2	0.7	-1.5	1.2	0.8146			
Week 52																	
Placebo		19	3.7	0.8	19 (82.6%)	0.8	0.6	-0.3	2.0								
Nera 18mg		26	3.2	0.7	26 (78.8%)	0.3	0.5	-0.7	1.3	-0.5	0.8	-2.1	1.0	0.4764			
Week 64																	
Placebo		15	3.9	0.9	15 (65.2%)	1.2	0.6	0.0	2.5								
Nera 18mg		15	2.8	0.9	15 (45.5%)	0.1	0.6	-1.0	1.3	-1.1	0.9	-2.8	0.5	0.1861			
Week 76																	
Placebo		8	4.0	1.2	8 (34.8%)												
Nera 18mg		7	4.6	1.9	7 (21.2%)												
Week 88																	
Placebo		3	2.3	0.9	3 (13.0%)												
Nera 18mg		2	5.5	4.5	2 (6.1%)												

Study: 1305-0014. 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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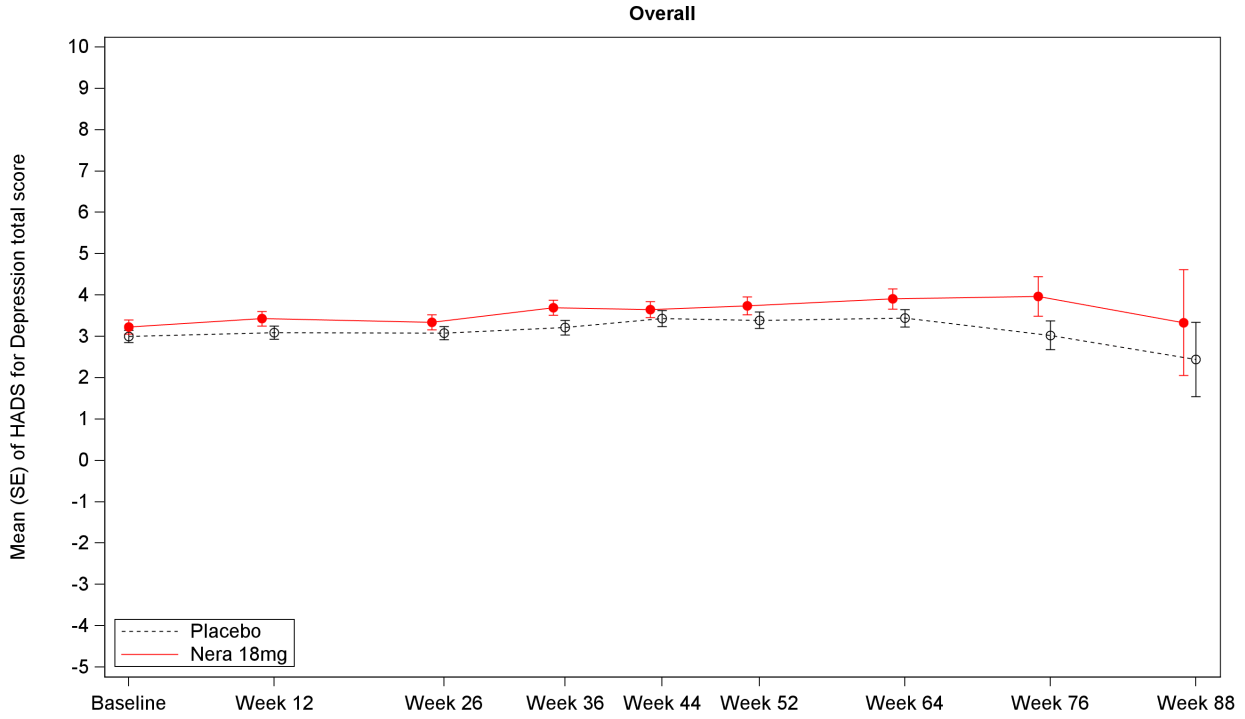

Number of patients

Placebo	306	291	274	268	268	257	207	73	9
Nera 18mg	305	290	273	270	254	259	199	62	9

Study: 1305-0014. Number of patients refers to the number of patients with observed data at visit.

Figure H.1.1.2.1.7: 2 Mean (SE) of HADS for Depression total score over the whole trial - 18mg - TS (AF background)

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Boehringer Ingelheim
BI Trial No.: x1305p3.hta

Figure H.1.1.2.1.7: 2

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H.1.1.3 Further analysis

H.1.1.3.1 Time to event analyses: treatment policy approach to lung transplant

Table H.1.1.3.1: 1 Cox model for time to first confirmed acute IPF exacerbation or death - treatment policy approach to lung transplant - over the whole trial - 18mg - FAS (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	306	44 (26/ 18)	14.4	10.84	305	39 (23/ 16)	12.8	9.74	0.92	(0.60, 1.42)	0.7153	
Age												0.7609
<65 years	69	7 (5/ 2)	10.1	7.36	63	5 (3/ 2)	7.9	5.94	0.78	(0.25, 2.47)	0.6754	
>=65 years	237	37 (21/ 16)	15.6	11.90	242	34 (20/ 14)	14.0	10.76	0.95	(0.59, 1.51)	0.8234	
Sex												0.2363
Male	269	43 (25/ 18)	16.0	12.15	255	33 (20/ 13)	12.9	9.87	0.88	(0.56, 1.38)	0.5652	
Female	37	1 (1/ 0)	2.7	1.92	50	6 (3/ 3)	12.0	9.12	3.25	(0.39, 27.15)	0.2765	
Baseline FVC percent predicted												0.7500
<=70%	109	24 (15/ 9)	22.0	17.42	112	23 (13/ 10)	20.5	17.02	0.95	(0.53, 1.68)	0.8513	
>70%	197	20 (11/ 9)	10.2	7.46	193	16 (10/ 6)	8.3	6.03	0.82	(0.42, 1.59)	0.5578	
Type of AF therapy												0.1721
Nintedanib	173	25 (15/ 10)	14.5	10.87	178	18 (12/ 6)	10.1	7.77	0.70	(0.38, 1.28)	0.2417	
Pirfenidone	133	19 (11/ 8)	14.3	10.79	127	21 (11/ 10)	16.5	12.46	1.28	(0.68, 2.39)	0.4427	
Region												0.2524
Europe	136	15 (11/ 4)	11.0	8.33	136	20 (11/ 9)	14.7	11.22	1.27	(0.65, 2.47)	0.4920	
Asia	72	14 (10/ 4)	19.4	15.21	79	7 (5/ 2)	8.9	6.69	0.50	(0.20, 1.24)	0.1349	
Canada and USA	75	13 (5/ 8)	17.3	12.89	56	7 (3/ 4)	12.5	9.09	0.70	(0.28, 1.76)	0.4486	
Rest of the World	23	2 (0/ 2)	8.7	6.06	34	5 (4/ 1)	14.7	12.39	2.29	(0.44, 11.93)	0.3239	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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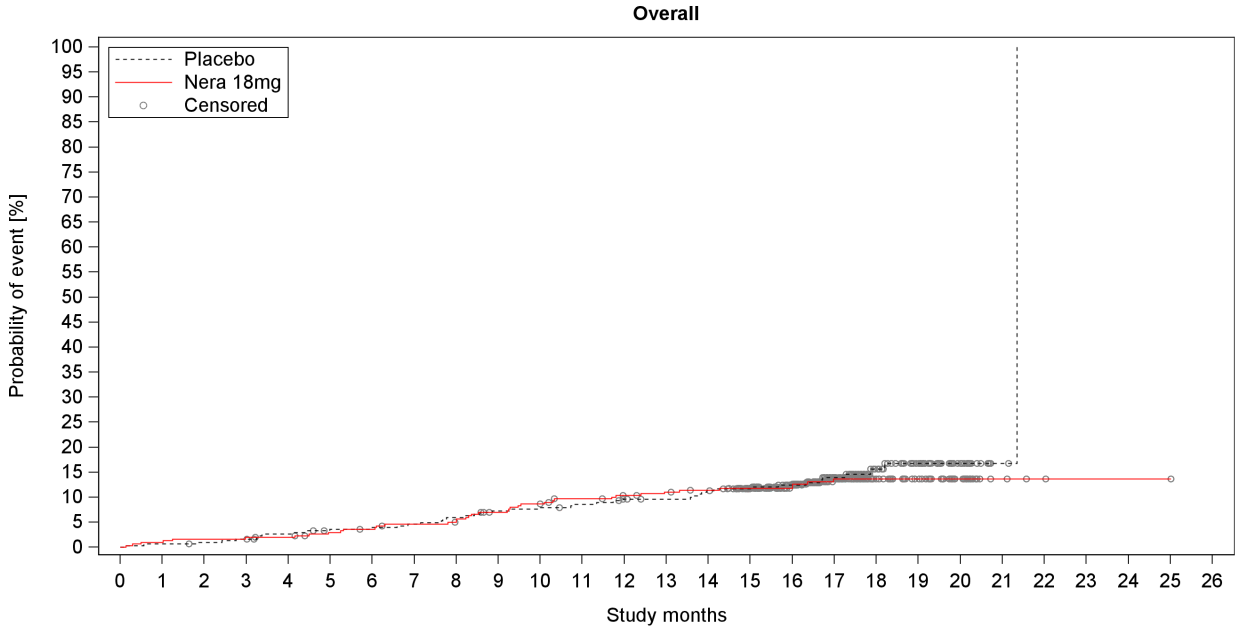

Number at risk (percentage relative to baseline)

Placebo	306	304	302	300	295	290	290	287	283	278	276	273	267	265	260	240	203	141	77	54	20	2	0	0	0	0	0
%	100.0	99.3	98.7	98.0	96.4	94.8	94.8	93.8	92.5	90.8	90.2	89.2	87.3	86.6	85.0	78.4	66.3	46.1	25.2	17.6	6.5	0.7	0.0	0.0	0.0	0.0	0.0
Nera 18mg	305	302	300	299	298	293	290	286	284	276	271	265	259	256	253	232	201	143	67	43	23	4	2	1	1	1	0
%	100.0	99.0	98.4	98.0	97.7	96.1	95.1	93.8	93.1	90.5	88.9	86.9	84.9	83.9	83.0	76.1	65.9	46.9	22.0	14.1	7.5	1.3	0.7	0.3	0.3	0.3	0.0

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

Placebo	0	0	1	1	3	5	5	5	5	6	6	7	10	12	12	31	66	125	187	209	243	261	262	262	262	262	262
%	0.0	0.0	0.3	0.3	1.0	1.6	1.6	1.6	1.6	2.0	2.0	2.3	3.3	3.9	3.9	10.1	21.6	40.8	61.1	68.3	79.4	85.3	85.6	85.6	85.6	85.6	85.6
Nera 18mg	0	0	0	0	1	3	4	5	6	8	8	11	15	16	18	38	69	123	199	223	243	262	264	265	265	265	266
%	0.0	0.0	0.0	0.0	0.3	1.0	1.3	1.6	2.0	2.6	2.6	3.6	4.9	5.2	5.9	12.5	22.6	40.3	65.2	73.1	79.7	85.9	86.6	86.9	86.9	86.9	87.2

Study: 1305-0014

Figure H.1.1.3.1: 1 Time to first confirmed acute IPF exacerbation or death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate - 18mg - FAS (AF background)

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Figure H.1.1.3.1: 1

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Table H.1.1.3.1: 2 Cox model for time to first confirmed or suspected acute IPF exacerbation or death - treatment policy approach to lung transplant - over the whole trial - 18mg - FAS (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	306	47 (30/ 17)	15.4	11.63	305	42 (29/ 13)	13.8	10.54	0.94	(0.62, 1.42)	0.7551	
Age												0.7356
<65 years	69	7 (5/ 2)	10.1	7.36	63	5 (3/ 2)	7.9	5.94	0.78	(0.25, 2.46)	0.6697	
>=65 years	237	40 (25/ 15)	16.9	12.94	242	37 (26/ 11)	15.3	11.78	0.96	(0.61, 1.51)	0.8689	
Sex												0.2495
Male	269	46 (29/ 17)	17.1	13.06	255	36 (26/ 10)	14.1	10.82	0.90	(0.58, 1.39)	0.6317	
Female	37	1 (1/ 0)	2.7	1.92	50	6 (3/ 3)	12.0	9.13	3.21	(0.38, 26.78)	0.2814	
Baseline FVC percent predicted												0.3050
<=70%	109	24 (15/ 9)	22.0	17.43	112	26 (18/ 8)	23.2	19.48	1.10	(0.63, 1.93)	0.7307	
>70%	197	23 (15/ 8)	11.7	8.63	193	16 (11/ 5)	8.3	6.04	0.71	(0.37, 1.34)	0.2897	
Type of AF therapy												0.1676
Nintedanib	173	27 (18/ 9)	15.6	11.81	178	20 (15/ 5)	11.2	8.66	0.72	(0.40, 1.28)	0.2562	
Pirfenidone	133	20 (12/ 8)	15.0	11.40	127	22 (14/ 8)	17.3	13.15	1.29	(0.70, 2.38)	0.4094	
Region												0.1979
Europe	136	16 (12/ 4)	11.8	8.92	136	21 (14/ 7)	15.4	11.86	1.25	(0.65, 2.40)	0.5049	
Asia	72	14 (10/ 4)	19.4	15.21	79	8 (6/ 2)	10.1	7.66	0.58	(0.24, 1.40)	0.2242	
Canada and USA	75	15 (8/ 7)	20.0	15.05	56	7 (3/ 4)	12.5	9.09	0.60	(0.25, 1.48)	0.2683	
Rest of the World	23	2 (0/ 2)	8.7	6.06	34	6 (6/ 0)	17.6	15.04	2.89	(0.58, 14.45)	0.1963	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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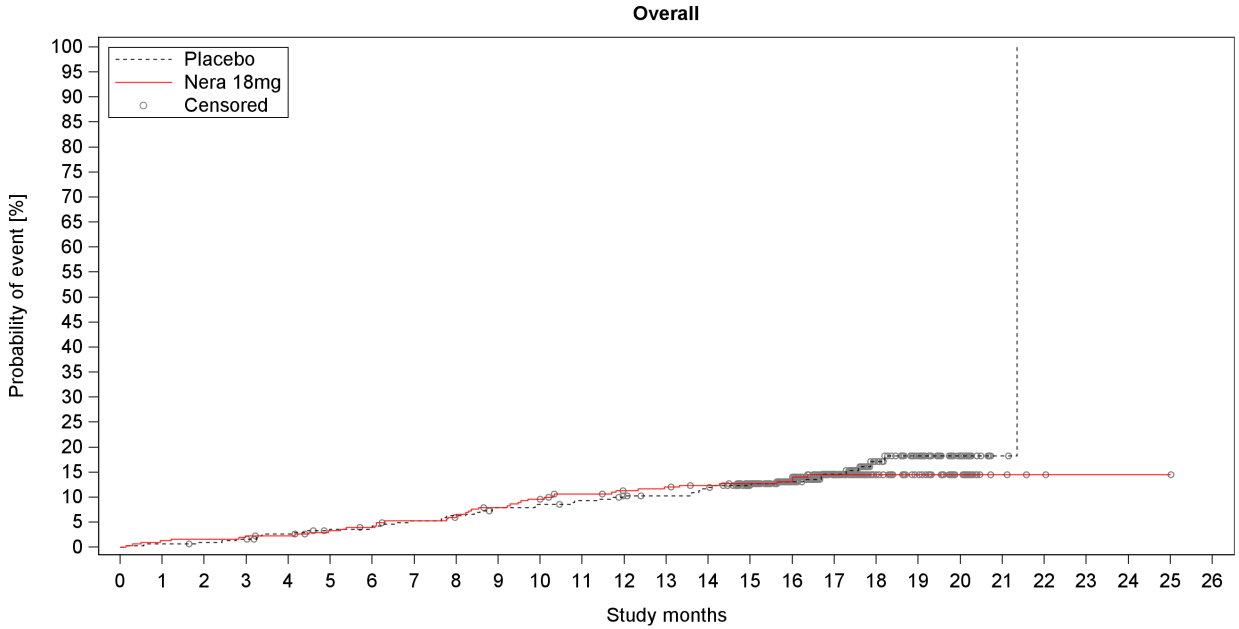

Number at risk (percentage relative to baseline)

Placebo	306	304	302	300	295	290	289	285	282	276	274	271	265	263	258	238	201	140	76	53	20	2	0	0	0	0	0
%	100.0	99.3	98.7	98.0	96.4	94.8	94.4	93.1	92.2	90.2	89.5	88.6	86.6	85.9	84.3	77.8	65.7	45.8	24.8	17.3	6.5	0.7	0.0	0.0	0.0	0.0	0.0
Nera 18mg	305	301	300	298	297	292	289	284	281	274	269	263	257	255	252	231	199	142	67	43	23	4	2	1	1	1	0
%	100.0	98.7	98.4	97.7	97.4	95.7	94.8	93.1	92.1	89.8	88.2	86.2	84.3	83.6	82.6	75.7	65.2	46.6	22.0	14.1	7.5	1.3	0.7	0.3	0.3	0.3	0.0

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

Placebo	0	0	1	1	3	5	5	5	5	6	6	7	10	12	12	31	66	124	185	207	240	258	259	259	259	259	259
%	0.0	0.0	0.3	0.3	1.0	1.6	1.6	1.6	1.6	2.0	2.0	2.3	3.3	3.9	3.9	10.1	21.6	40.5	60.5	67.6	78.4	84.3	84.6	84.6	84.6	84.6	84.6
Nera 18mg	0	0	0	0	1	3	4	5	6	7	7	10	14	14	16	36	67	121	196	220	240	259	261	262	262	262	263
%	0.0	0.0	0.0	0.0	0.3	1.0	1.3	1.6	2.0	2.3	2.3	3.3	4.6	4.6	5.2	11.8	22.0	39.7	64.3	72.1	78.7	84.9	85.6	85.9	85.9	85.9	86.2

Study: 1305-0014

Figure H.1.1.3.1: 2 Time to first confirmed or suspected acute IPF exacerbation or death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate - 18mg - FAS (AF background)

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Figure H.1.1.3.1: 2

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Table H.1.1.3.1: 3 Cox model for time to death - treatment policy approach to lung transplant - over the whole trial - 18mg - FAS (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	306	30	9.8	7.15	305	23	7.5	5.53	0.81	(0.47, 1.39)	0.4448	
Age												0.6378
<65 years	69	4	5.8	4.13	63	2	3.2	2.31	0.55	(0.10, 3.01)	0.4919	
>=65 years	237	26	11.0	8.05	242	21	8.7	6.38	0.85	(0.48, 1.51)	0.5743	
Sex												0.1893
Male	269	29	10.8	7.89	255	17	6.7	4.87	0.68	(0.37, 1.24)	0.2109	
Female	37	1	2.7	1.92	50	6	12.0	9.00	3.00	(0.36, 25.21)	0.3119	
Baseline FVC percent predicted												0.4628
<=70%	109	16	14.7	11.03	112	15	13.4	10.47	0.97	(0.47, 1.97)	0.9249	
>70%	197	14	7.1	5.09	193	8	4.1	2.94	0.63	(0.26, 1.52)	0.3066	
Type of AF therapy												0.3346
Nintedanib	173	17	9.8	7.19	178	11	6.2	4.57	0.63	(0.30, 1.35)	0.2356	
Pirfenidone	133	13	9.8	7.09	127	12	9.4	6.85	1.08	(0.49, 2.40)	0.8403	
Region												0.1484
Europe	136	9	6.6	4.92	136	13	9.6	7.00	1.32	(0.56, 3.09)	0.5282	
Asia	72	9	12.5	9.03	79	2	2.5	1.83	0.24	(0.05, 1.10)	0.0664	
Canada and USA	75	10	13.3	9.59	56	4	7.1	5.05	0.53	(0.16, 1.69)	0.2805	
Rest of the World	23	2	8.7	6.06	34	4	11.8	9.65	2.09	(0.38, 11.60)	0.3999	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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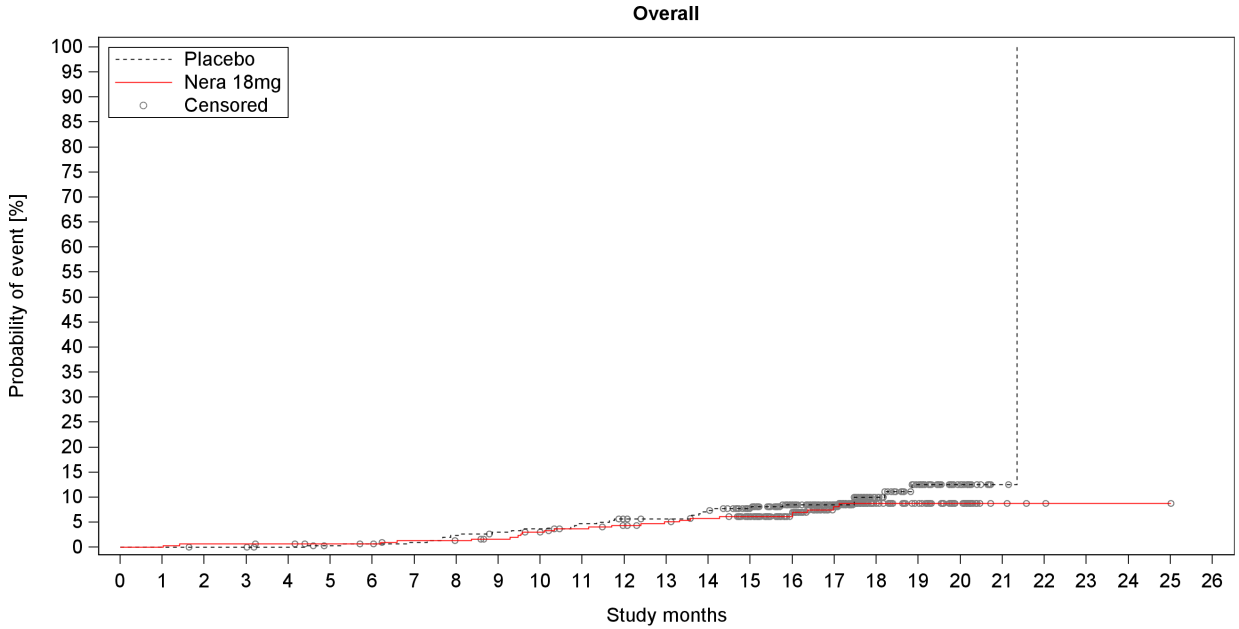

Number at risk (percentage relative to baseline)

Placebo	306	306	305	305	303	300	299	297	293	290	288	284	278	276	271	251	213	151	83	57	21	2	0	0	0	0	0
%	100.0	100.0	99.7	99.7	99.0	98.0	97.7	97.1	95.8	94.8	94.1	92.8	90.8	90.2	88.6	82.0	69.6	49.3	27.1	18.6	6.9	0.7	0.0	0.0	0.0	0.0	0.0
Nera 18mg	305	305	303	303	302	300	299	296	295	292	287	282	276	272	268	246	212	151	68	44	23	4	2	1	1	1	0
%	100.0	100.0	99.3	99.3	99.0	98.4	98.0	97.0	96.7	95.7	94.1	92.5	90.5	89.2	87.9	80.7	69.5	49.5	22.3	14.4	7.5	1.3	0.7	0.3	0.3	0.3	0.0

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

Placebo	0	0	1	1	3	5	5	6	6	7	7	8	11	13	13	32	68	130	196	220	256	275	276	276	276	276	276
%	0.0	0.0	0.3	0.3	1.0	1.6	1.6	2.0	2.0	2.3	2.3	2.6	3.6	4.2	4.2	10.5	22.2	42.5	64.1	71.9	83.7	89.9	90.2	90.2	90.2	90.2	90.2
Nera 18mg	0	0	0	0	1	3	4	5	6	8	9	12	16	18	20	41	75	132	214	238	259	278	280	281	281	281	282
%	0.0	0.0	0.0	0.0	0.3	1.0	1.3	1.6	2.0	2.6	3.0	3.9	5.2	5.9	6.6	13.4	24.6	43.3	70.2	78.0	84.9	91.1	91.8	92.1	92.1	92.1	92.5

Study: 1305-0014

Figure H.1.1.3.1: 3 Time to death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate - 18mg - FAS (AF background)

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Figure H.1.1.3.1: 3

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Table H.1.1.3.1: 4 Cox model for time to first confirmed acute IPF exacerbation - treatment policy approach to lung transplant - over the whole trial - 18mg - FAS (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	306	26	8.5	6.41	305	23	7.5	5.75	0.92	(0.53, 1.62)	0.7833	
Age												0.6033
<65 years	69	5	7.2	5.26	63	3	4.8	3.56	0.66	(0.16, 2.75)	0.5636	
>=65 years	237	21	8.9	6.76	242	20	8.3	6.33	0.99	(0.54, 1.83)	0.9765	
Sex												0.5609
Male	269	25	9.3	7.07	255	20	7.8	5.98	0.90	(0.50, 1.63)	0.7336	
Female	37	1	2.7	1.92	50	3	6.0	4.56	1.81	(0.19, 17.50)	0.6084	
Baseline FVC percent predicted												0.9039
<=70%	109	15	13.8	10.89	112	13	11.6	9.62	0.86	(0.41, 1.81)	0.6896	
>70%	197	11	5.6	4.10	193	10	5.2	3.77	0.92	(0.39, 2.17)	0.8512	
Type of AF therapy												0.4755
Nintedanib	173	15	8.7	6.52	178	12	6.7	5.18	0.77	(0.36, 1.65)	0.5050	
Pirfenidone	133	11	8.3	6.25	127	11	8.7	6.53	1.17	(0.50, 2.71)	0.7194	
Region												0.8255
Europe	136	11	8.1	6.11	136	11	8.1	6.17	0.96	(0.41, 2.21)	0.9172	
Asia	72	10	13.9	10.86	79	5	6.3	4.78	0.50	(0.17, 1.46)	0.2036	
Canada and USA	75	5	6.7	4.96	56	3	5.4	3.89	0.82	(0.20, 3.42)	0.7819	
Rest of the World	23	0	0.0	0.00	34	4	11.8	9.91	>10	(NC, NC)	0.9856	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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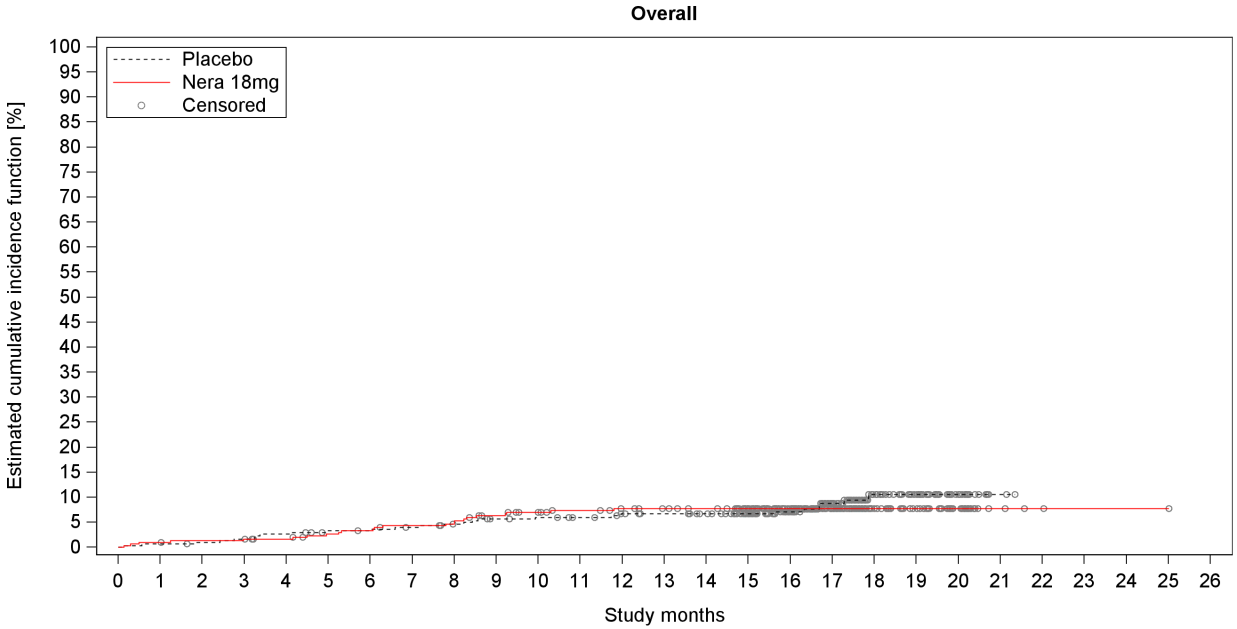

Number at risk (percentage relative to baseline)

Placebo	306	304	302	300	295	290	290	287	283	278	276	273	267	264	260	240	203	141	77	54	20	2	0	0	0	0	0
%	100.0	99.3	98.7	98.0	96.4	94.8	94.8	93.8	92.5	90.8	90.2	89.2	87.3	86.3	85.0	78.4	66.3	46.1	25.2	17.6	6.5	0.7	0.0	0.0	0.0	0.0	0.0
Nera 18mg	305	302	300	299	298	293	290	286	284	276	271	265	259	256	253	232	201	143	67	43	23	4	2	1	1	1	0
%	100.0	99.0	98.4	98.0	97.7	96.1	95.1	93.8	93.1	90.5	88.9	86.9	84.9	83.9	83.0	76.1	65.9	46.9	22.0	14.1	7.5	1.3	0.7	0.3	0.3	0.3	0.0

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

Placebo	0	0	1	1	3	6	6	7	9	11	12	15	19	22	26	46	82	141	203	226	260	278	280	280	280	280	280
%	0.0	0.0	0.3	0.3	1.0	2.0	2.0	2.3	2.9	3.6	3.9	4.9	6.2	7.2	8.5	15.0	26.8	46.1	66.3	73.9	85.0	90.8	91.5	91.5	91.5	91.5	91.5
Nera 18mg	0	0	1	1	2	4	5	6	7	10	13	18	23	26	29	50	81	139	215	239	259	278	280	281	281	281	282
%	0.0	0.0	0.3	0.3	0.7	1.3	1.6	2.0	2.3	3.3	4.3	5.9	7.5	8.5	9.5	16.4	26.6	45.6	70.5	78.4	84.9	91.1	91.8	92.1	92.1	92.1	92.5

Study: 1305-0014

Figure H.1.1.3.1: 4 Time to first confirmed acute IPF exacerbation - treatment policy approach to lung transplant - over the whole trial, estimated cumulative incidence function - 18mg - FAS (AF background)

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Figure H.1.1.3.1: 4

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Table H.1.1.3.1: 5 Cox model for time to first confirmed or suspected acute IPF exacerbation - treatment policy approach to lung transplant - over the whole trial - 18mg - FAS (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	306	30	9.8	7.43	305	29	9.5	7.28	1.01	(0.60, 1.68)	0.9764	
Age												0.5055
<65 years	69	5	7.2	5.26	63	3	4.8	3.56	0.64	(0.15, 2.70)	0.5472	
>=65 years	237	25	10.5	8.09	242	26	10.7	8.28	1.08	(0.63, 1.88)	0.7732	
Sex												0.6667
Male	269	29	10.8	8.24	255	26	10.2	7.82	1.02	(0.60, 1.73)	0.9553	
Female	37	1	2.7	1.92	50	3	6.0	4.57	1.69	(0.18, 16.34)	0.6489	
Baseline FVC percent predicted												0.3361
<=70%	109	15	13.8	10.89	112	18	16.1	13.49	1.22	(0.61, 2.43)	0.5714	
>70%	197	15	7.6	5.63	193	11	5.7	4.15	0.73	(0.34, 1.60)	0.4355	
Type of AF therapy												0.3063
Nintedanib	173	18	10.4	7.87	178	15	8.4	6.49	0.80	(0.40, 1.59)	0.5205	
Pirfenidone	133	12	9.0	6.84	127	14	11.0	8.37	1.37	(0.63, 2.98)	0.4257	
Region												0.7005
Europe	136	12	8.8	6.69	136	14	10.3	7.91	1.10	(0.51, 2.39)	0.8032	
Asia	72	10	13.9	10.86	79	6	7.6	5.75	0.60	(0.22, 1.68)	0.3321	
Canada and USA	75	8	10.7	8.03	56	3	5.4	3.89	0.50	(0.13, 1.90)	0.3107	
Rest of the World	23	0	0.0	0.00	34	6	17.6	15.04	>10	(NC, NC)	0.9839	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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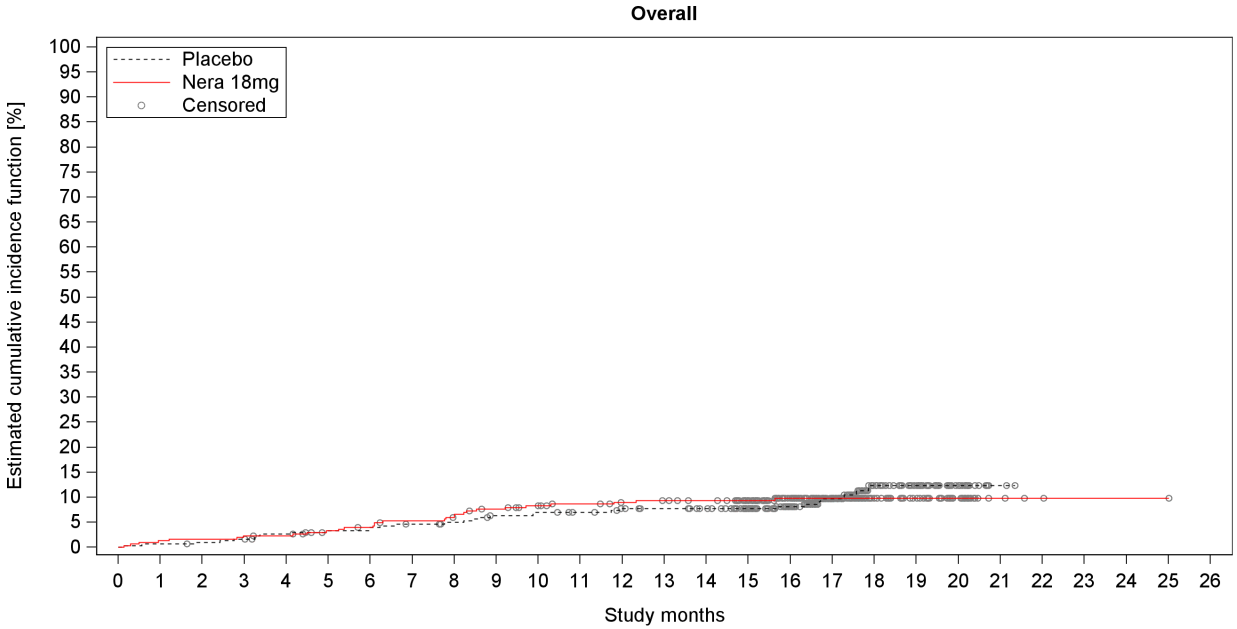

Number at risk (percentage relative to baseline)

Placebo	306	304	302	300	295	290	289	285	282	276	274	271	265	262	258	238	201	140	76	53	20	2	0	0	0	0	0
%	100.0	99.3	98.7	98.0	96.4	94.8	94.4	93.1	92.2	90.2	89.5	88.6	86.6	85.6	84.3	77.8	65.7	45.8	24.8	17.3	6.5	0.7	0.0	0.0	0.0	0.0	0.0
Nera 18mg	305	301	300	298	297	292	289	284	281	274	269	263	257	255	252	231	199	142	67	43	23	4	2	1	1	1	0
%	100.0	98.7	98.4	97.7	97.4	95.7	94.8	93.1	92.1	89.8	88.2	86.2	84.3	83.6	82.6	75.7	65.2	46.6	22.0	14.1	7.5	1.3	0.7	0.3	0.3	0.3	0.0

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

Placebo	0	0	1	1	3	6	6	7	9	11	11	14	18	21	25	45	81	139	200	223	256	274	276	276	276	276	276
%	0.0	0.0	0.3	0.3	1.0	2.0	2.0	2.3	2.9	3.6	3.6	4.6	5.9	6.9	8.2	14.7	26.5	45.4	65.4	72.9	83.7	89.5	90.2	90.2	90.2	90.2	90.2
Nera 18mg	0	0	0	0	1	3	4	5	6	8	11	16	21	22	25	46	77	134	209	233	253	272	274	275	275	275	276
%	0.0	0.0	0.0	0.0	0.3	1.0	1.3	1.6	2.0	2.6	3.6	5.2	6.9	7.2	8.2	15.1	25.2	43.9	68.5	76.4	83.0	89.2	89.8	90.2	90.2	90.2	90.5

Study: 1305-0014

Figure H.1.1.3.1: 5 Time to first confirmed or suspected acute IPF exacerbation - treatment policy approach to lung transplant - over the whole trial, estimated cumulative incidence function - 18mg - FAS (AF background)

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Figure H.1.1.3.1: 5

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H.1.2 Population with non-AF background

H.1.2.1 Efficacy Analysis

H.1.2.1.1 Time to event analyses

H.1.2.1.1.1 Analyses of composite endpoints

H.1.2.1.1.1.1 Time to first confirmed acute IPF exacerbation or death

Table H.1.2.1.1.1.1: 1 Cox model for time to first confirmed acute IPF exacerbation or death over the whole trial - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo e/	Placebo d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg e/	Nera 18mg d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	87	17	8/	9)	19.5	15.53	87	10	8/	2)	11.5	8.72	0.64	(0.29,	1.45)	0.2867	
Age																	0.4183
<65 years	17	4	2/	2)	23.5	19.13	20	2	2/	0)	10.0	7.31	0.35	(0.06,	1.98)	0.2339	
>=65 years	70	13	6/	7)	18.6	14.68	67	8	6/	2)	11.9	9.17	0.78	(0.31,	1.94)	0.5899	
Sex																	0.4959
Male	68	15	6/	9)	22.1	17.70	68	7	5/	2)	10.3	7.79	0.57	(0.22,	1.43)	0.2291	
Female	19	2	2/	0)	10.5	8.10	19	3	3/	0)	15.8	12.12	1.14	(0.19,	6.91)	0.8867	
Baseline FVC percent predicted																	0.2897
<=70%	24	10	6/	4)	41.7	38.78	19	4	2/	2)	21.1	17.69	0.35	(0.10,	1.27)	0.1092	
>70%	63	7	2/	5)	11.1	8.36	68	6	6/	0)	8.8	6.52	0.86	(0.29,	2.56)	0.7831	
Region																	0.9725
Europe	14	2	1/	1)	14.3	10.59	12	1	1/	0)	8.3	6.31	1.28	(0.11,	14.61)	0.8429	
Asia	41	7	4/	3)	17.1	13.31	49	6	5/	1)	12.2	8.87	0.70	(0.23,	2.10)	0.5205	
Canada and USA	13	5	1/	4)	38.5	33.81	14	3	2/	1)	21.4	20.04	0.91	(0.21,	3.95)	0.9010	
Rest of the World	19	3	2/	1)	15.8	12.92	12	0	0/	0)	0.0	0.00	0.00	(NC,	NC)	0.9883	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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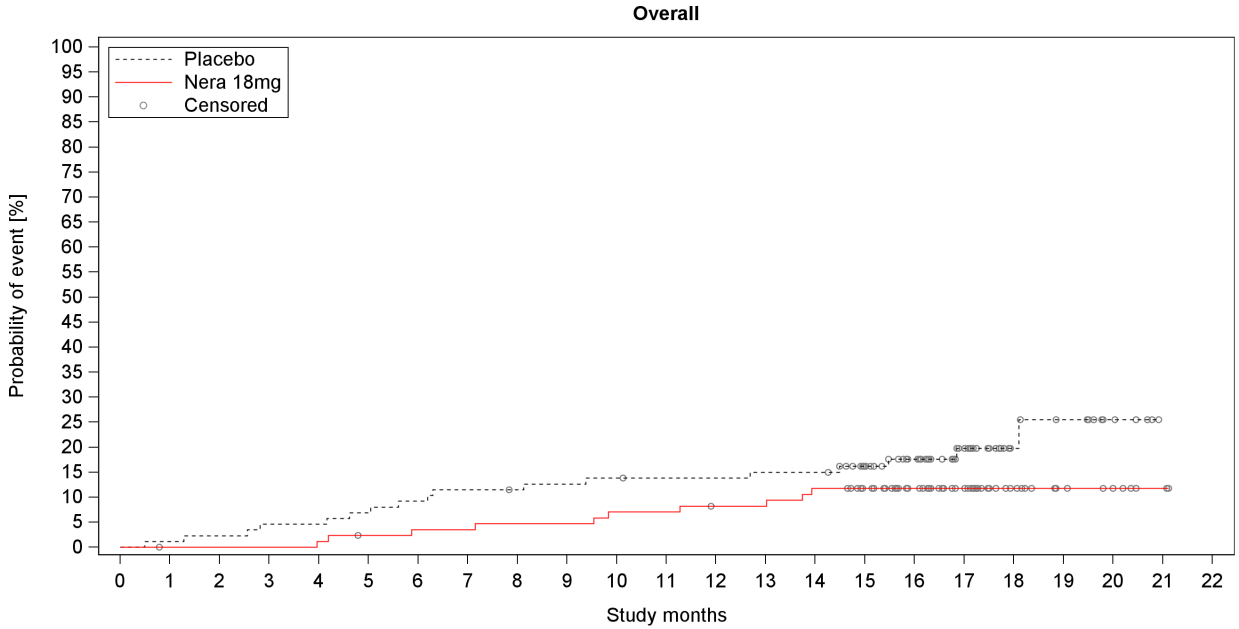

Number at risk (percentage relative to baseline)

Placebo	87	86	85	83	83	81	79	77	76	75	74	73	73	72	72	64	51	35	14	10	5	0	0
%	100.0	98.9	97.7	95.4	95.4	93.1	90.8	88.5	87.4	86.2	85.1	83.9	83.9	82.8	82.8	73.6	58.6	40.2	16.1	11.5	5.7	0.0	0.0
Nera 18mg	87	86	86	86	85	83	82	82	81	81	79	79	77	77	74	67	53	40	17	9	7	2	0
%	100.0	98.9	98.9	98.9	97.7	95.4	94.3	94.3	93.1	93.1	90.8	90.8	88.5	88.5	85.1	77.0	60.9	46.0	19.5	10.3	8.0	2.3	0.0

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

Placebo	0	0	0	0	0	0	0	0	1	1	1	2	2	2	2	9	21	36	57	60	65	70	70
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	2.3	2.3	2.3	2.3	10.3	24.1	41.4	65.5	69.0	74.7	80.5	80.5
Nera 18mg	0	1	1	1	1	2	2	2	2	2	2	2	3	3	3	10	24	37	60	68	70	75	77
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	2.3	2.3	3.4	3.4	3.4	11.5	27.6	42.5	69.0	78.2	80.5	86.2	88.5

Study: 1305-0014

Figure H.1.2.1.1.1.1: 1 Time to first confirmed acute IPF exacerbation or death over the whole trial, Kaplan-Meier estimate - 18mg - FAS (non-AF background)

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Figure H.1.2.1.1.1.1: 1

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H.1.2.1.1.1.2 Time to first confirmed or suspected acute IPF exacerbation or death

Table H.1.2.1.1.1.2: 1 Cox model for time to first confirmed or suspected acute IPF 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	87	21 (12/ 9)	24.1	19.70	87	12 (11/ 1)	13.8	10.67	0.63 (0.30, 1.32)	0.2231	
Age											0.4741
<65 years	17	4 (2/ 2)	23.5	19.13	20	2 (2/ 0)	10.0	7.31	0.36 (0.06, 2.03)	0.2476	
>=65 years	70	17 (10/ 7)	24.3	19.84	67	10 (9/ 1)	14.9	11.75	0.72 (0.32, 1.61)	0.4257	
Sex											0.5336
Male	68	17 (8/ 9)	25.0	20.34	68	7 (6/ 1)	10.3	7.85	0.53 (0.22, 1.31)	0.1711	
Female	19	4 (4/ 0)	21.1	17.37	19	5 (5/ 0)	26.3	21.43	0.89 (0.23, 3.40)	0.8625	
Baseline FVC percent predicted											0.0972
<=70%	24	13 (9/ 4)	54.2	56.22	19	4 (3/ 1)	21.1	18.32	0.29 (0.09, 0.95)	0.0411	
>70%	63	8 (3/ 5)	12.7	9.58	68	8 (8/ 0)	11.8	8.83	1.05 (0.39, 2.81)	0.9235	
Region											0.7937
Europe	14	4 (3/ 1)	28.6	22.61	12	1 (1/ 0)	8.3	6.31	0.59 (0.06, 5.46)	0.6426	
Asia	41	8 (5/ 3)	19.5	15.44	49	8 (7/ 1)	16.3	12.05	0.79 (0.29, 2.14)	0.6422	
Canada and USA	13	6 (2/ 4)	46.2	43.30	14	3 (3/ 0)	21.4	21.36	1.76 (0.42, 7.41)	0.4396	
Rest of the World	19	3 (2/ 1)	15.8	12.92	12	0 (0/ 0)	0.0	0.00	0.00 (NC, NC)	0.9913	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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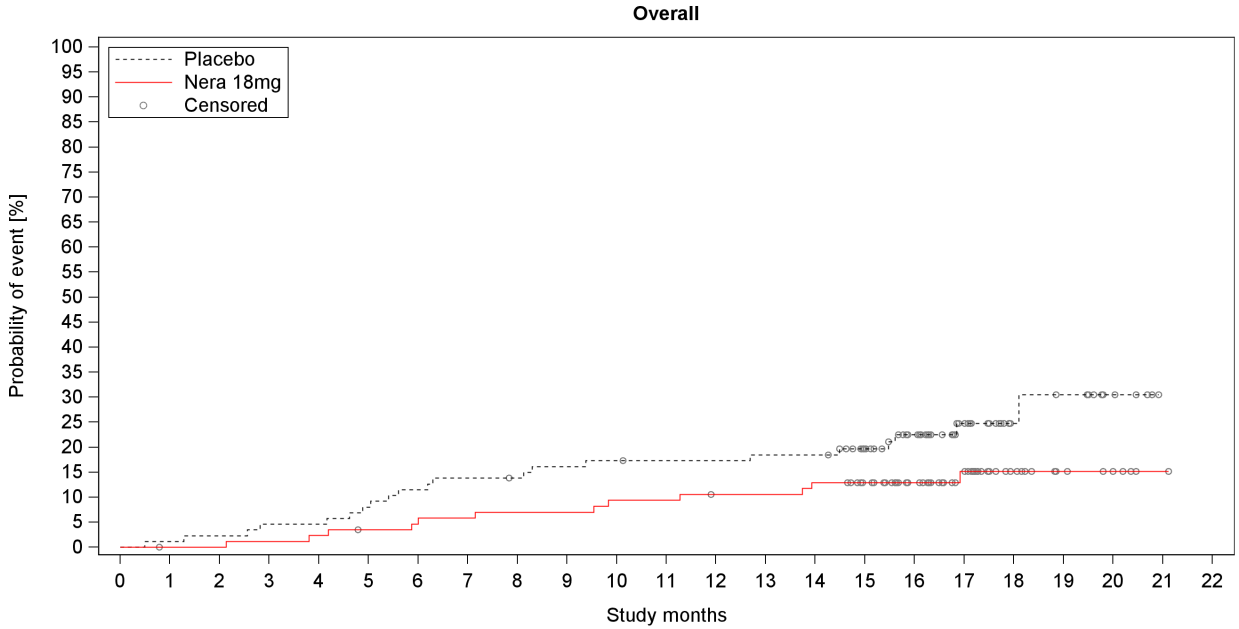

Number at risk (percentage relative to baseline)

Placebo	87	86	85	83	83	80	77	75	74	72	71	70	70	69	69	61	47	32	13	10	5	0	0
%	100.0	98.9	97.7	95.4	95.4	92.0	88.5	86.2	85.1	82.8	81.6	80.5	80.5	79.3	79.3	70.1	54.0	36.8	14.9	11.5	5.7	0.0	0.0
Nera 18mg	87	86	86	85	84	82	81	80	79	79	77	77	75	75	73	66	52	38	16	8	6	1	0
%	100.0	98.9	98.9	97.7	96.6	94.3	93.1	92.0	90.8	90.8	88.5	88.5	86.2	86.2	83.9	75.9	59.8	43.7	18.4	9.2	6.9	1.1	0.0

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

Placebo	0	0	0	0	0	0	0	0	1	1	1	2	2	2	2	9	21	35	54	56	61	66	66
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	2.3	2.3	2.3	2.3	10.3	24.1	40.2	62.1	64.4	70.1	75.9	75.9
Nera 18mg	0	1	1	1	1	2	2	2	2	2	2	2	3	3	3	10	24	37	59	67	69	74	75
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	2.3	2.3	3.4	3.4	3.4	11.5	27.6	42.5	67.8	77.0	79.3	85.1	86.2

Study: 1305-0014

Figure H.1.2.1.1.1.2: 1 Time to first confirmed or suspected acute IPF exacerbation or death over the whole trial, Kaplan-Meier estimate - 18mg - FAS (non-AF background)

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H.1.2.1.1.2 Analyses of single endpoints

H.1.2.1.1.2.1 Time to death

Table H.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	87	12	13.8	10.53	87	3	3.4	2.48	0.25	(0.07, 0.93)	0.0380	
Age												0.9925
<65 years	17	2	11.8	9.08	20	0	0.0	0.00	0.00	(NC, NC)	0.9920	
>=65 years	70	10	14.3	10.88	67	3	4.5	3.25	0.33	(0.09, 1.25)	0.1032	
Sex												0.9944
Male	68	10	14.7	11.38	68	3	4.4	3.23	0.36	(0.09, 1.39)	0.1369	
Female	19	2	10.5	7.68	19	0	0.0	0.00	0.00	(NC, NC)	0.9940	
Baseline FVC percent predicted												
<=70%	24	7	29.2		19	2	10.5					
>70%	63	5	7.9		68	1	1.5					
Region												
Europe	14	2	14.3		12	0	0.0					
Asia	41	4	9.8		49	2	4.1					
Canada and USA	13	4	30.8		14	1	7.1					
Rest of the World	19	2	10.5		12	0	0.0					

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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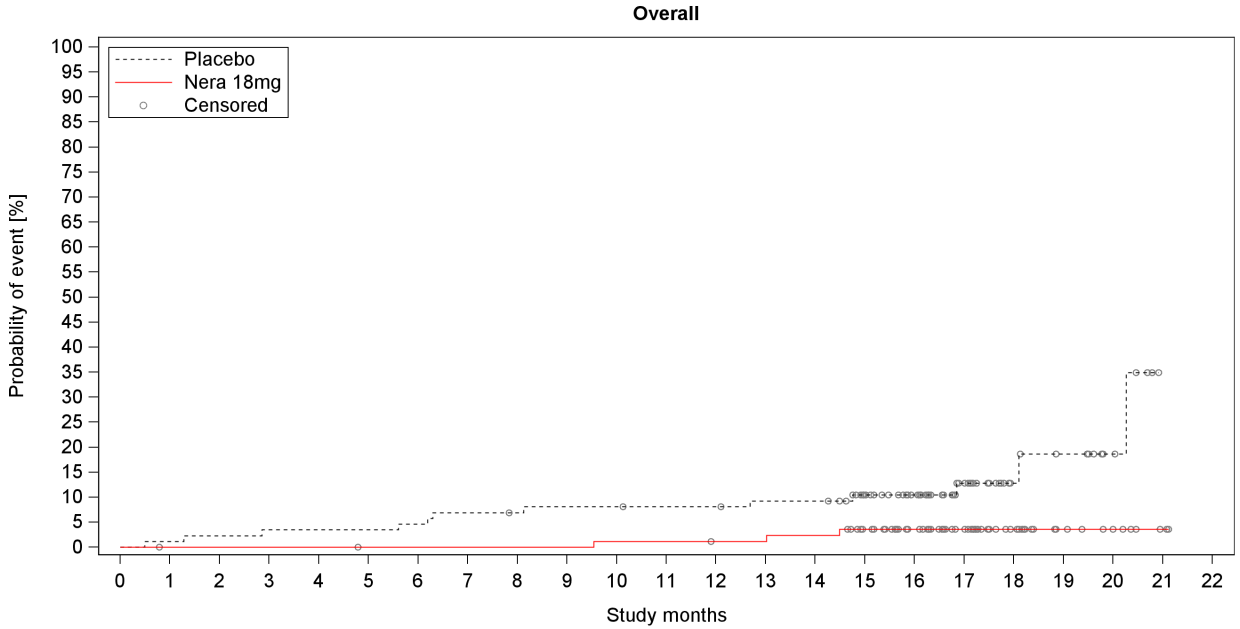

Number at risk (percentage relative to baseline)

Placebo	87	86	85	84	84	84	83	81	80	79	79	78	78	76	76	66	53	36	15	11	6	0	0
%	100.0	98.9	97.7	96.6	96.6	96.6	95.4	93.1	92.0	90.8	90.8	89.7	89.7	87.4	87.4	75.9	60.9	41.4	17.2	12.6	6.9	0.0	0.0
Nera 18mg	87	86	86	86	86	85	85	85	85	85	84	84	83	83	82	74	60	46	22	11	8	2	0
%	100.0	98.9	98.9	98.9	98.9	97.7	97.7	97.7	97.7	97.7	96.6	96.6	95.4	95.4	94.3	85.1	69.0	52.9	25.3	12.6	9.2	2.3	0.0

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

Placebo	0	0	0	0	0	0	0	0	1	1	1	2	2	3	3	12	25	41	62	65	70	75	75
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	2.3	2.3	3.4	3.4	13.8	28.7	47.1	71.3	74.7	80.5	86.2	86.2
Nera 18mg	0	1	1	1	1	2	2	2	2	2	2	2	3	3	3	10	24	38	62	73	76	82	84
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	2.3	2.3	3.4	3.4	3.4	11.5	27.6	43.7	71.3	83.9	87.4	94.3	96.6

Study: 1305-0014

Figure H.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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H.1.2.1.1.2.2 Time to first confirmed acute IPF exacerbation

Table H.1.2.1.1.2.2: 1 Cox model for time to first confirmed acute IPF 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	87	8	9.2	7.32	87	8	9.2	6.98	1.15	(0.41, 3.23)	0.7967	
Age												0.5199
<65 years	17	2	11.8	9.56	20	2	10.0	7.31	0.64	(0.09, 4.78)	0.6637	
>=65 years	70	6	8.6	6.79	67	6	9.0	6.87	1.37	(0.41, 4.57)	0.6094	
Sex												0.9099
Male	68	6	8.8	7.10	68	5	7.4	5.56	1.08	(0.31, 3.82)	0.8992	
Female	19	2	10.5	8.10	19	3	15.8	12.12	1.23	(0.20, 7.47)	0.8217	
Baseline FVC percent predicted												
<=70%	24	6	25.0		19	2	10.5					
>70%	63	2	3.2		68	6	8.8					
Region												
Europe	14	1	7.1		12	1	8.3					
Asia	41	4	9.8		49	5	10.2					
Canada and USA	13	1	7.7		14	2	14.3					
Rest of the World	19	2	10.5		12	0	0.0					

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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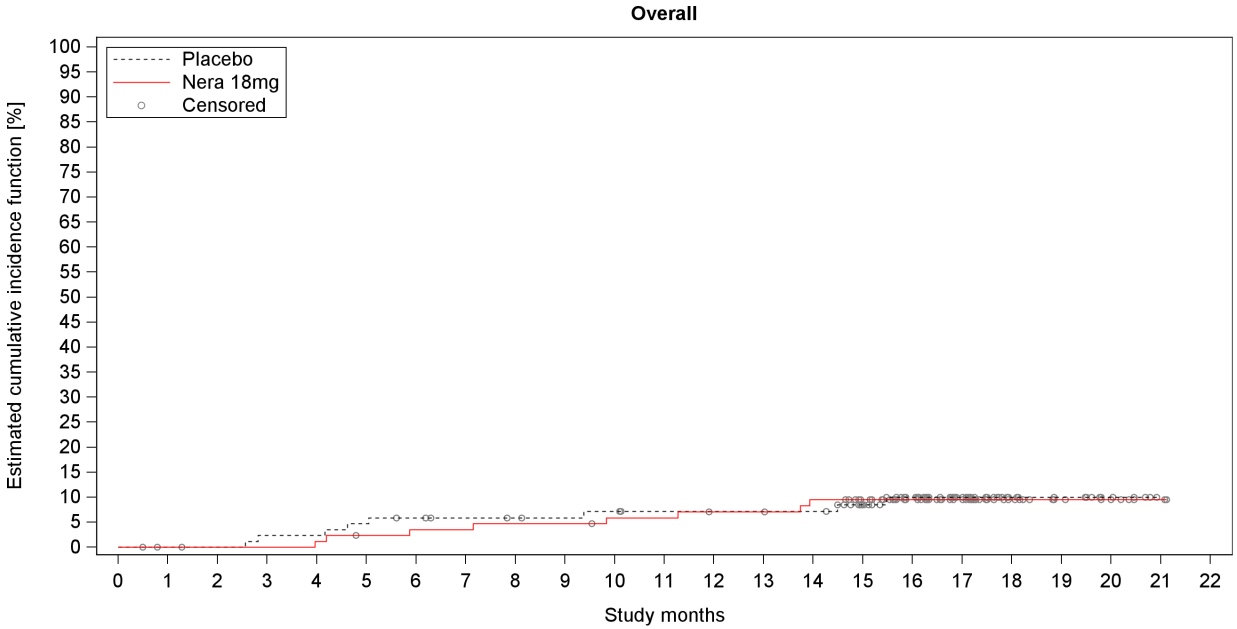

Number at risk (percentage relative to baseline)

Placebo	87	86	85	83	83	81	79	77	76	75	74	72	72	72	72	64	51	35	14	10	5	0	0
%	100.0	98.9	97.7	95.4	95.4	93.1	90.8	88.5	87.4	86.2	85.1	82.8	82.8	82.8	82.8	73.6	58.6	40.2	16.1	11.5	5.7	0.0	0.0
Nera 18mg	87	86	86	86	85	83	82	82	81	81	79	79	77	77	74	67	53	40	17	9	7	2	0
%	100.0	98.9	98.9	98.9	97.7	95.4	94.3	94.3	93.1	93.1	90.8	90.8	88.5	88.5	85.1	77.0	60.9	46.0	19.5	10.3	8.0	2.3	0.0

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

Placebo	0	1	2	2	2	2	3	5	6	7	7	9	9	9	9	16	28	44	65	69	74	79	79
%	0.0	1.1	2.3	2.3	2.3	2.3	3.4	5.7	6.9	8.0	8.0	10.3	10.3	10.3	10.3	18.4	32.2	50.6	74.7	79.3	85.1	90.8	90.8
Nera 18mg	0	1	1	1	1	2	2	2	2	2	3	3	4	4	5	12	26	39	62	70	72	77	79
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	3.4	3.4	4.6	4.6	5.7	13.8	29.9	44.8	71.3	80.5	82.8	88.5	90.8

Study: 1305-0014

Figure H.1.2.1.1.2.2: 1 Time to first confirmed acute IPF exacerbation over the whole trial, estimated cumulative incidence function - 18mg - FAS (non-AF background)

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Figure H.1.2.1.1.2.2: 1

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H.1.2.1.1.2.3 Time to first confirmed or suspected acute IPF exacerbation

Table H.1.2.1.1.2.3: 1 Cox model for time to first confirmed or suspected acute IPF 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	87	12	13.8	11.28	87	11	12.6	9.78	1.01	(0.43, 2.38)	0.9836	
Age												0.6859
<65 years	17	2	11.8	9.56	20	2	10.0	7.31	0.70	(0.10, 5.10)	0.7213	
>=65 years	70	10	14.3	11.70	67	9	13.4	10.58	1.09	(0.43, 2.79)	0.8520	
Sex												0.9041
Male	68	8	11.8	9.60	68	6	8.8	6.73	0.99	(0.33, 2.99)	0.9926	
Female	19	4	21.1	17.37	19	5	26.3	21.43	0.89	(0.23, 3.43)	0.8710	
Baseline FVC percent predicted												0.0229
<=70%	24	9	37.5	38.92	19	3	15.8	13.74	0.29	(0.07, 1.20)	0.0871	
>70%	63	3	4.8	3.60	68	8	11.8	8.83	2.72	(0.72, 10.30)	0.1399	
Region												0.4914
Europe	14	3	21.4	16.96	12	1	8.3	6.31	0.86	(0.09, 8.72)	0.9018	
Asia	41	5	12.2	9.65	49	7	14.3	10.55	1.00	(0.31, 3.24)	0.9956	
Canada and USA	13	2	15.4	14.66	14	3	21.4	21.36	5.18	(0.82, 32.83)	0.0807	
Rest of the World	19	2	10.5	8.61	12	0	0.0	0.00	0.00	(NC, NC)	0.9920	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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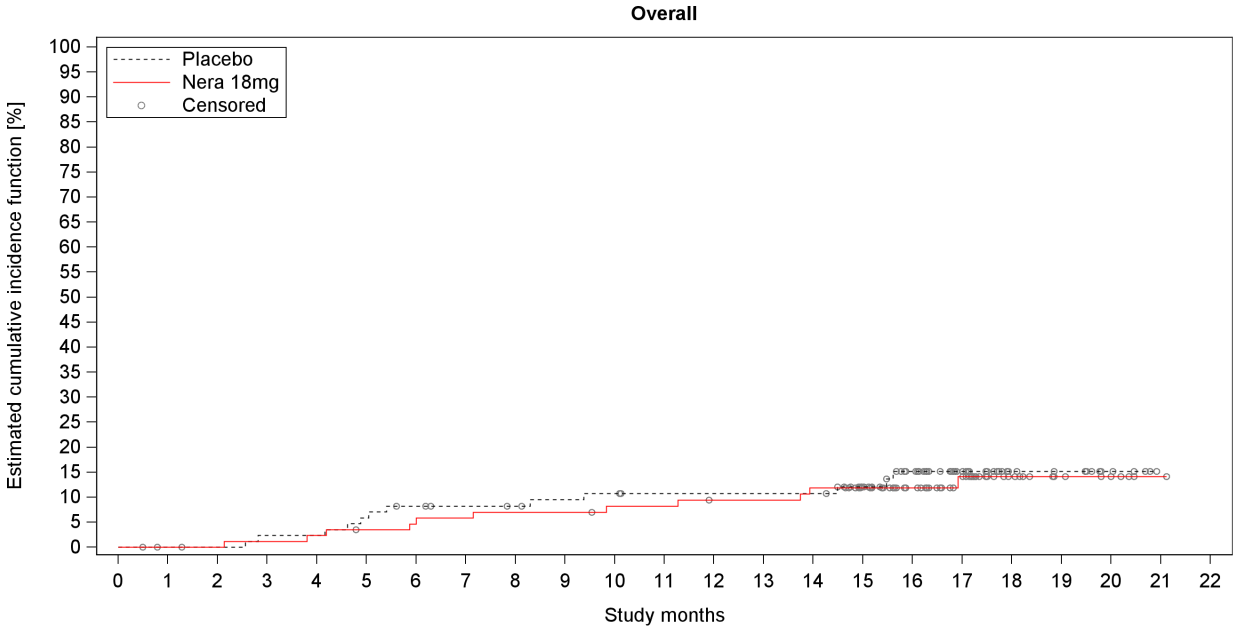

Number at risk (percentage relative to baseline)

Placebo	87	86	85	83	83	80	77	75	74	72	71	69	69	69	69	61	47	32	13	10	5	0	0
%	100.0	98.9	97.7	95.4	95.4	92.0	88.5	86.2	85.1	82.8	81.6	79.3	79.3	79.3	79.3	70.1	54.0	36.8	14.9	11.5	5.7	0.0	0.0
Nera 18mg	87	86	86	85	84	82	81	80	79	79	77	77	75	75	73	66	52	38	16	8	6	1	0
%	100.0	98.9	98.9	97.7	96.6	94.3	93.1	92.0	90.8	90.8	88.5	88.5	86.2	86.2	83.9	75.9	59.8	43.7	18.4	9.2	6.9	1.1	0.0

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

Placebo	0	1	2	2	2	2	3	5	6	7	7	9	9	9	9	16	28	43	62	65	70	75	75
%	0.0	1.1	2.3	2.3	2.3	2.3	3.4	5.7	6.9	8.0	8.0	10.3	10.3	10.3	10.3	18.4	32.2	49.4	71.3	74.7	80.5	86.2	86.2
Nera 18mg	0	1	1	1	1	2	2	2	2	2	3	3	4	4	4	11	25	38	60	68	70	75	76
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	3.4	3.4	4.6	4.6	4.6	12.6	28.7	43.7	69.0	78.2	80.5	86.2	87.4

Study: 1305-0014

Figure H.1.2.1.1.2.3: 1 Time to first confirmed or suspected acute IPF exacerbation over the whole trial, estimated cumulative incidence function - 18mg - FAS (non-AF background)

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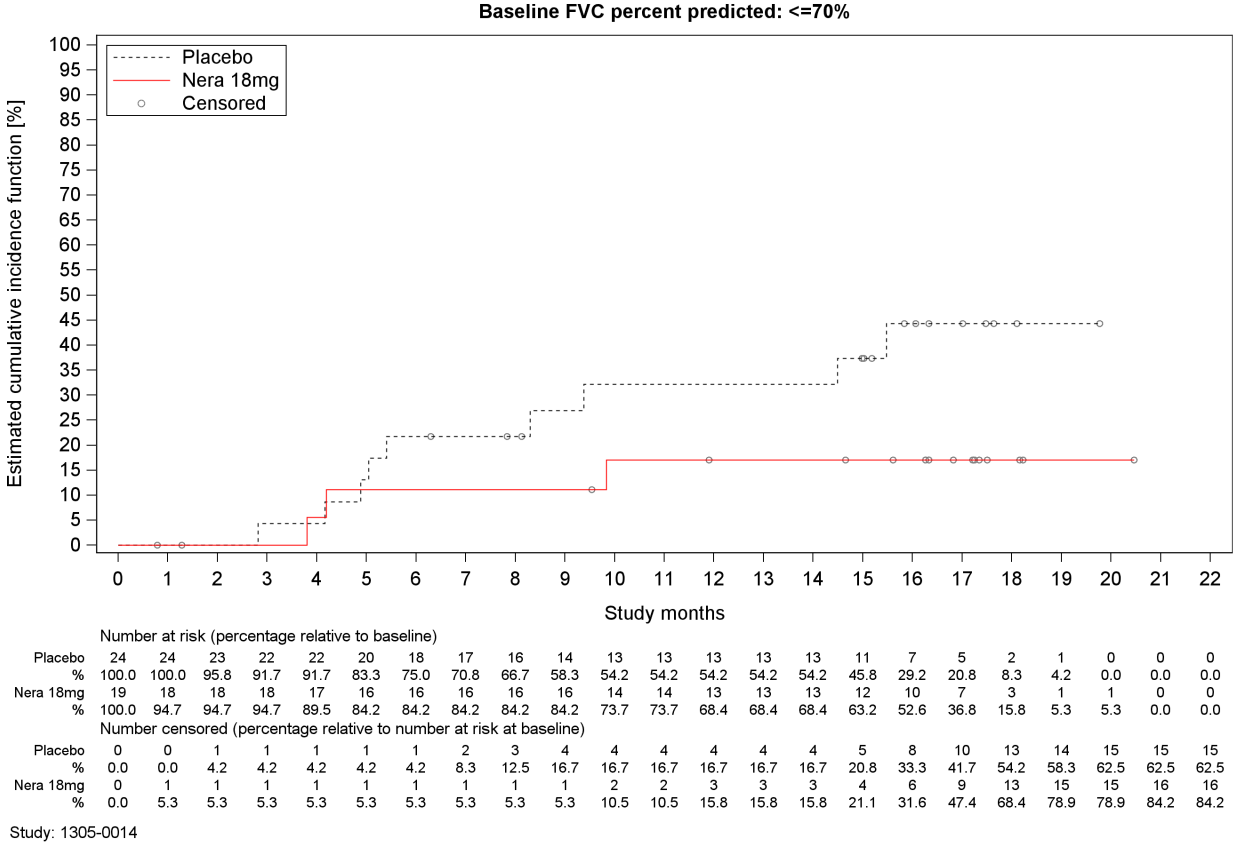

Number at risk (percentage relative to baseline)

Placebo	24	24	23	22	22	20	18	17	16	14	13	13	13	13	11	7	5	2	1	0	0	0
%	100.0	100.0	95.8	91.7	91.7	83.3	75.0	70.8	66.7	58.3	54.2	54.2	54.2	54.2	54.2	45.8	29.2	20.8	8.3	4.2	0.0	0.0	0.0
Nera 18mg	19	18	18	18	17	16	16	16	16	16	14	14	13	13	13	12	10	7	3	1	1	0	0
%	100.0	94.7	94.7	94.7	89.5	84.2	84.2	84.2	84.2	84.2	73.7	73.7	68.4	68.4	68.4	63.2	52.6	36.8	15.8	5.3	5.3	0.0	0.0

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

Placebo	0	0	1	1	1	1	1	2	3	4	4	4	4	4	4	5	8	10	13	14	15	15	15
%	0.0	0.0	4.2	4.2	4.2	4.2	4.2	8.3	12.5	16.7	16.7	16.7	16.7	16.7	16.7	20.8	33.3	41.7	54.2	58.3	62.5	62.5	62.5
Nera 18mg	0	1	1	1	1	1	1	1	1	1	2	2	3	3	3	4	6	9	13	15	15	16	16
%	0.0	5.3	5.3	5.3	5.3	5.3	5.3	5.3	5.3	5.3	10.5	10.5	15.8	15.8	15.8	21.1	31.6	47.4	68.4	78.9	78.9	84.2	84.2

Study: 1305-0014

Figure H.1.2.1.1.2.3: 1 Time to first confirmed or suspected acute IPF exacerbation over the whole trial, estimated cumulative incidence function - 18mg - FAS (non-AF background)

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Figure H.1.2.1.1.2.3: 1

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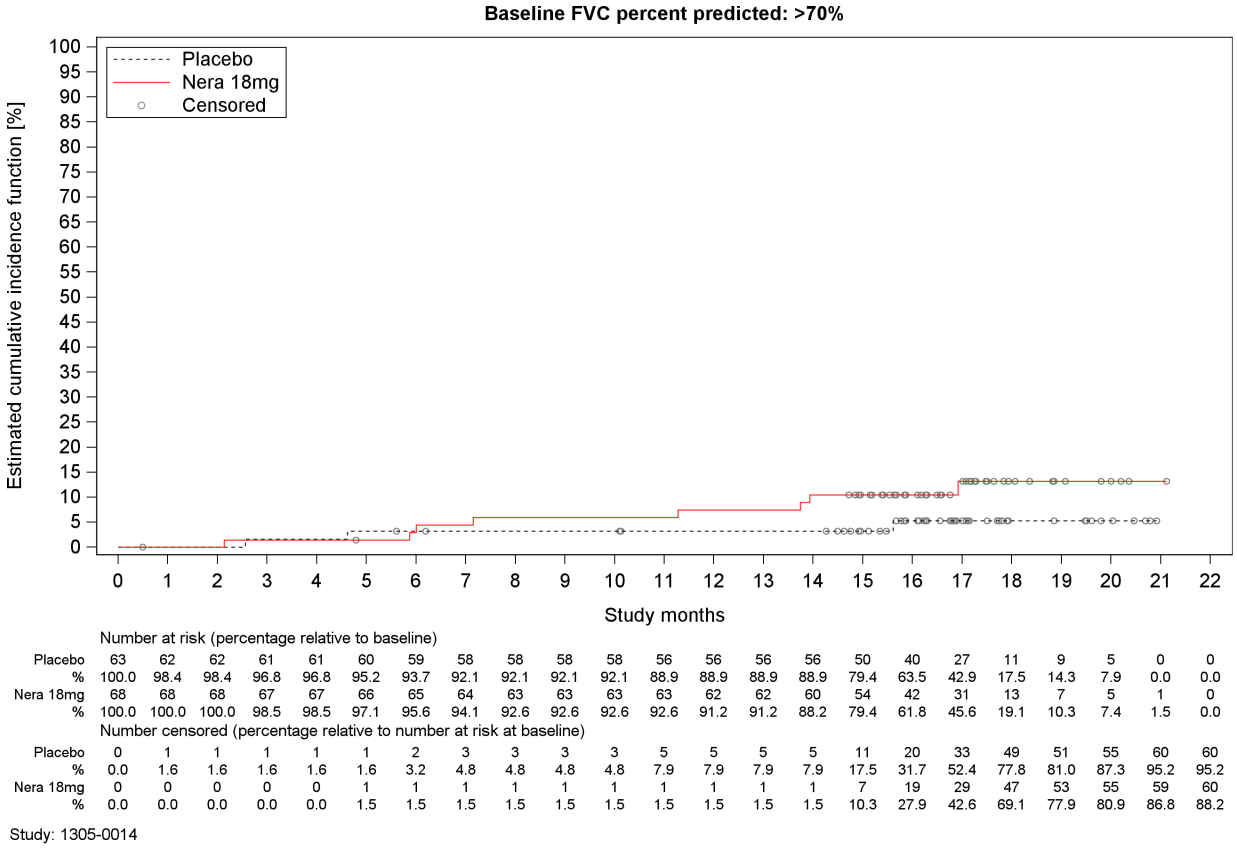

Number at risk (percentage relative to baseline)

Placebo	63	62	62	61	61	60	59	58	58	58	58	56	56	56	56	50	40	27	11	9	5	0	0
%	100.0	98.4	98.4	96.8	96.8	95.2	93.7	92.1	92.1	92.1	92.1	88.9	88.9	88.9	88.9	79.4	63.5	42.9	17.5	14.3	7.9	0.0	0.0
Nera 18mg	68	68	68	67	67	66	65	64	63	63	63	63	62	62	60	54	42	31	13	7	5	1	0
%	100.0	100.0	100.0	98.5	98.5	97.1	95.6	94.1	92.6	92.6	92.6	92.6	91.2	91.2	88.2	79.4	61.8	45.6	19.1	10.3	7.4	1.5	0.0

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

Placebo	0	1	1	1	1	1	2	3	3	3	3	5	5	5	5	11	20	33	49	51	55	60	60
%	0.0	1.6	1.6	1.6	1.6	1.6	3.2	4.8	4.8	4.8	4.8	7.9	7.9	7.9	7.9	17.5	31.7	52.4	77.8	81.0	87.3	95.2	95.2
Nera 18mg	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	7	19	29	47	53	55	59	60
%	0.0	0.0	0.0	0.0	0.0	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	10.3	27.9	42.6	69.1	77.9	80.9	86.8	88.2

Study: 1305-0014

Figure H.1.2.1.1.2.3: 1 Time to first confirmed or suspected acute IPF exacerbation over the whole trial, estimated cumulative incidence function - 18mg - FAS (non-AF background)

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Figure H.1.2.1.1.2.3: 1

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H.1.2.1.2 Analyses of continuous variables

H.1.2.1.2.1 MMRM Analysis

Table H.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	87	85	74.9	1.8	83 (100.0%)												
Nera 18mg	87	85	76.4	1.6	84 (100.0%)												
Week 6																	
Placebo		84	76.7	1.8	82 (98.8%)	1.2	1.3	-1.3	3.8								
Nera 18mg		86	81.7	1.4	84 (100.0%)	5.5	1.3	3.0	8.0	4.3	1.8	0.7	7.9	0.0205	0.36	0.06	0.67
Week 12																	
Placebo		81	76.7	2.1	79 (95.2%)	1.4	1.5	-1.7	4.4								
Nera 18mg		84	78.2	1.6	82 (97.6%)	2.2	1.5	-0.8	5.1	0.8	2.2	-3.5	5.1	0.7111			
Week 18																	
Placebo		80	76.2	1.6	78 (94.0%)	1.3	1.3	-1.2	3.8								
Nera 18mg		83	79.0	1.6	81 (96.4%)	2.8	1.3	0.3	5.3	1.5	1.8	-2.0	5.1	0.3892			
Week 26																	
Placebo		76	73.1	2.0	75 (90.4%)	-2.3	1.6	-5.5	0.9								
Nera 18mg		81	77.7	1.9	79 (94.0%)	0.8	1.6	-2.4	4.0	3.1	2.3	-1.5	7.6	0.1826			
Week 36																	
Placebo		73	75.2	1.8	71 (85.5%)	-0.3	1.5	-3.3	2.8								
Nera 18mg		79	78.8	1.9	77 (91.7%)	2.2	1.5	-0.7	5.2	2.5	2.1	-1.7	6.7	0.2456			
Week 44																	
Placebo		72	73.7	2.0	70 (84.3%)	-1.7	1.7	-5.0	1.6								
Nera 18mg		78	77.1	1.9	76 (90.5%)	0.1	1.6	-3.0	3.3	1.8	2.3	-2.7	6.4	0.4242			
Week 52																	
Placebo		70	73.9	2.1	68 (81.9%)	-1.6	1.7	-4.9	1.8								
Nera 18mg		78	77.6	1.7	76 (90.5%)	0.5	1.6	-2.8	3.7	2.1	2.4	-2.6	6.7	0.3859			
Week 64																	
Placebo		67	75.7	2.1	65 (78.3%)	0.8	1.6	-2.4	4.1								
Nera 18mg		76	78.8	1.9	74 (88.1%)	1.1	1.6	-2.0	4.2	0.3	2.3	-4.2	4.8	0.9061			
Week 76																	
Placebo		41	76.2	2.4	40 (48.2%)												
Nera 18mg		54	78.1	1.9	52 (61.9%)												
Week 88																	
Placebo		7	77.0	5.7	7 (8.4%)												
Nera 18mg		10	69.7	7.9	10 (11.9%)												

Study: 1305-0014. 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, 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 H.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 95% CI value	lower	upper
Age																	
Test for homogeneity (H0)^																	
Week 6														0.2030			
Week 12														0.8907			
Week 18														0.3620			
Week 26														0.2535			
Week 36														0.8586			
Week 44														0.5637			
Week 52														0.9712			
Week 64														0.7853			
<65 years																	
Baseline																	
Placebo	17	17	80.2	3.9	16 (100.0%)												
Nera 18mg	20	20	82.0	3.2	20 (100.0%)												
Week 6																	
Placebo		15	84.4	3.1	15 (93.8%)	5.5	3.0	-0.4	11.5								
Nera 18mg		20	84.5	2.3	20 (100.0%)	5.2	2.6	-0.1	10.4	-0.4	4.0	-8.2	7.5	0.9275			
Week 12																	
Placebo		15	77.9	5.1	15 (93.8%)	0.1	3.5	-6.9	7.0								
Nera 18mg		20	80.2	2.9	20 (100.0%)	0.4	3.1	-5.7	6.5	0.3	4.7	-8.9	9.6	0.9435			
Week 18																	
Placebo		14	79.9	3.7	14 (87.5%)	2.7	3.0	-3.2	8.6								
Nera 18mg		20	80.4	3.3	20 (100.0%)	1.1	2.6	-4.0	6.2	-1.6	3.9	-9.4	6.2	0.6844			
Week 26																	
Placebo		14	80.9	3.5	14 (87.5%)	2.6	3.8	-4.9	10.1								
Nera 18mg		19	80.3	4.1	19 (95.0%)	0.5	3.3	-6.0	7.0	-2.1	5.0	-12.0	7.8	0.6736			
Week 36																	
Placebo		13	77.6	3.9	13 (81.3%)	0.3	3.6	-6.9	7.4								
Nera 18mg		19	81.8	3.5	19 (95.0%)	2.0	3.1	-4.0	8.1	1.8	4.7	-7.5	11.1	0.7086			
Week 44																	
Placebo		13	76.4	4.3	13 (81.3%)	-1.0	3.8	-8.6	6.6								
Nera 18mg		19	77.9	3.1	19 (95.0%)	-1.7	3.3	-8.1	4.8	-0.7	5.0	-10.6	9.3	0.8934			
Week 52																	
Placebo		13	75.0	5.5	13 (81.3%)	-2.3	3.9	-10.1	5.5								
Nera 18mg		19	78.8	3.3	19 (95.0%)	-0.0	3.4	-6.7	6.7	2.3	5.2	-7.9	12.5	0.6605			

Study: 1305-0014. 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, 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 H.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 64																	
Placebo		12	85.0	3.8	12 (75.0%)	4.6	3.8	-2.9	12.1								
Nera 18mg		19	83.2	3.3	19 (95.0%)	3.5	3.2	-2.8	9.7	-1.1	4.9	-10.9	8.6	0.8193			
Week 76																	
Placebo		9	79.2	5.5	9 (56.3%)												
Nera 18mg		13	77.2	3.8	13 (65.0%)												
Week 88																	
Placebo		2	90.0	0.0	2 (12.5%)												
Nera 18mg		3	73.3	12.0	3 (15.0%)												
>=65 years																	
Baseline																	
Placebo	70	68	73.6	2.0	67 (100.0%)												
Nera 18mg	67	65	74.7	1.8	64 (100.0%)												
Week 6																	
Placebo		69	75.0	2.0	67 (100.0%)	0.3	1.4	-2.6	3.1								
Nera 18mg		66	80.8	1.6	64 (100.0%)	5.6	1.5	2.7	8.5	5.4	2.0	1.3	9.4	0.0098	0.45	0.11	0.80
Week 12																	
Placebo		66	76.5	2.3	64 (95.5%)	1.7	1.7	-1.7	5.0								
Nera 18mg		64	77.5	2.0	62 (96.9%)	2.7	1.7	-0.7	6.2	1.1	2.4	-3.8	5.9	0.6646			
Week 18																	
Placebo		66	75.5	1.7	64 (95.5%)	1.0	1.4	-1.9	3.8								
Nera 18mg		63	78.5	1.8	61 (95.3%)	3.4	1.5	0.5	6.3	2.4	2.0	-1.6	6.4	0.2305			
Week 26																	
Placebo		62	71.4	2.3	61 (91.0%)	-3.5	1.8	-7.1	0.1								
Nera 18mg		62	76.9	2.2	60 (93.8%)	0.9	1.8	-2.8	4.5	4.3	2.6	-0.8	9.5	0.0955			
Week 36																	
Placebo		60	74.7	2.0	58 (86.6%)	-0.4	1.7	-3.8	3.0								
Nera 18mg		60	77.9	2.3	58 (90.6%)	2.3	1.7	-1.1	5.7	2.7	2.4	-2.1	7.5	0.2661			
Week 44																	
Placebo		59	73.1	2.3	57 (85.1%)	-1.9	1.8	-5.5	1.8								
Nera 18mg		59	76.8	2.2	57 (89.1%)	0.7	1.8	-2.9	4.4	2.6	2.6	-2.5	7.8	0.3194			
Week 52																	
Placebo		57	73.6	2.2	55 (82.1%)	-1.4	1.9	-5.2	2.4								
Nera 18mg		59	77.2	2.0	57 (89.1%)	0.7	1.9	-3.1	4.4	2.1	2.7	-3.2	7.4	0.4435			
Week 64																	
Placebo		55	73.7	2.3	53 (79.1%)	-0.1	1.8	-3.7	3.5								

Study: 1305-0014. 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, 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 H.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		57	77.4	2.3	55 (85.9%)	0.3	1.8	-3.3	3.8	0.4	2.6	-4.7	5.5	0.8807			
Week 76																	
Placebo		32	75.4	2.7	31 (46.3%)												
Nera 18mg		41	78.3	2.2	39 (60.9%)												
Week 88																	
Placebo		5	71.8	6.7	5 (7.5%)												
Nera 18mg		7	68.1	10.5	7 (10.9%)												
Sex																	
Test for homogeneity (H0)^																	
Week 6														0.9981			
Week 12														0.4276			
Week 18														0.2397			
Week 26														0.5181			
Week 36														0.7191			
Week 44														0.9724			
Week 52														0.1932			
Week 64														0.3635			
Male																	
Baseline																	
Placebo	68	66	76.1	1.9	64 (100.0%)												
Nera 18mg	68	66	76.2	1.8	65 (100.0%)												
Week 6																	
Placebo		66	78.2	1.9	64 (100.0%)	2.3	1.4	-0.5	5.2								
Nera 18mg		67	82.6	1.5	65 (100.0%)	6.6	1.4	3.8	9.5	4.3	2.0	0.3	8.3	0.0371	0.37	0.02	0.71
Week 12																	
Placebo		63	77.0	2.4	61 (95.3%)	1.2	1.7	-2.3	4.6								
Nera 18mg		65	78.7	1.8	63 (96.9%)	2.9	1.7	-0.5	6.3	1.7	2.5	-3.1	6.6	0.4871			
Week 18																	
Placebo		62	76.2	1.6	60 (93.8%)	0.9	1.5	-2.0	3.7								
Nera 18mg		64	79.5	1.8	62 (95.4%)	3.6	1.4	0.7	6.4	2.7	2.0	-1.3	6.7	0.1883			
Week 26																	
Placebo		59	74.9	2.1	58 (90.6%)	-0.7	1.9	-4.3	3.0								
Nera 18mg		62	78.6	2.3	60 (92.3%)	1.6	1.8	-2.0	5.2	2.3	2.6	-2.9	7.4	0.3809			

Study: 1305-0014. 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 H.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 36																	
Placebo		56	76.3	2.0	54 (84.4%)	0.5	1.8	-3.0	4.0								
Nera 18mg		60	79.1	2.4	58 (89.2%)	2.5	1.7	-0.9	5.9	2.0	2.5	-2.8	6.9	0.4116			
Week 44																	
Placebo		55	74.3	2.3	53 (82.8%)	-1.4	1.9	-5.1	2.4								
Nera 18mg		59	77.6	2.2	57 (87.7%)	0.5	1.8	-3.2	4.1	1.8	2.6	-3.4	7.1	0.4876			
Week 52																	
Placebo		53	74.2	2.4	51 (79.7%)	-1.6	1.9	-5.4	2.3								
Nera 18mg		59	79.6	1.8	57 (87.7%)	2.2	1.9	-1.4	5.9	3.8	2.7	-1.5	9.1	0.1595			
Week 64																	
Placebo		51	76.2	2.4	49 (76.6%)	0.8	1.9	-2.9	4.5								
Nera 18mg		57	80.4	2.1	55 (84.6%)	2.2	1.8	-1.4	5.8	1.4	2.6	-3.8	6.6	0.5945			
Week 76																	
Placebo		30	76.1	2.9	29 (45.3%)												
Nera 18mg		40	79.0	2.3	38 (58.5%)												
Week 88																	
Placebo		4	82.3	5.0	4 (6.3%)												
Nera 18mg		7	65.6	9.6	7 (10.8%)												
Female																	
Baseline																	
Placebo	19	19	70.8	4.8	19 (100.0%)												
Nera 18mg	19	19	77.3	3.2	19 (100.0%)												
Week 6																	
Placebo		18	71.0	4.5	18 (94.7%)	-2.7	2.7	-8.0	2.7								
Nera 18mg		19	78.3	3.5	19 (100.0%)	1.6	2.7	-3.6	6.9	4.3	3.8	-3.2	11.8	0.2626			
Week 12																	
Placebo		18	75.7	3.9	18 (94.7%)	2.0	3.2	-4.4	8.4								
Nera 18mg		19	76.4	3.9	19 (100.0%)	-0.4	3.2	-6.6	5.9	-2.4	4.5	-11.3	6.6	0.5991			
Week 18																	
Placebo		18	76.4	4.1	18 (94.7%)	2.7	2.7	-2.6	8.0								
Nera 18mg		19	77.1	3.4	19 (100.0%)	0.4	2.6	-4.8	5.5	-2.3	3.7	-9.7	5.1	0.5344			
Week 26																	
Placebo		17	67.1	5.2	17 (89.5%)	-7.9	3.4	-14.6	-1.1								
Nera 18mg		19	74.7	3.8	19 (100.0%)	-2.1	3.3	-8.6	4.4	5.8	4.8	-3.6	15.2	0.2247			
Week 36																	
Placebo		17	71.9	3.9	17 (89.5%)	-2.7	3.2	-9.0	3.6								

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

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Table H.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		19	77.9	3.1	19 (100.0%)	1.2	3.1	-4.9	7.2	3.9	4.4	-4.9	12.6	0.3856			
Week 44																	
Placebo		17	71.6	4.2	17 (89.5%)	-2.9	3.4	-9.6	3.9								
Nera 18mg		19	75.5	3.5	19 (100.0%)	-1.2	3.3	-7.7	5.3	1.7	4.7	-7.7	11.0	0.7277			
Week 52																	
Placebo		17	72.9	4.1	17 (89.5%)	-1.7	3.5	-8.6	5.2								
Nera 18mg		19	71.5	3.7	19 (100.0%)	-5.1	3.3	-11.7	1.5	-3.4	4.8	-12.9	6.1	0.4809			
Week 64																	
Placebo		16	74.2	3.8	16 (84.2%)	0.9	3.4	-5.8	7.5								
Nera 18mg		19	74.2	4.7	19 (100.0%)	-2.6	3.2	-8.9	3.7	-3.4	4.6	-12.6	5.7	0.4585			
Week 76																	
Placebo		11	76.6	4.4	11 (57.9%)												
Nera 18mg		14	75.4	3.4	14 (73.7%)												
Week 88																	
Placebo		3	70.0	11.5	3 (15.8%)												
Nera 18mg		3	79.3	14.7	3 (15.8%)												
Baseline FVC percent predicted																	
Test for homogeneity (H0)^																	
Week 6														0.3153			
Week 12														0.8496			
Week 18														0.7771			
Week 26														0.7649			
Week 36														0.8170			
Week 44														0.7367			
Week 52														0.8455			
Week 64														0.4938			
<=70%																	
Baseline																	
Placebo	24	22	68.6	3.8	21 (100.0%)												
Nera 18mg	19	19	70.8	3.8	19 (100.0%)												
Week 6																	
Placebo		23	69.6	3.3	21 (100.0%)	-3.2	2.6	-8.2	1.9								
Nera 18mg		19	77.4	2.9	19 (100.0%)	4.3	2.7	-1.0	9.6	7.4	3.7	0.1	14.7	0.0458	0.62	-0.00	1.24

Study: 1305-0014. 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 H.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		21	70.7	4.0	19 (90.5%)	-2.9	3.1	-9.0	3.1								
Nera 18mg		18	69.7	4.1	18 (94.7%)	-3.0	3.2	-9.3	3.3	-0.1	4.4	-8.8	8.6	0.9846			
Week 18																	
Placebo		22	70.8	2.8	20 (95.2%)	-2.6	2.5	-7.6	2.5								
Nera 18mg		18	72.8	3.1	18 (94.7%)	-0.2	2.7	-5.5	5.1	2.4	3.7	-4.9	9.6	0.5206			
Week 26																	
Placebo		19	67.3	3.8	18 (85.7%)	-5.3	3.4	-12.0	1.3								
Nera 18mg		15	70.0	4.0	15 (78.9%)	-3.7	3.6	-10.8	3.4	1.6	4.9	-8.0	11.3	0.7367			
Week 36																	
Placebo		18	71.2	2.6	16 (76.2%)	-2.0	3.2	-8.4	4.4								
Nera 18mg		15	75.0	2.4	15 (78.9%)	1.4	3.3	-5.2	8.0	3.4	4.6	-5.7	12.5	0.4646			
Week 44																	
Placebo		18	65.6	4.3	16 (76.2%)	-8.6	3.4	-15.3	-1.9								
Nera 18mg		15	68.7	3.4	15 (78.9%)	-5.5	3.5	-12.4	1.5	3.1	4.8	-6.5	12.7	0.5245			
Week 52																	
Placebo		18	66.3	3.8	16 (76.2%)	-8.8	3.4	-15.6	-2.0								
Nera 18mg		16	68.4	3.3	16 (84.2%)	-6.1	3.5	-13.0	0.9	2.7	4.9	-6.9	12.3	0.5778			
Week 64																	
Placebo		17	66.6	4.2	15 (71.4%)	-5.8	3.4	-12.4	0.9								
Nera 18mg		14	71.8	5.3	14 (73.7%)	-2.8	3.5	-9.6	4.1	3.0	4.8	-6.4	12.5	0.5276			
Week 76																	
Placebo		8	65.1	5.3	7 (33.3%)												
Nera 18mg		12	69.8	3.6	12 (63.2%)												
Week 88																	
Placebo		1	69.0	NC	1 (4.8%)												
Nera 18mg		1	60.0	NC	1 (5.3%)												
>70%																	
Baseline																	
Placebo	63	63	77.1	2.0	62 (100.0%)												
Nera 18mg	68	66	78.1	1.7	65 (100.0%)												
Week 6																	
Placebo		61	79.4	2.0	61 (98.4%)	2.7	1.5	-0.2	5.7								
Nera 18mg		67	82.9	1.5	65 (100.0%)	5.9	1.5	3.0	8.7	3.2	2.1	-0.9	7.3	0.1293			
Week 12																	
Placebo		60	78.9	2.4	60 (96.8%)	2.8	1.7	-0.7	6.2								

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

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Table H.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		66	80.5	1.7	64 (98.5%)	3.6	1.7	0.3	7.0	0.9	2.4	-3.9	5.7	0.7206			
Week 18																	
Placebo		58	78.3	1.8	58 (93.5%)	2.5	1.5	-0.4	5.4								
Nera 18mg		65	80.7	1.8	63 (96.9%)	3.7	1.4	0.9	6.5	1.2	2.0	-2.9	5.2	0.5692			
Week 26																	
Placebo		57	75.1	2.3	57 (91.9%)	-1.3	1.9	-5.0	2.4								
Nera 18mg		66	79.4	2.2	64 (98.5%)	2.0	1.8	-1.6	5.5	3.3	2.6	-1.8	8.4	0.2064			
Week 36																	
Placebo		55	76.6	2.2	55 (88.7%)	0.4	1.8	-3.1	3.8								
Nera 18mg		64	79.7	2.3	62 (95.4%)	2.5	1.7	-0.8	5.8	2.2	2.4	-2.6	7.0	0.3735			
Week 44																	
Placebo		54	76.4	2.2	54 (87.1%)	0.4	1.9	-3.3	4.1								
Nera 18mg		63	79.1	2.1	61 (93.8%)	1.7	1.8	-1.8	5.2	1.2	2.6	-3.8	6.3	0.6280			
Week 52																	
Placebo		52	76.5	2.4	52 (83.9%)	0.7	1.9	-3.1	4.5								
Nera 18mg		62	80.0	1.8	60 (92.3%)	2.3	1.8	-1.3	5.9	1.6	2.6	-3.6	6.8	0.5362			
Week 64																	
Placebo		50	78.8	2.2	50 (80.6%)	2.9	1.9	-0.8	6.6								
Nera 18mg		62	80.4	2.0	60 (92.3%)	2.2	1.7	-1.3	5.7	-0.7	2.6	-5.7	4.4	0.7888			
Week 76																	
Placebo		33	78.9	2.5	33 (53.2%)												
Nera 18mg		42	80.4	2.1	40 (61.5%)												
Week 88																	
Placebo		6	78.3	6.5	6 (9.7%)												
Nera 18mg		9	70.8	8.7	9 (13.8%)												
Region																	
Test for homogeneity (H0)^																	
Week 6														0.9685			
Week 12														0.3675			
Week 18														0.3266			
Week 26														0.9053			
Week 36														0.8801			
Week 44														0.7221			
Week 52														0.3355			

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

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Table H.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 64														0.8406			
Europe																	
Baseline																	
Placebo	14	13	79.7	3.2	13 (100.0%)												
Nera 18mg	12	10	64.6	5.1	10 (100.0%)												
Week 6																	
Placebo		14	75.8	4.8	13 (100.0%)	-2.3	3.2	-8.5	4.0								
Nera 18mg		12	73.7	4.6	10 (100.0%)	3.5	3.6	-3.7	10.7	5.7	4.9	-3.8	15.3	0.2385			
Week 12																	
Placebo		14	84.3	3.5	13 (100.0%)	5.8	3.8	-1.7	13.4								
Nera 18mg		12	70.7	4.2	10 (100.0%)	2.5	4.4	-6.2	11.2	-3.3	5.9	-14.9	8.2	0.5693			
Week 18																	
Placebo		14	77.7	3.4	13 (100.0%)	-0.2	3.1	-6.4	6.1								
Nera 18mg		12	67.2	6.1	10 (100.0%)	-2.7	3.6	-9.9	4.5	-2.6	4.9	-12.2	7.0	0.5973			
Week 26																	
Placebo		12	69.3	5.4	12 (92.3%)	-8.0	4.1	-16.0	0.0								
Nera 18mg		11	67.7	7.7	9 (90.0%)	-4.3	4.7	-13.7	5.0	3.6	6.3	-8.8	16.1	0.5625			
Week 36																	
Placebo		14	74.1	3.2	13 (100.0%)	-4.3	3.6	-11.5	2.8								
Nera 18mg		11	68.3	8.4	9 (90.0%)	-3.6	4.3	-12.1	4.9	0.8	5.6	-10.4	11.9	0.8934			
Week 44																	
Placebo		14	70.9	4.8	13 (100.0%)	-7.8	3.9	-15.4	-0.1								
Nera 18mg		9	65.3	8.0	7 (70.0%)	-4.6	4.9	-14.3	5.1	3.2	6.3	-9.2	15.6	0.6126			
Week 52																	
Placebo		14	75.2	4.0	13 (100.0%)	-2.5	4.0	-10.4	5.3								
Nera 18mg		12	68.3	4.9	10 (100.0%)	-4.6	4.6	-13.8	4.5	-2.1	6.1	-14.2	10.0	0.7294			
Week 64																	
Placebo		13	76.6	3.6	12 (92.3%)	-0.6	3.9	-8.3	7.1								
Nera 18mg		11	72.7	5.7	9 (90.0%)	0.9	4.5	-8.1	9.9	1.5	6.0	-10.4	13.4	0.8061			
Week 76																	
Placebo		10	74.4	4.1	9 (69.2%)												
Nera 18mg		8	68.8	6.1	6 (60.0%)												
Week 88																	
Placebo		1	70.0	NC	1 (7.7%)												
Nera 18mg		2	54.5	35.5	2 (20.0%)												

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Table H.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
Asia																	
Baseline																	
Placebo	41	41	79.2	2.2	40 (100.0%)												
Nera 18mg	49	49	80.5	1.7	48 (100.0%)												
Week 6																	
Placebo		40	82.2	2.0	40 (100.0%)	4.8	1.8	1.2	8.3								
Nera 18mg		48	83.6	1.5	48 (100.0%)	5.0	1.7	1.7	8.3	0.2	2.4	-4.6	5.0	0.9235			
Week 12																	
Placebo		37	80.1	2.7	37 (92.5%)	2.2	2.2	-2.2	6.7								
Nera 18mg		48	80.5	2.3	48 (100.0%)	1.6	2.0	-2.4	5.6	-0.6	3.0	-6.5	5.2	0.8297			
Week 18																	
Placebo		36	80.9	1.9	36 (90.0%)	3.7	1.9	0.0	7.4								
Nera 18mg		47	82.6	1.8	47 (97.9%)	3.9	1.7	0.6	7.2	0.2	2.5	-4.7	5.1	0.9318			
Week 26																	
Placebo		35	79.1	2.4	35 (87.5%)	1.1	2.4	-3.6	5.8								
Nera 18mg		46	81.6	2.2	46 (95.8%)	2.2	2.1	-2.1	6.4	1.0	3.2	-5.2	7.3	0.7442			
Week 36																	
Placebo		33	80.5	2.5	33 (82.5%)	2.4	2.2	-1.9	6.8								
Nera 18mg		46	83.1	1.8	46 (95.8%)	3.9	1.9	0.1	7.8	1.5	2.9	-4.3	7.3	0.6092			
Week 44																	
Placebo		33	79.6	2.6	33 (82.5%)	1.7	2.4	-3.0	6.3								
Nera 18mg		45	81.0	1.9	45 (93.8%)	1.6	2.1	-2.6	5.7	-0.1	3.1	-6.3	6.1	0.9787			
Week 52																	
Placebo		32	79.3	2.8	32 (80.0%)	2.4	2.4	-2.4	7.2								
Nera 18mg		45	79.9	2.1	45 (93.8%)	1.1	2.1	-3.1	5.3	-1.3	3.2	-7.6	5.1	0.6909			
Week 64																	
Placebo		31	82.4	2.5	31 (77.5%)	3.8	2.4	-0.9	8.5								
Nera 18mg		44	82.0	2.2	44 (91.7%)	2.0	2.1	-2.2	6.1	-1.8	3.1	-8.0	4.4	0.5663			
Week 76																	
Placebo		24	79.8	3.1	24 (60.0%)												
Nera 18mg		34	78.7	2.3	34 (70.8%)												
Week 88																	
Placebo		4	87.5	2.5	4 (10.0%)												
Nera 18mg		6	74.2	7.1	6 (12.5%)												
Canada and USA																	
Baseline																	

Study: 1305-0014. 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, 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 H.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	13	13	69.5	5.4	12 (100.0%)												
Nera 18mg	14	14	76.5	4.3	14 (100.0%)												
Week 6																	
Placebo		12	76.9	4.1	12 (100.0%)	3.5	3.3	-3.0	10.0								
Nera 18mg		14	87.6	2.0	14 (100.0%)	11.4	3.0	5.4	17.4	7.9	4.5	-0.9	16.7	0.0796			
Week 12																	
Placebo		11	76.9	5.2	11 (91.7%)	2.6	4.1	-5.4	10.6								
Nera 18mg		12	82.8	3.1	12 (85.7%)	6.4	3.8	-1.2	14.0	3.8	5.6	-7.2	14.8	0.4954			
Week 18																	
Placebo		11	73.2	4.1	11 (91.7%)	0.5	3.4	-6.1	7.2								
Nera 18mg		12	82.3	3.4	12 (85.7%)	5.2	3.2	-1.1	11.5	4.6	4.7	-4.6	13.9	0.3205			
Week 26																	
Placebo		12	72.2	5.3	12 (100.0%)	-0.9	4.1	-9.1	7.3								
Nera 18mg		12	80.3	4.8	12 (85.7%)	2.9	4.1	-5.1	11.0	3.8	5.8	-7.6	15.3	0.5095			
Week 36																	
Placebo		10	78.7	3.6	10 (83.3%)	7.1	4.0	-0.7	15.0								
Nera 18mg		11	80.1	5.5	11 (78.6%)	3.7	3.8	-3.8	11.2	-3.4	5.5	-14.3	7.4	0.5352			
Week 44																	
Placebo		9	76.2	5.5	9 (75.0%)	5.3	4.4	-3.3	14.0								
Nera 18mg		12	80.0	5.1	12 (85.7%)	2.8	4.0	-5.0	10.6	-2.5	5.9	-14.2	9.2	0.6704			
Week 52																	
Placebo		9	71.9	6.3	9 (75.0%)	-1.0	4.5	-9.8	7.9								
Nera 18mg		10	86.8	2.4	10 (71.4%)	6.8	4.2	-1.5	15.1	7.7	6.2	-4.4	19.9	0.2108			
Week 64																	
Placebo		7	73.9	6.7	7 (58.3%)	2.3	4.7	-7.1	11.6								
Nera 18mg		10	84.9	3.2	10 (71.4%)	3.3	4.1	-4.9	11.4	1.0	6.3	-11.5	13.5	0.8721			
Week 76																	
Placebo		3	74.7	13.6	3 (25.0%)												
Nera 18mg		6	86.0	3.0	6 (42.9%)												
Week 88																	
Placebo		2	59.5	9.5	2 (16.7%)												
Nera 18mg		2	71.5	21.5	2 (14.3%)												
Rest of the World																	
Baseline																	
Placebo	19	18	65.5	4.6	18 (100.0%)												
Nera 18mg	12	12	69.6	4.7	12 (100.0%)												

Study: 1305-0014. 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, 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 H.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 6																	
Placebo		18	65.0	4.4	17 (94.4%)	-6.0	2.8	-11.5	-0.5								
Nera 18mg		12	75.0	4.7	12 (100.0%)	2.4	3.3	-4.1	8.9	8.5	4.3	0.1	16.9	0.0485	0.72	-0.02	1.46
Week 12																	
Placebo		19	64.6	5.0	18 (100.0%)	-5.0	3.3	-11.5	1.6								
Nera 18mg		12	71.7	3.6	12 (100.0%)	-0.6	4.0	-8.4	7.3	4.4	5.1	-5.6	14.5	0.3860			
Week 18																	
Placebo		19	68.0	3.6	18 (100.0%)	-2.8	2.7	-8.2	2.6								
Nera 18mg		12	73.3	3.6	12 (100.0%)	0.6	3.3	-5.9	7.1	3.4	4.2	-5.0	11.7	0.4248			
Week 26																	
Placebo		17	64.4	4.4	16 (88.9%)	-6.5	3.6	-13.6	0.6								
Nera 18mg		12	69.2	4.2	12 (100.0%)	-2.9	4.2	-11.2	5.3	3.6	5.4	-7.1	14.3	0.5105			
Week 36																	
Placebo		16	63.3	4.0	15 (83.3%)	-8.3	3.3	-14.9	-1.7								
Nera 18mg		11	70.5	4.7	11 (91.7%)	-1.2	3.9	-8.8	6.4	7.1	5.0	-2.9	17.0	0.1627			
Week 44																	
Placebo		16	62.5	4.1	15 (83.3%)	-8.9	3.6	-16.0	-1.8								
Nera 18mg		12	68.3	4.6	12 (100.0%)	-4.2	4.0	-12.2	3.8	4.7	5.3	-5.8	15.2	0.3750			
Week 52																	
Placebo		15	62.3	4.3	14 (77.8%)	-10.5	3.7	-17.8	-3.2								
Nera 18mg		11	69.7	3.9	11 (91.7%)	-3.4	4.2	-11.8	5.0	7.1	5.5	-3.9	18.1	0.2023			
Week 64																	
Placebo		16	63.1	4.7	15 (83.3%)	-5.8	3.5	-12.8	1.2								
Nera 18mg		11	66.8	6.9	11 (91.7%)	-4.7	4.1	-12.8	3.4	1.1	5.3	-9.4	11.7	0.8347			
Week 76																	
Placebo		4	60.3	4.5	4 (22.2%)												
Nera 18mg		6	78.8	5.2	6 (50.0%)												
Week 88																	
Placebo		0	NC	NC	0 (0.0%)												
Nera 18mg		0	NC	NC	0 (0.0%)												

Study: 1305-0014. 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, 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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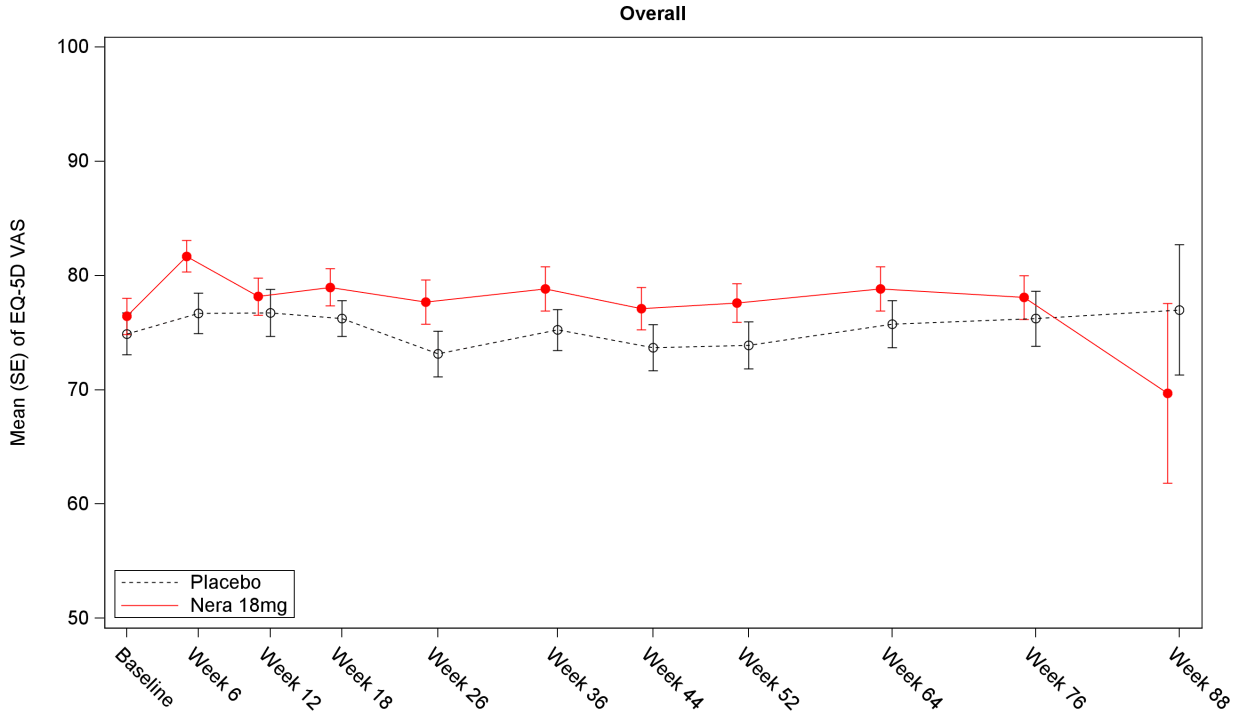

Number of patients

Placebo	85	84	81	80	76	73	72	70	67	41	7
Nera 18mg	85	86	84	83	81	79	78	78	76	54	10

Study: 1305-0014. Number of patients refers to the number of patients with observed data at visit.

Figure H.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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Figure H.1.2.1.2.1: 1

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H.1.2.2 Safety analysis

H.1.2.2.1 Safety analysis over the whole trial

H.1.2.2.1.1 Adverse events overall over the whole trial

Table H.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	87	87	100.0	87	81	93.1	0.0127	0.93 (0.88, 0.99)	0.00 (NC, NC)	-6.90 (-14.24, -1.28)	
Age											0.6715
<65 years	17	17	100.0	20	19	95.0	0.3500	0.95 (0.86, 1.05)	0.00 (NC, NC)	-5.00 (-23.61, 13.88)	
>=65 years	70	70	100.0	67	62	92.5	0.0199	0.93 (0.86, 0.99)	0.00 (NC, NC)	-7.46 (-16.31, -0.76)	
Sex											0.5485
Male	68	68	100.0	68	64	94.1	0.0423	0.94 (0.89, 1.00)	0.00 (NC, NC)	-5.88 (-14.17, 0.55)	
Female	19	19	100.0	19	17	89.5	0.1462	0.89 (0.77, 1.04)	0.00 (NC, NC)	-10.53 (-31.39, 7.93)	
Baseline FVC percent predicted											0.1414
<=70%	24	24	100.0	19	19	100.0	0.9100	0.99 (0.91, 1.09)	NC (NC, NC)	0.00 (NC, NC)	
>70%	63	63	100.0	68	62	91.2	0.0158	0.91 (0.85, 0.98)	0.00 (NC, NC)	-8.82 (-17.94, -1.39)	
Region											0.2631
Europe	14	14	100.0	12	12	100.0	0.9419	0.99 (0.86, 1.15)	NC (NC, NC)	0.00 (NC, NC)	
Asia	41	41	100.0	49	48	98.0	0.3576	0.98 (0.94, 1.02)	0.00 (NC, NC)	-2.04 (-10.69, 6.69)	
Canada and USA	13	13	100.0	14	11	78.6	0.0767	0.79 (0.60, 1.03)	0.00 (NC, NC)	-21.43 (-47.59, 5.26)	
Rest of the World	19	19	100.0	12	10	83.3	0.0658	0.83 (0.65, 1.07)	0.00 (NC, NC)	-16.67 (-44.80, 3.98)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	86	98.9	87	81	93.1	0.0537	0.94 (0.89, 1.00)	0.16 (0.02, 1.33)	-5.75 (-13.15, 0.53)	
Age											0.8518
<65 years	17	17	100.0	20	19	95.0	0.3500	0.95 (0.86, 1.05)	0.00 (NC, NC)	-5.00 (-23.61, 13.88)	
>=65 years	70	69	98.6	67	62	92.5	0.0845	0.94 (0.87, 1.01)	0.18 (0.02, 1.58)	-6.03 (-14.96, 1.50)	
Sex											0.9724
Male	68	68	100.0	68	64	94.1	0.0423	0.94 (0.89, 1.00)	0.00 (NC, NC)	-5.88 (-14.17, 0.55)	
Female	19	18	94.7	19	17	89.5	0.5475	0.94 (0.78, 1.14)	0.47 (0.04, 5.70)	-5.26 (-26.58, 15.55)	
Baseline FVC percent predicted											0.0177
<=70%	24	23	95.8	19	19	100.0	0.3680	1.04 (0.96, 1.13)	NC (NC, NC)	4.17 (-13.00, 20.24)	
>70%	63	63	100.0	68	62	91.2	0.0158	0.91 (0.85, 0.98)	0.00 (NC, NC)	-8.82 (-17.94, -1.39)	
Region											0.1974
Europe	14	14	100.0	12	12	100.0	0.9419	0.99 (0.86, 1.15)	NC (NC, NC)	0.00 (NC, NC)	
Asia	41	40	97.6	49	48	98.0	0.8984	1.00 (0.94, 1.07)	1.20 (0.07, 19.80)	0.40 (-8.48, 10.69)	
Canada and USA	13	13	100.0	14	11	78.6	0.0767	0.79 (0.60, 1.03)	0.00 (NC, NC)	-21.43 (-47.59, 5.26)	
Rest of the World	19	19	100.0	12	10	83.3	0.0658	0.83 (0.65, 1.07)	0.00 (NC, NC)	-16.67 (-44.80, 3.98)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	42	48.3	87	30	34.5	0.0647	0.71 (0.50, 1.03)	0.56 (0.31, 1.04)	-13.79 (-27.60, 0.81)	
Age											0.4087
<65 years	17	7	41.2	20	4	20.0	0.1602	0.49 (0.17, 1.38)	0.36 (0.08, 1.54)	-21.18 (-46.93, 7.97)	
>=65 years	70	35	50.0	67	26	38.8	0.1876	0.78 (0.53, 1.14)	0.63 (0.32, 1.25)	-11.19 (-26.87, 5.34)	
Sex											0.4336
Male	68	36	52.9	68	24	35.3	0.0382	0.67 (0.45, 0.99)	0.48 (0.24, 0.97)	-17.65 (-33.00, -0.98)	
Female	19	6	31.6	19	6	31.6	1.0000	1.00 (0.39, 2.55)	1.00 (0.25, 3.93)	0.00 (-27.66, 27.66)	
Baseline FVC percent predicted											0.8917
<=70%	24	15	62.5	19	9	47.4	0.3211	0.76 (0.43, 1.34)	0.54 (0.16, 1.83)	-15.13 (-40.99, 13.67)	
>70%	63	27	42.9	68	21	30.9	0.1552	0.72 (0.46, 1.14)	0.60 (0.29, 1.22)	-11.97 (-27.63, 4.44)	
Region											0.5430
Europe	14	6	42.9	12	3	25.0	0.3400	0.58 (0.18, 1.85)	0.44 (0.08, 2.39)	-17.86 (-47.22, 17.61)	
Asia	41	18	43.9	49	19	38.8	0.6225	0.88 (0.54, 1.45)	0.81 (0.35, 1.88)	-5.13 (-24.60, 14.67)	
Canada and USA	13	10	76.9	14	5	35.7	0.0313	0.46 (0.22, 1.00)	0.17 (0.03, 0.90)	-41.21 (-65.64, -3.93)	
Rest of the World	19	8	42.1	12	3	25.0	0.3323	0.59 (0.20, 1.81)	0.46 (0.09, 2.25)	-17.11 (-44.06, 16.90)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	41	47.1	87	29	33.3	0.0636	0.71 (0.49, 1.03)	0.56 (0.30, 1.04)	-13.79 (-27.55, 0.75)	
Age											0.4207
<65 years	17	7	41.2	20	4	20.0	0.1602	0.49 (0.17, 1.38)	0.36 (0.08, 1.54)	-21.18 (-46.93, 7.97)	
>=65 years	70	34	48.6	67	25	37.3	0.1834	0.77 (0.52, 1.14)	0.63 (0.32, 1.25)	-11.26 (-26.88, 5.22)	
Sex											0.7228
Male	68	35	51.5	68	24	35.3	0.0570	0.69 (0.46, 1.02)	0.51 (0.26, 1.02)	-16.18 (-31.59, 0.44)	
Female	19	6	31.6	19	5	26.3	0.7206	0.83 (0.31, 2.27)	0.77 (0.19, 3.16)	-5.26 (-31.96, 22.45)	
Baseline FVC percent predicted											0.6583
<=70%	24	14	58.3	19	9	47.4	0.4741	0.81 (0.45, 1.45)	0.64 (0.19, 2.16)	-10.96 (-37.37, 17.64)	
>70%	63	27	42.9	68	20	29.4	0.1089	0.69 (0.43, 1.09)	0.56 (0.27, 1.14)	-13.45 (-28.97, 2.93)	
Region											0.4028
Europe	14	5	35.7	12	3	25.0	0.5551	0.70 (0.21, 2.34)	0.60 (0.11, 3.30)	-10.71 (-40.89, 23.52)	
Asia	41	18	43.9	49	19	38.8	0.6225	0.88 (0.54, 1.45)	0.81 (0.35, 1.88)	-5.13 (-24.60, 14.67)	
Canada and USA	13	10	76.9	14	4	28.6	0.0120	0.37 (0.15, 0.90)	0.12 (0.02, 0.68)	-48.35 (-70.84, -10.69)	
Rest of the World	19	8	42.1	12	3	25.0	0.3323	0.59 (0.20, 1.81)	0.46 (0.09, 2.25)	-17.11 (-44.06, 16.90)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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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H.1.2.2.1.2 Adverse events by intensity over the whole trial

Table H.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: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	37	42.5	87	22	25.3	0.0163	0.59 (0.38, 0.92)	0.46 (0.24, 0.87)	-17.24 (-30.40, -3.17)	
Age											0.4600
<65 years	17	8	47.1	20	4	20.0	0.0797	0.43 (0.15, 1.17)	0.28 (0.07, 1.20)	-27.06 (-52.07, 2.99)	
>=65 years	70	29	41.4	67	18	26.9	0.0727	0.65 (0.40, 1.05)	0.52 (0.25, 1.07)	-14.56 (-29.40, 1.32)	
Sex											0.2887
Male	68	32	47.1	68	17	25.0	0.0074	0.53 (0.33, 0.86)	0.38 (0.18, 0.78)	-22.06 (-36.68, -5.92)	
Female	19	5	26.3	19	5	26.3	1.0000	1.00 (0.35, 2.90)	1.00 (0.24, 4.24)	0.00 (-26.75, 26.75)	
Baseline FVC percent predicted											0.8761
<=70%	24	15	62.5	19	7	36.8	0.0946	0.59 (0.30, 1.15)	0.35 (0.10, 1.22)	-25.66 (-49.74, 4.02)	
>70%	63	22	34.9	68	15	22.1	0.1023	0.63 (0.36, 1.11)	0.53 (0.24, 1.14)	-12.86 (-27.67, 2.55)	
Region											0.1755
Europe	14	6	42.9	12	2	16.7	0.1492	0.39 (0.10, 1.58)	0.27 (0.04, 1.70)	-26.19 (-53.51, 9.21)	
Asia	41	15	36.6	49	16	32.7	0.6958	0.89 (0.51, 1.58)	0.84 (0.35, 2.01)	-3.93 (-23.03, 15.15)	
Canada and USA	13	10	76.9	14	3	21.4	0.0039	0.28 (0.10, 0.79)	0.08 (0.01, 0.50)	-55.49 (-75.84, -17.77)	
Rest of the World	19	6	31.6	12	1	8.3	0.1316	0.26 (0.04, 1.93)	0.20 (0.02, 1.90)	-23.25 (-46.68, 8.30)	

Study: 1305-0014. 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 H.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: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	36	41.4	87	20	23.0	0.0094	0.56 (0.35, 0.88)	0.42 (0.22, 0.82)	-18.39 (-31.34, -4.50)	
Age											0.7728
<65 years	17	7	41.2	20	4	20.0	0.1602	0.49 (0.17, 1.38)	0.36 (0.08, 1.54)	-21.18 (-46.93, 7.97)	
>=65 years	70	29	41.4	67	16	23.9	0.0288	0.58 (0.35, 0.96)	0.44 (0.21, 0.93)	-17.55 (-32.07, -1.81)	
Sex											0.4937
Male	68	31	45.6	68	16	23.5	0.0068	0.52 (0.31, 0.85)	0.37 (0.18, 0.77)	-22.06 (-36.56, -6.07)	
Female	19	5	26.3	19	4	21.1	0.7028	0.80 (0.25, 2.53)	0.75 (0.17, 3.36)	-5.26 (-31.00, 21.33)	
Baseline FVC percent predicted											0.9522
<=70%	24	15	62.5	19	7	36.8	0.0946	0.59 (0.30, 1.15)	0.35 (0.10, 1.22)	-25.66 (-49.74, 4.02)	
>70%	63	21	33.3	68	13	19.1	0.0637	0.57 (0.31, 1.05)	0.47 (0.21, 1.05)	-14.22 (-28.67, 0.83)	
Region											0.0613
Europe	14	6	42.9	12	1	8.3	0.0479	0.19 (0.03, 1.40)	0.12 (0.01, 1.21)	-34.52 (-60.01, 0.02)	
Asia	41	14	34.1	49	16	32.7	0.8810	0.96 (0.53, 1.72)	0.94 (0.39, 2.25)	-1.49 (-20.60, 17.31)	
Canada and USA	13	10	76.9	14	2	14.3	0.0011	0.19 (0.05, 0.69)	0.05 (0.01, 0.36)	-62.64 (-80.74, -25.26)	
Rest of the World	19	6	31.6	12	1	8.3	0.1316	0.26 (0.04, 1.93)	0.20 (0.02, 1.90)	-23.25 (-46.68, 8.30)	

Study: 1305-0014. 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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H.1.2.2.1.3 Adverse events leading to treatment discontinuation over the whole trial

Table H.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	87	11	12.6	87	8	9.2	0.4659	0.73 (0.31, 1.72)	0.70 (0.27, 1.83)	-3.45 (-13.13, 6.15)	
Age											0.7442
<65 years	17	3	17.6	20	2	10.0	0.4977	0.57 (0.11, 3.01)	0.52 (0.08, 3.54)	-7.65 (-32.12, 15.49)	
>=65 years	70	8	11.4	67	6	9.0	0.6328	0.78 (0.29, 2.14)	0.76 (0.25, 2.33)	-2.47 (-13.14, 8.29)	
Sex											0.8060
Male	68	10	14.7	68	7	10.3	0.4367	0.70 (0.28, 1.73)	0.67 (0.24, 1.87)	-4.41 (-15.95, 7.08)	
Female	19	1	5.3	19	1	5.3	1.0000	1.00 (0.07, 14.85)	1.00 (0.06, 17.25)	0.00 (-19.85, 19.85)	
Baseline FVC percent predicted											0.3210
<=70%	24	4	16.7	19	4	21.1	0.7136	1.26 (0.36, 4.40)	1.33 (0.29, 6.21)	4.39 (-18.54, 28.80)	
>70%	63	7	11.1	68	4	5.9	0.2810	0.53 (0.16, 1.72)	0.50 (0.14, 1.80)	-5.23 (-15.94, 4.79)	
Region											0.9437
Europe	14	1	7.1	12	0	0.0	0.5283	0.38 (0.02, 8.65)	0.00 (NC, NC)	-7.14 (-31.47, 17.81)	
Asia	41	6	14.6	49	6	12.2	0.7398	0.84 (0.29, 2.40)	0.81 (0.24, 2.75)	-2.39 (-17.66, 11.90)	
Canada and USA	13	2	15.4	14	1	7.1	0.4959	0.46 (0.05, 4.53)	0.42 (0.03, 5.32)	-8.24 (-35.73, 18.48)	
Rest of the World	19	2	10.5	12	1	8.3	0.8406	0.79 (0.08, 7.81)	0.77 (0.06, 9.58)	-2.19 (-24.16, 25.91)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	11	12.6	87	8	9.2	0.4659	0.73 (0.31, 1.72)	0.70 (0.27, 1.83)	-3.45 (-13.13, 6.15)	
Age											0.7442
<65 years	17	3	17.6	20	2	10.0	0.4977	0.57 (0.11, 3.01)	0.52 (0.08, 3.54)	-7.65 (-32.12, 15.49)	
>=65 years	70	8	11.4	67	6	9.0	0.6328	0.78 (0.29, 2.14)	0.76 (0.25, 2.33)	-2.47 (-13.14, 8.29)	
Sex											0.8060
Male	68	10	14.7	68	7	10.3	0.4367	0.70 (0.28, 1.73)	0.67 (0.24, 1.87)	-4.41 (-15.95, 7.08)	
Female	19	1	5.3	19	1	5.3	1.0000	1.00 (0.07, 14.85)	1.00 (0.06, 17.25)	0.00 (-19.85, 19.85)	
Baseline FVC percent predicted											0.3210
<=70%	24	4	16.7	19	4	21.1	0.7136	1.26 (0.36, 4.40)	1.33 (0.29, 6.21)	4.39 (-18.54, 28.80)	
>70%	63	7	11.1	68	4	5.9	0.2810	0.53 (0.16, 1.72)	0.50 (0.14, 1.80)	-5.23 (-15.94, 4.79)	
Region											0.9437
Europe	14	1	7.1	12	0	0.0	0.5283	0.38 (0.02, 8.65)	0.00 (NC, NC)	-7.14 (-31.47, 17.81)	
Asia	41	6	14.6	49	6	12.2	0.7398	0.84 (0.29, 2.40)	0.81 (0.24, 2.75)	-2.39 (-17.66, 11.90)	
Canada and USA	13	2	15.4	14	1	7.1	0.4959	0.46 (0.05, 4.53)	0.42 (0.03, 5.32)	-8.24 (-35.73, 18.48)	
Rest of the World	19	2	10.5	12	1	8.3	0.8406	0.79 (0.08, 7.81)	0.77 (0.06, 9.58)	-2.19 (-24.16, 25.91)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	11	12.6	87	8	9.2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		3	3.4		3	3.4
Lung neoplasm malignant		0	0.0		2	2.3
Ductal adenocarcinoma of pancreas		1	1.1		0	0.0
Metastases to liver		1	1.1		0	0.0
Metastases to lung		1	1.1		0	0.0
Prostate cancer		0	0.0		1	1.1
Rectal cancer		1	1.1		0	0.0
Transitional cell carcinoma		1	1.1		0	0.0
Gastrointestinal disorders		1	1.1		1	1.1
Abdominal pain		1	1.1		0	0.0
Diarrhoea		0	0.0		1	1.1
Vomiting		0	0.0		1	1.1
General disorders and administration site conditions		1	1.1		1	1.1
Asthenia		0	0.0		1	1.1
Condition aggravated		1	1.1		0	0.0
Fatigue		0	0.0		1	1.1
Infections and infestations		2	2.3		0	0.0
Pneumonia		2	2.3		0	0.0
Metabolism and nutrition disorders		0	0.0		2	2.3
Decreased appetite		0	0.0		2	2.3
Respiratory, thoracic and mediastinal disorders		2	2.3		0	0.0
Idiopathic pulmonary fibrosis		1	1.1		0	0.0
Respiratory failure		1	1.1		0	0.0
Injury, poisoning and procedural complications		1	1.1		0	0.0
Fall		1	1.1		0	0.0
Investigations		0	0.0		1	1.1
Red blood cell sedimentation rate increased		0	0.0		1	1.1
Nervous system disorders		1	1.1		0	0.0
Syncope		1	1.1		0	0.0
Vascular disorders		0	0.0		1	1.1

Study: 1305-0014. 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 H.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			Nera 18mg		
	N	n	%	N	n	%
Vasculitis		0	0.0		1	1.1

Study: 1305-0014. 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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H.1.2.2.1.4 Adverse events on SOC level over the whole trial

Table H.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	87	10	11.5	87	11	12.6	0.8160	1.10 (0.49, 2.46)	1.11 (0.45, 2.78)	1.15 (-8.84, 11.16)	
Age											
<65 years	17	3	17.6	20	2	10.0					
>=65 years	70	7	10.0	67	9	13.4					
Sex											
Male	68	8	11.8	68	10	14.7					
Female	19	2	10.5	19	1	5.3					
Baseline FVC percent predicted											
<=70%	24	5	20.8	19	3	15.8					
>70%	63	5	7.9	68	8	11.8					
Region											
Europe	14	2	14.3	12	2	16.7					
Asia	41	4	9.8	49	7	14.3					
Canada and USA	13	2	15.4	14	2	14.3					
Rest of the World	19	2	10.5	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	27	31.0	87	39	44.8	0.0608	1.44 (0.98, 2.13)	1.81 (0.97, 3.36)	13.79 (-0.61, 27.42)	
Age											
<65 years	17	6	35.3	20	10	50.0					
>=65 years	70	21	30.0	67	29	43.3					
Sex											
Male	68	17	25.0	68	33	48.5					
Female	19	10	52.6	19	6	31.6					
Baseline FVC percent predicted											
<=70%	24	10	41.7	19	6	31.6					
>70%	63	17	27.0	68	33	48.5					
Region											
Europe	14	6	42.9	12	7	58.3					
Asia	41	13	31.7	49	24	49.0					
Canada and USA	13	5	38.5	14	6	42.9					
Rest of the World	19	3	15.8	12	2	16.7					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	28	32.2	87	29	33.3	0.8717	1.04 (0.68, 1.59)	1.05 (0.56, 1.98)	1.15 (-12.61, 14.85)	
Age											
<65 years	17	7	41.2	20	8	40.0					
>=65 years	70	21	30.0	67	21	31.3					
Sex											
Male	68	21	30.9	68	18	26.5					
Female	19	7	36.8	19	11	57.9					
Baseline FVC percent predicted											
<=70%	24	13	54.2	19	10	52.6					
>70%	63	15	23.8	68	19	27.9					
Region											
Europe	14	6	42.9	12	4	33.3					
Asia	41	12	29.3	49	17	34.7					
Canada and USA	13	5	38.5	14	5	35.7					
Rest of the World	19	5	26.3	12	3	25.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	50	57.5	87	56	64.4	0.3512	1.12 (0.88, 1.42)	1.34 (0.73, 2.46)	6.90 (-7.49, 20.89)	
Age											
<65 years	17	11	64.7	20	9	45.0					
>=65 years	70	39	55.7	67	47	70.1					
Sex											
Male	68	35	51.5	68	45	66.2					
Female	19	15	78.9	19	11	57.9					
Baseline FVC percent predicted											
<=70%	24	14	58.3	19	11	57.9					
>70%	63	36	57.1	68	45	66.2					
Region											
Europe	14	12	85.7	12	10	83.3					
Asia	41	20	48.8	49	30	61.2					
Canada and USA	13	7	53.8	14	9	64.3					
Rest of the World	19	11	57.9	12	7	58.3					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	10	11.5	87	12	13.8	0.6482	1.20 (0.55, 2.63)	1.23 (0.50, 3.02)	2.30 (-7.85, 12.47)	
Age											
<65 years	17	1	5.9	20	1	5.0					
>=65 years	70	9	12.9	67	11	16.4					
Sex											
Male	68	7	10.3	68	8	11.8					
Female	19	3	15.8	19	4	21.1					
Baseline FVC percent predicted											
<=70%	24	4	16.7	19	0	0.0					
>70%	63	6	9.5	68	12	17.6					
Region											
Europe	14	2	14.3	12	0	0.0					
Asia	41	5	12.2	49	9	18.4					
Canada and USA	13	1	7.7	14	3	21.4					
Rest of the World	19	2	10.5	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	16	18.4	87	19	21.8	0.5705	1.19 (0.66, 2.15)	1.24 (0.59, 2.61)	3.45 (-8.52, 15.32)	
Age											
<65 years	17	3	17.6	20	4	20.0					
>=65 years	70	13	18.6	67	15	22.4					
Sex											
Male	68	14	20.6	68	15	22.1					
Female	19	2	10.5	19	4	21.1					
Baseline FVC percent predicted											
<=70%	24	5	20.8	19	5	26.3					
>70%	63	11	17.5	68	14	20.6					
Region											
Europe	14	5	35.7	12	4	33.3					
Asia	41	7	17.1	49	13	26.5					
Canada and USA	13	2	15.4	14	1	7.1					
Rest of the World	19	2	10.5	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	9	10.3	87	17	19.5	0.0889	1.89 (0.89, 4.00)	2.10 (0.88, 5.02)	9.20 (-1.53, 19.88)	
Age											
<65 years	17	4	23.5	20	3	15.0					
>=65 years	70	5	7.1	67	14	20.9					
Sex											
Male	68	6	8.8	68	12	17.6					
Female	19	3	15.8	19	5	26.3					
Baseline FVC percent predicted											
<=70%	24	3	12.5	19	4	21.1					
>70%	63	6	9.5	68	13	19.1					
Region											
Europe	14	2	14.3	12	2	16.7					
Asia	41	3	7.3	49	12	24.5					
Canada and USA	13	2	15.4	14	3	21.4					
Rest of the World	19	2	10.5	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	19	21.8	87	17	19.5	0.7082	0.89 (0.50, 1.60)	0.87 (0.42, 1.81)	-2.30 (-14.30, 9.77)	
Age											
<65 years	17	3	17.6	20	4	20.0					
>=65 years	70	16	22.9	67	13	19.4					
Sex											
Male	68	17	25.0	68	13	19.1					
Female	19	2	10.5	19	4	21.1					
Baseline FVC percent predicted											
<=70%	24	6	25.0	19	3	15.8					
>70%	63	13	20.6	68	14	20.6					
Region											
Europe	14	5	35.7	12	3	25.0					
Asia	41	8	19.5	49	9	18.4					
Canada and USA	13	2	15.4	14	4	28.6					
Rest of the World	19	4	21.1	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	9	10.3	87	4	4.6	0.1494	0.44 (0.14, 1.39)	0.42 (0.12, 1.41)	-5.75 (-14.37, 2.45)	
Age											
<65 years	17	0	0.0	20	1	5.0					
>=65 years	70	9	12.9	67	3	4.5					
Sex											
Male	68	7	10.3	68	4	5.9					
Female	19	2	10.5	19	0	0.0					
Baseline FVC percent predicted											
<=70%	24	1	4.2	19	1	5.3					
>70%	63	8	12.7	68	3	4.4					
Region											
Europe	14	0	0.0	12	0	0.0					
Asia	41	4	9.8	49	2	4.1					
Canada and USA	13	4	30.8	14	1	7.1					
Rest of the World	19	1	5.3	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	20	23.0	87	14	16.1	0.2513	0.70 (0.38, 1.29)	0.64 (0.30, 1.37)	-6.90 (-18.58, 4.97)	
Age											
<65 years	17	6	35.3	20	2	10.0					
>=65 years	70	14	20.0	67	12	17.9					
Sex											
Male	68	14	20.6	68	10	14.7					
Female	19	6	31.6	19	4	21.1					
Baseline FVC percent predicted											
<=70%	24	6	25.0	19	3	15.8					
>70%	63	14	22.2	68	11	16.2					
Region											
Europe	14	5	35.7	12	2	16.7					
Asia	41	5	12.2	49	7	14.3					
Canada and USA	13	5	38.5	14	4	28.6					
Rest of the World	19	5	26.3	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	18	20.7	87	21	24.1	0.5855	1.17 (0.67, 2.03)	1.22 (0.60, 2.49)	3.45 (-8.95, 15.73)	
Age											
<65 years	17	5	29.4	20	6	30.0					
>=65 years	70	13	18.6	67	15	22.4					
Sex											
Male	68	13	19.1	68	15	22.1					
Female	19	5	26.3	19	6	31.6					
Baseline FVC percent predicted											
<=70%	24	3	12.5	19	5	26.3					
>70%	63	15	23.8	68	16	23.5					
Region											
Europe	14	3	21.4	12	5	41.7					
Asia	41	9	22.0	49	11	22.4					
Canada and USA	13	3	23.1	14	3	21.4					
Rest of the World	19	3	15.8	12	2	16.7					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	3	3.4	87	13	14.9	0.0087	4.33 (1.28, 14.67)	4.92 (1.35, 17.94)	11.49 (2.86, 20.74)	
Age											0.9455
<65 years	17	0	0.0	20	2	10.0	0.2863	4.29 (0.22, 83.57)	NC (NC, NC)	10.00 (-9.79, 30.10)	
>=65 years	70	3	4.3	67	11	16.4	0.0191	3.83 (1.12, 13.13)	4.39 (1.17, 16.50)	12.13 (1.82, 23.14)	
Sex											0.1572
Male	68	1	1.5	68	10	14.7	0.0046	10.00 (1.32, 75.99)	>10 (1.44, 92.97)	13.24 (4.10, 23.60)	
Female	19	2	10.5	19	3	15.8	0.6313	1.50 (0.28, 7.99)	1.59 (0.23, 10.82)	5.26 (-17.99, 28.32)	
Baseline FVC percent predicted											0.3809
<=70%	24	0	0.0	19	4	21.1	0.0297	>10 (0.64, >99)	NC (NC, NC)	21.05 (2.40, 43.33)	
>70%	63	3	4.8	68	9	13.2	0.0930	2.78 (0.79, 9.81)	3.05 (0.79, 11.83)	8.47 (-1.86, 18.99)	
Region											
Europe	14	0	0.0	12	3	25.0					
Asia	41	0	0.0	49	7	14.3					
Canada and USA	13	1	7.7	14	2	14.3					
Rest of the World	19	2	10.5	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	35	40.2	87	32	36.8	0.6402	0.91 (0.63, 1.33)	0.86 (0.47, 1.59)	-3.45 (-17.53, 10.83)	
Age											
<65 years	17	7	41.2	20	7	35.0					
>=65 years	70	28	40.0	67	25	37.3					
Sex											
Male	68	28	41.2	68	25	36.8					
Female	19	7	36.8	19	7	36.8					
Baseline FVC percent predicted											
<=70%	24	14	58.3	19	8	42.1					
>70%	63	21	33.3	68	24	35.3					
Region											
Europe	14	7	50.0	12	7	58.3					
Asia	41	14	34.1	49	15	30.6					
Canada and USA	13	8	61.5	14	8	57.1					
Rest of the World	19	6	31.6	12	2	16.7					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	16	18.4	87	13	14.9	0.5417	0.81 (0.42, 1.59)	0.78 (0.35, 1.74)	-3.45 (-14.61, 7.77)	
Age											
<65 years	17	5	29.4	20	3	15.0					
>=65 years	70	11	15.7	67	10	14.9					
Sex											
Male	68	11	16.2	68	11	16.2					
Female	19	5	26.3	19	2	10.5					
Baseline FVC percent predicted											
<=70%	24	3	12.5	19	0	0.0					
>70%	63	13	20.6	68	13	19.1					
Region											
Europe	14	5	35.7	12	4	33.3					
Asia	41	4	9.8	49	7	14.3					
Canada and USA	13	3	23.1	14	2	14.3					
Rest of the World	19	4	21.1	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	6	6.9	87	4	4.6	0.5148	0.67 (0.19, 2.28)	0.65 (0.18, 2.39)	-2.30 (-10.16, 5.30)	
Age											
<65 years	17	1	5.9	20	0	0.0					
>=65 years	70	5	7.1	67	4	6.0					
Sex											
Male	68	5	7.4	68	4	5.9					
Female	19	1	5.3	19	0	0.0					
Baseline FVC percent predicted											
<=70%	24	4	16.7	19	0	0.0					
>70%	63	2	3.2	68	4	5.9					
Region											
Europe	14	1	7.1	12	1	8.3					
Asia	41	2	4.9	49	2	4.1					
Canada and USA	13	2	15.4	14	1	7.1					
Rest of the World	19	1	5.3	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 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	87	9	10.3	87	8	9.2	0.7985	0.89 (0.36, 2.20)	0.88 (0.32, 2.39)	-1.15 (-10.45, 8.11)	
Age											
<65 years	17	2	11.8	20	2	10.0					
>=65 years	70	7	10.0	67	6	9.0					
Sex											
Male	68	7	10.3	68	5	7.4					
Female	19	2	10.5	19	3	15.8					
Baseline FVC percent predicted											
<=70%	24	6	25.0	19	2	10.5					
>70%	63	3	4.8	68	6	8.8					
Region											
Europe	14	4	28.6	12	1	8.3					
Asia	41	3	7.3	49	4	8.2					
Canada and USA	13	1	7.7	14	2	14.3					
Rest of the World	19	1	5.3	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	13	14.9	87	7	8.0	0.1538	0.54 (0.23, 1.28)	0.50 (0.19, 1.32)	-6.90 (-16.75, 2.82)	
Age											
<65 years	17	3	17.6	20	2	10.0					
>=65 years	70	10	14.3	67	5	7.5					
Sex											
Male	68	10	14.7	68	6	8.8					
Female	19	3	15.8	19	1	5.3					
Baseline FVC percent predicted											
<=70%	24	5	20.8	19	2	10.5					
>70%	63	8	12.7	68	5	7.4					
Region											
Europe	14	2	14.3	12	1	8.3					
Asia	41	9	22.0	49	5	10.2					
Canada and USA	13	0	0.0	14	1	7.1					
Rest of the World	19	2	10.5	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	9	10.3	87	4	4.6	0.1494	0.44 (0.14, 1.39)	0.42 (0.12, 1.41)	-5.75 (-14.37, 2.45)	
Age											
<65 years	17	0	0.0	20	1	5.0					
>=65 years	70	9	12.9	67	3	4.5					
Sex											
Male	68	7	10.3	68	4	5.9					
Female	19	2	10.5	19	0	0.0					
Baseline FVC percent predicted											
<=70%	24	1	4.2	19	1	5.3					
>70%	63	8	12.7	68	3	4.4					
Region											
Europe	14	0	0.0	12	0	0.0					
Asia	41	4	9.8	49	2	4.1					
Canada and USA	13	4	30.8	14	1	7.1					
Rest of the World	19	1	5.3	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	5	5.7	87	4	4.6	0.7321	0.80 (0.22, 2.88)	0.79 (0.20, 3.05)	-1.15 (-8.70, 6.25)	
Age											
<65 years	17	1	5.9	20	0	0.0					
>=65 years	70	4	5.7	67	4	6.0					
Sex											
Male	68	5	7.4	68	4	5.9					
Female	19	0	0.0	19	0	0.0					
Baseline FVC percent predicted											
<=70%	24	2	8.3	19	1	5.3					
>70%	63	3	4.8	68	3	4.4					
Region											
Europe	14	1	7.1	12	0	0.0					
Asia	41	1	2.4	49	3	6.1					
Canada and USA	13	2	15.4	14	1	7.1					
Rest of the World	19	1	5.3	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	16	18.4	87	10	11.5	0.2020	0.63 (0.30, 1.30)	0.58 (0.25, 1.35)	-6.90 (-17.62, 3.86)	
Age											
<65 years	17	3	17.6	20	3	15.0					
>=65 years	70	13	18.6	67	7	10.4					
Sex											
Male	68	14	20.6	68	8	11.8					
Female	19	2	10.5	19	2	10.5					
Baseline FVC percent predicted											
<=70%	24	8	33.3	19	3	15.8					
>70%	63	8	12.7	68	7	10.3					
Region											
Europe	14	1	7.1	12	1	8.3					
Asia	41	5	12.2	49	7	14.3					
Canada and USA	13	5	38.5	14	1	7.1					
Rest of the World	19	5	26.3	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	6	6.9	87	2	2.3	0.1476	0.33 (0.07, 1.61)	0.32 (0.06, 1.62)	-4.60	(-12.13, 2.20)	
Age												
<65 years	17	1	5.9	20	0	0.0						
>=65 years	70	5	7.1	67	2	3.0						
Sex												
Male	68	5	7.4	68	2	2.9						
Female	19	1	5.3	19	0	0.0						
Baseline FVC percent predicted												
<=70%	24	4	16.7	19	0	0.0						
>70%	63	2	3.2	68	2	2.9						
Region												
Europe	14	1	7.1	12	0	0.0						
Asia	41	2	4.9	49	1	2.0						
Canada and USA	13	2	15.4	14	1	7.1						
Rest of the World	19	1	5.3	12	0	0.0						

Study: 1305-0014. 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 H.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	87	11	12.6	87	8	9.2	0.4659	0.73 (0.31, 1.72)	0.70 (0.27, 1.83)	-3.45 (-13.13, 6.15)	
Age											
<65 years	17	2	11.8	20	2	10.0					
>=65 years	70	9	12.9	67	6	9.0					
Sex											
Male	68	9	13.2	68	5	7.4					
Female	19	2	10.5	19	3	15.8					
Baseline FVC percent predicted											
<=70%	24	7	29.2	19	1	5.3					
>70%	63	4	6.3	68	7	10.3					
Region											
Europe	14	4	28.6	12	1	8.3					
Asia	41	4	9.8	49	5	10.2					
Canada and USA	13	1	7.7	14	2	14.3					
Rest of the World	19	2	10.5	12	0	0.0					

Study: 1305-0014. 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 H.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	87	11	12.6	87	6	6.9	0.2017	0.55 (0.21, 1.41)	0.51 (0.18, 1.45)	-5.75 (-15.10, 3.39)	
Age											
<65 years	17	3	17.6	20	2	10.0					
>=65 years	70	8	11.4	67	4	6.0					
Sex											
Male	68	8	11.8	68	6	8.8					
Female	19	3	15.8	19	0	0.0					
Baseline FVC percent predicted											
<=70%	24	4	16.7	19	2	10.5					
>70%	63	7	11.1	68	4	5.9					
Region											
Europe	14	2	14.3	12	0	0.0					
Asia	41	8	19.5	49	5	10.2					
Canada and USA	13	0	0.0	14	1	7.1					
Rest of the World	19	1	5.3	12	0	0.0					

Study: 1305-0014. 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 H.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: 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	87	6	6.9	87	2	2.3	0.1476	0.33 (0.07, 1.61)	0.32 (0.06, 1.62)	-4.60 (-12.13, 2.20)	
Age											
<65 years	17	0	0.0	20	1	5.0					
>=65 years	70	6	8.6	67	1	1.5					
Sex											
Male	68	5	7.4	68	2	2.9					
Female	19	1	5.3	19	0	0.0					
Baseline FVC percent predicted											
<=70%	24	1	4.2	19	1	5.3					
>70%	63	5	7.9	68	1	1.5					
Region											
Europe	14	0	0.0	12	0	0.0					
Asia	41	3	7.3	49	2	4.1					
Canada and USA	13	3	23.1	14	0	0.0					
Rest of the World	19	0	0.0	12	0	0.0					

Study: 1305-0014. 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 H.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 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	87	14	16.1	87	9	10.3	0.2631	0.64 (0.29, 1.41)	0.60 (0.25, 1.47)	-5.75 (-16.06, 4.54)	
Age											
<65 years	17	1	5.9	20	2	10.0					
>=65 years	70	13	18.6	67	7	10.4					
Sex											
Male	68	11	16.2	68	7	10.3					
Female	19	3	15.8	19	2	10.5					
Baseline FVC percent predicted											
<=70%	24	10	41.7	19	3	15.8					
>70%	63	4	6.3	68	6	8.8					
Region											
Europe	14	2	14.3	12	1	8.3					
Asia	41	3	7.3	49	6	12.2					
Canada and USA	13	5	38.5	14	1	7.1					
Rest of the World	19	4	21.1	12	1	8.3					

Study: 1305-0014. 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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H.1.2.2.1.5 Adverse events on PT level over the whole trial

Table H.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	87	7	8.0	87	24	27.6	0.0008	3.43 (1.56, 7.54)	4.35 (1.76, 10.76)	19.54 (8.26, 30.52)	
Age											0.5291
<65 years	17	1	5.9	20	7	35.0	0.0320	5.95 (0.81, 43.66)	8.62 (0.94, 79.28)	29.12 (2.10, 51.36)	
>=65 years	70	6	8.6	67	17	25.4	0.0085	2.96 (1.24, 7.05)	3.63 (1.33, 9.87)	16.80 (4.23, 29.23)	
Sex											0.8745
Male	68	6	8.8	68	20	29.4	0.0023	3.33 (1.43, 7.78)	4.31 (1.60, 11.55)	20.59 (7.42, 33.20)	
Female	19	1	5.3	19	4	21.1	0.1500	4.00 (0.49, 32.57)	4.80 (0.48, 47.68)	15.79 (-7.29, 38.49)	
Baseline FVC percent predicted											0.6821
<=70%	24	2	8.3	19	4	21.1	0.2319	2.53 (0.52, 12.35)	2.93 (0.48, 18.10)	12.72 (-8.83, 35.80)	
>70%	63	5	7.9	68	20	29.4	0.0018	3.71 (1.48, 9.28)	4.83 (1.69, 13.84)	21.48 (8.16, 34.01)	
Region											0.8303
Europe	14	1	7.1	12	5	41.7	0.0373	5.83 (0.79, 43.27)	9.29 (0.90, 95.95)	34.52 (1.50, 61.55)	
Asia	41	3	7.3	49	13	26.5	0.0176	3.63 (1.11, 11.86)	4.57 (1.20, 17.39)	19.21 (3.30, 33.76)	
Canada and USA	13	2	15.4	14	4	28.6	0.4102	1.86 (0.41, 8.49)	2.20 (0.33, 14.73)	13.19 (-18.51, 41.51)	
Rest of the World	19	1	5.3	12	2	16.7	0.2955	3.17 (0.32, 31.24)	3.60 (0.29, 44.83)	11.40 (-11.37, 39.87)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	14	16.1	87	11	12.6	0.5167	0.79 (0.38, 1.63)	0.75 (0.32, 1.77)	-3.45 (-14.07, 7.18)	
Age											
<65 years	17	3	17.6	20	2	10.0					
>=65 years	70	11	15.7	67	9	13.4					
Sex											
Male	68	10	14.7	68	6	8.8					
Female	19	4	21.1	19	5	26.3					
Baseline FVC percent predicted											
<=70%	24	9	37.5	19	3	15.8					
>70%	63	5	7.9	68	8	11.8					
Region											
Europe	14	4	28.6	12	1	8.3					
Asia	41	6	14.6	49	7	14.3					
Canada and USA	13	2	15.4	14	3	21.4					
Rest of the World	19	2	10.5	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	9	10.3	87	5	5.7	0.2649	0.56 (0.19, 1.59)	0.53 (0.17, 1.65)	-4.60 (-13.39, 3.90)	
Age											
<65 years	17	2	11.8	20	1	5.0					
>=65 years	70	7	10.0	67	4	6.0					
Sex											
Male	68	5	7.4	68	3	4.4					
Female	19	4	21.1	19	2	10.5					
Baseline FVC percent predicted											
<=70%	24	4	16.7	19	0	0.0					
>70%	63	5	7.9	68	5	7.4					
Region											
Europe	14	4	28.6	12	4	33.3					
Asia	41	1	2.4	49	0	0.0					
Canada and USA	13	0	0.0	14	0	0.0					
Rest of the World	19	4	21.1	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	6	6.9	87	17	19.5	0.0138	2.83 (1.17, 6.84)	3.28 (1.23, 8.77)	12.64 (2.52, 22.88)	
Age											0.6317
<65 years	17	1	5.9	20	2	10.0	0.6475	1.70 (0.17, 17.16)	1.78 (0.15, 21.51)	4.12 (-18.18, 24.79)	
>=65 years	70	5	7.1	67	15	22.4	0.0115	3.13 (1.21, 8.15)	3.75 (1.28, 11.00)	15.25 (3.34, 27.27)	
Sex											0.1084
Male	68	4	5.9	68	16	23.5	0.0037	4.00 (1.41, 11.35)	4.92 (1.55, 15.63)	17.65 (5.78, 29.52)	
Female	19	2	10.5	19	1	5.3	0.5475	0.50 (0.05, 5.06)	0.47 (0.04, 5.70)	-5.26 (-26.58, 15.55)	
Baseline FVC percent predicted											0.8572
<=70%	24	2	8.3	19	4	21.1	0.2319	2.53 (0.52, 12.35)	2.93 (0.48, 18.10)	12.72 (-8.83, 35.80)	
>70%	63	4	6.3	68	13	19.1	0.0298	3.01 (1.04, 8.75)	3.49 (1.07, 11.34)	12.77 (1.09, 24.32)	
Region											
Europe	14	1	7.1	12	4	33.3					
Asia	41	1	2.4	49	8	16.3					
Canada and USA	13	1	7.7	14	5	35.7					
Rest of the World	19	3	15.8	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	12	13.8	87	10	11.5	0.6482	0.83 (0.38, 1.83)	0.81 (0.33, 1.99)	-2.30 (-12.47, 7.85)	
Age											
<65 years	17	3	17.6	20	1	5.0					
>=65 years	70	9	12.9	67	9	13.4					
Sex											
Male	68	9	13.2	68	8	11.8					
Female	19	3	15.8	19	2	10.5					
Baseline FVC percent predicted											
<=70%	24	2	8.3	19	2	10.5					
>70%	63	10	15.9	68	8	11.8					
Region											
Europe	14	2	14.3	12	2	16.7					
Asia	41	6	14.6	49	6	12.2					
Canada and USA	13	1	7.7	14	1	7.1					
Rest of the World	19	3	15.8	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	8	9.2	87	15	17.2	0.1172	1.88 (0.84, 4.19)	2.06 (0.82, 5.14)	8.05 (-2.20, 18.34)	
Age											
<65 years	17	2	11.8	20	3	15.0					
>=65 years	70	6	8.6	67	12	17.9					
Sex											
Male	68	7	10.3	68	13	19.1					
Female	19	1	5.3	19	2	10.5					
Baseline FVC percent predicted											
<=70%	24	2	8.3	19	4	21.1					
>70%	63	6	9.5	68	11	16.2					
Region											
Europe	14	0	0.0	12	0	0.0					
Asia	41	5	12.2	49	12	24.5					
Canada and USA	13	1	7.7	14	2	14.3					
Rest of the World	19	2	10.5	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	7	8.0	87	9	10.3	0.5998	1.29 (0.50, 3.30)	1.32 (0.47, 3.72)	2.30 (-6.73, 11.43)	
Age											
<65 years	17	1	5.9	20	3	15.0					
>=65 years	70	6	8.6	67	6	9.0					
Sex											
Male	68	5	7.4	68	5	7.4					
Female	19	2	10.5	19	4	21.1					
Baseline FVC percent predicted											
<=70%	24	2	8.3	19	2	10.5					
>70%	63	5	7.9	68	7	10.3					
Region											
Europe	14	1	7.1	12	4	33.3					
Asia	41	3	7.3	49	4	8.2					
Canada and USA	13	1	7.7	14	0	0.0					
Rest of the World	19	2	10.5	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	5	5.7	87	10	11.5	0.1768	2.00 (0.71, 5.61)	2.13 (0.70, 6.51)	5.75 (-2.94, 14.75)	
Age											
<65 years	17	1	5.9	20	1	5.0					
>=65 years	70	4	5.7	67	9	13.4					
Sex											
Male	68	3	4.4	68	8	11.8					
Female	19	2	10.5	19	2	10.5					
Baseline FVC percent predicted											
<=70%	24	0	0.0	19	2	10.5					
>70%	63	5	7.9	68	8	11.8					
Region											
Europe	14	3	21.4	12	4	33.3					
Asia	41	1	2.4	49	3	6.1					
Canada and USA	13	1	7.7	14	3	21.4					
Rest of the World	19	0	0.0	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	13	14.9	87	9	10.3	0.3615	0.69 (0.31, 1.53)	0.66 (0.27, 1.63)	-4.60 (-14.77, 5.53)	
Age											
<65 years	17	2	11.8	20	1	5.0					
>=65 years	70	11	15.7	67	8	11.9					
Sex											
Male	68	12	17.6	68	7	10.3					
Female	19	1	5.3	19	2	10.5					
Baseline FVC percent predicted											
<=70%	24	6	25.0	19	0	0.0					
>70%	63	7	11.1	68	9	13.2					
Region											
Europe	14	4	28.6	12	3	25.0					
Asia	41	2	4.9	49	4	8.2					
Canada and USA	13	5	38.5	14	2	14.3					
Rest of the World	19	2	10.5	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	7	8.0	87	6	6.9	0.7731	0.86 (0.30, 2.45)	0.85 (0.27, 2.63)	-1.15 (-9.64, 7.26)	
Age											
<65 years	17	2	11.8	20	2	10.0					
>=65 years	70	5	7.1	67	4	6.0					
Sex											
Male	68	5	7.4	68	4	5.9					
Female	19	2	10.5	19	2	10.5					
Baseline FVC percent predicted											
<=70%	24	5	20.8	19	1	5.3					
>70%	63	2	3.2	68	5	7.4					
Region											
Europe	14	3	21.4	12	1	8.3					
Asia	41	3	7.3	49	4	8.2					
Canada and USA	13	1	7.7	14	1	7.1					
Rest of the World	19	0	0.0	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	6	6.9	87	3	3.4	0.3045	0.50 (0.13, 1.94)	0.48 (0.12, 1.99)	-3.45 (-11.13, 3.78)	
Age											
<65 years	17	1	5.9	20	1	5.0					
>=65 years	70	5	7.1	67	2	3.0					
Sex											
Male	68	5	7.4	68	2	2.9					
Female	19	1	5.3	19	1	5.3					
Baseline FVC percent predicted											
<=70%	24	2	8.3	19	2	10.5					
>70%	63	4	6.3	68	1	1.5					
Region											
Europe	14	0	0.0	12	0	0.0					
Asia	41	5	12.2	49	3	6.1					
Canada and USA	13	0	0.0	14	0	0.0					
Rest of the World	19	1	5.3	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	8	9.2	87	7	8.0	0.7871	0.88 (0.33, 2.31)	0.86 (0.30, 2.50)	-1.15 (-10.06, 7.70)	
Age											
<65 years	17	2	11.8	20	2	10.0					
>=65 years	70	6	8.6	67	5	7.5					
Sex											
Male	68	6	8.8	68	4	5.9					
Female	19	2	10.5	19	3	15.8					
Baseline FVC percent predicted											
<=70%	24	5	20.8	19	1	5.3					
>70%	63	3	4.8	68	6	8.8					
Region											
Europe	14	3	21.4	12	1	8.3					
Asia	41	4	9.8	49	5	10.2					
Canada and USA	13	1	7.7	14	1	7.1					
Rest of the World	19	0	0.0	12	0	0.0					

Study: 1305-0014. 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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H.1.2.3 Further analysis

H.1.2.3.1 Further safety analysis

Table H.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	87	2	2.3	87	2	2.3	1.0000	1.00 (0.14, 6.94)	1.00 (0.14, 7.26)	0.00 (-5.94, 5.94)	
Age											
<65 years	17	0	0.0	20	0	0.0					
>=65 years	70	2	2.9	67	2	3.0					
Sex											
Male	68	1	1.5	68	2	2.9					
Female	19	1	5.3	19	0	0.0					
Baseline FVC percent predicted											
<=70%	24	0	0.0	19	0	0.0					
>70%	63	2	3.2	68	2	2.9					
Region											
Europe	14	1	7.1	12	2	16.7					
Asia	41	1	2.4	49	0	0.0					
Canada and USA	13	0	0.0	14	0	0.0					
Rest of the World	19	0	0.0	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	7	8.0	87	24	27.6	0.0008	3.43 (1.56, 7.54)	4.35 (1.76, 10.76)	19.54 (8.26, 30.52)	
Age											0.5291
<65 years	17	1	5.9	20	7	35.0	0.0320	5.95 (0.81, 43.66)	8.62 (0.94, 79.28)	29.12 (2.10, 51.36)	
>=65 years	70	6	8.6	67	17	25.4	0.0085	2.96 (1.24, 7.05)	3.63 (1.33, 9.87)	16.80 (4.23, 29.23)	
Sex											0.8745
Male	68	6	8.8	68	20	29.4	0.0023	3.33 (1.43, 7.78)	4.31 (1.60, 11.55)	20.59 (7.42, 33.20)	
Female	19	1	5.3	19	4	21.1	0.1500	4.00 (0.49, 32.57)	4.80 (0.48, 47.68)	15.79 (-7.29, 38.49)	
Baseline FVC percent predicted											0.6821
<=70%	24	2	8.3	19	4	21.1	0.2319	2.53 (0.52, 12.35)	2.93 (0.48, 18.10)	12.72 (-8.83, 35.80)	
>70%	63	5	7.9	68	20	29.4	0.0018	3.71 (1.48, 9.28)	4.83 (1.69, 13.84)	21.48 (8.16, 34.01)	
Region											0.8303
Europe	14	1	7.1	12	5	41.7	0.0373	5.83 (0.79, 43.27)	9.29 (0.90, 95.95)	34.52 (1.50, 61.55)	
Asia	41	3	7.3	49	13	26.5	0.0176	3.63 (1.11, 11.86)	4.57 (1.20, 17.39)	19.21 (3.30, 33.76)	
Canada and USA	13	2	15.4	14	4	28.6	0.4102	1.86 (0.41, 8.49)	2.20 (0.33, 14.73)	13.19 (-18.51, 41.51)	
Rest of the World	19	1	5.3	12	2	16.7	0.2955	3.17 (0.32, 31.24)	3.60 (0.29, 44.83)	11.40 (-11.37, 39.87)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	3	3.4	87	4	4.6	0.6996	1.33 (0.31, 5.78)	1.35 (0.29, 6.22)	1.15 (-5.66, 8.16)	
Age											
<65 years	17	0	0.0	20	0	0.0					
>=65 years	70	3	4.3	67	4	6.0					
Sex											
Male	68	2	2.9	68	3	4.4					
Female	19	1	5.3	19	1	5.3					
Baseline FVC percent predicted											
<=70%	24	2	8.3	19	1	5.3					
>70%	63	1	1.6	68	3	4.4					
Region											
Europe	14	1	7.1	12	1	8.3					
Asia	41	0	0.0	49	1	2.0					
Canada and USA	13	2	15.4	14	2	14.3					
Rest of the World	19	0	0.0	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	2	2.3	87	4	4.6	0.4060	2.00 (0.38, 10.64)	2.05 (0.37, 11.49)	2.30 (-4.05, 9.14)	
Age											
<65 years	17	1	5.9	20	0	0.0					
>=65 years	70	1	1.4	67	4	6.0					
Sex											
Male	68	1	1.5	68	3	4.4					
Female	19	1	5.3	19	1	5.3					
Baseline FVC percent predicted											
<=70%	24	0	0.0	19	1	5.3					
>70%	63	2	3.2	68	3	4.4					
Region											
Europe	14	0	0.0	12	0	0.0					
Asia	41	1	2.4	49	1	2.0					
Canada and USA	13	1	7.7	14	3	21.4					
Rest of the World	19	0	0.0	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	27	31.0	87	39	44.8	0.0608	1.44 (0.98, 2.13)	1.81 (0.97, 3.36)	13.79 (-0.61, 27.42)	
Age											0.9683
<65 years	17	6	35.3	20	10	50.0	0.3682	1.42 (0.65, 3.09)	1.83 (0.49, 6.90)	14.71 (-16.13, 41.65)	
>=65 years	70	21	30.0	67	29	43.3	0.1064	1.44 (0.92, 2.26)	1.78 (0.88, 3.60)	13.28 (-2.79, 28.49)	
Sex											0.0125
Male	68	17	25.0	68	33	48.5	0.0044	1.94 (1.20, 3.13)	2.83 (1.37, 5.85)	23.53 (7.32, 38.10)	
Female	19	10	52.6	19	6	31.6	0.1888	0.60 (0.27, 1.32)	0.42 (0.11, 1.56)	-21.05 (-46.83, 9.61)	
Baseline FVC percent predicted											0.0721
<=70%	24	10	41.7	19	6	31.6	0.4967	0.76 (0.34, 1.71)	0.65 (0.18, 2.28)	-10.09 (-35.45, 18.16)	
>70%	63	17	27.0	68	33	48.5	0.0112	1.80 (1.12, 2.89)	2.55 (1.23, 5.30)	21.55 (4.91, 36.50)	
Region											0.9220
Europe	14	6	42.9	12	7	58.3	0.4314	1.36 (0.63, 2.94)	1.87 (0.39, 8.89)	15.48 (-20.56, 46.47)	
Asia	41	13	31.7	49	24	49.0	0.0972	1.54 (0.91, 2.63)	2.07 (0.87, 4.91)	17.27 (-3.05, 35.47)	
Canada and USA	13	5	38.5	14	6	42.9	0.8163	1.11 (0.45, 2.78)	1.20 (0.26, 5.59)	4.40 (-29.34, 36.54)	
Rest of the World	19	3	15.8	12	2	16.7	0.9484	1.06 (0.21, 5.42)	1.07 (0.15, 7.54)	0.88 (-23.97, 30.83)	

Study: 1305-0014. MedDRA version: 27.1
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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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H.1.2.3.2 Time to event analyses: treatment policy approach to lung transplant

Table H.1.2.3.2: 1 Cox model for time to first confirmed acute IPF 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	87	17 (8/ 9)	19.5	15.53	87	10 (8/ 2)	11.5	8.72	0.64 (0.29, 1.45)	0.2867	
Age											0.4183
<65 years	17	4 (2/ 2)	23.5	19.13	20	2 (2/ 0)	10.0	7.31	0.35 (0.06, 1.98)	0.2339	
>=65 years	70	13 (6/ 7)	18.6	14.68	67	8 (6/ 2)	11.9	9.17	0.78 (0.31, 1.94)	0.5899	
Sex											0.4959
Male	68	15 (6/ 9)	22.1	17.70	68	7 (5/ 2)	10.3	7.79	0.57 (0.22, 1.43)	0.2291	
Female	19	2 (2/ 0)	10.5	8.10	19	3 (3/ 0)	15.8	12.12	1.14 (0.19, 6.91)	0.8867	
Baseline FVC percent predicted											0.2897
<=70%	24	10 (6/ 4)	41.7	38.78	19	4 (2/ 2)	21.1	17.69	0.35 (0.10, 1.27)	0.1092	
>70%	63	7 (2/ 5)	11.1	8.36	68	6 (6/ 0)	8.8	6.52	0.86 (0.29, 2.56)	0.7831	
Region											0.9725
Europe	14	2 (1/ 1)	14.3	10.59	12	1 (1/ 0)	8.3	6.31	1.28 (0.11, 14.61)	0.8429	
Asia	41	7 (4/ 3)	17.1	13.31	49	6 (5/ 1)	12.2	8.87	0.70 (0.23, 2.10)	0.5205	
Canada and USA	13	5 (1/ 4)	38.5	33.81	14	3 (2/ 1)	21.4	20.04	0.91 (0.21, 3.95)	0.9010	
Rest of the World	19	3 (2/ 1)	15.8	12.92	12	0 (0/ 0)	0.0	0.00	0.00 (NC, NC)	0.9883	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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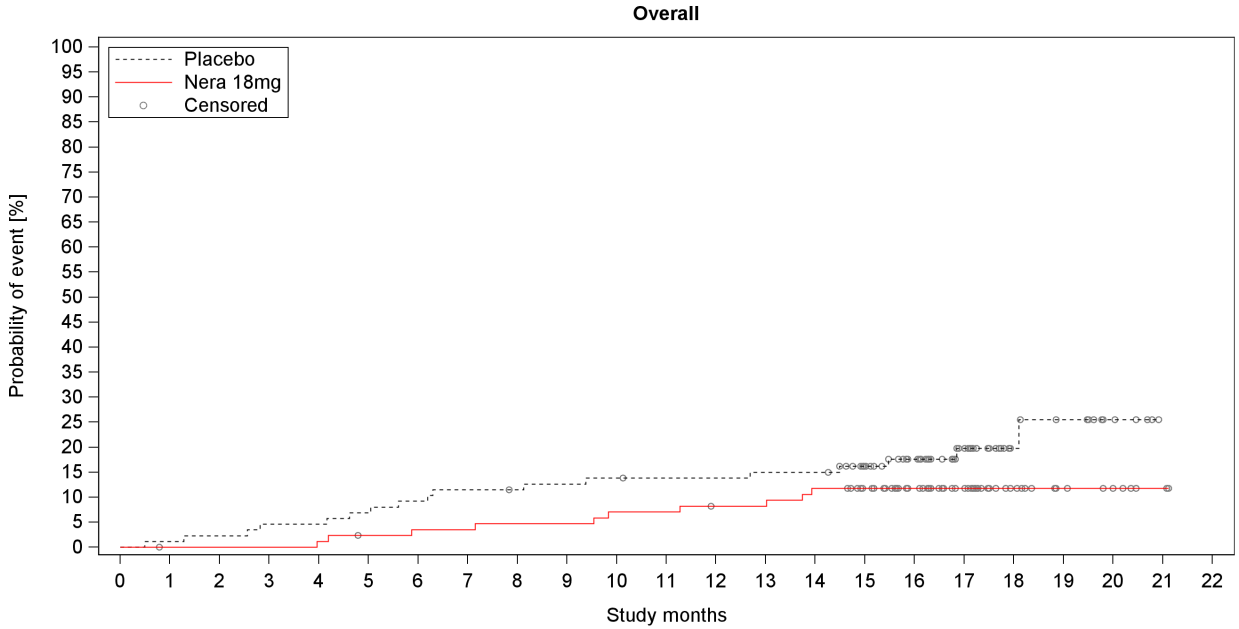

Number at risk (percentage relative to baseline)

Placebo	87	86	85	83	83	81	79	77	76	75	74	73	73	72	72	64	51	35	14	10	5	0	0
%	100.0	98.9	97.7	95.4	95.4	93.1	90.8	88.5	87.4	86.2	85.1	83.9	83.9	82.8	82.8	73.6	58.6	40.2	16.1	11.5	5.7	0.0	0.0
Nera 18mg	87	86	86	86	85	83	82	82	81	81	79	79	77	77	74	67	53	40	17	9	7	2	0
%	100.0	98.9	98.9	98.9	97.7	95.4	94.3	94.3	93.1	93.1	90.8	90.8	88.5	88.5	85.1	77.0	60.9	46.0	19.5	10.3	8.0	2.3	0.0

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

Placebo	0	0	0	0	0	0	0	0	1	1	1	2	2	2	2	9	21	36	57	60	65	70	70
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	2.3	2.3	2.3	2.3	10.3	24.1	41.4	65.5	69.0	74.7	80.5	80.5
Nera 18mg	0	1	1	1	1	2	2	2	2	2	2	2	3	3	3	10	24	37	60	68	70	75	77
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	2.3	2.3	3.4	3.4	3.4	11.5	27.6	42.5	69.0	78.2	80.5	86.2	88.5

Study: 1305-0014

Figure H.1.2.3.2: 1 Time to first confirmed acute IPF 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 H.1.2.3.2: 2 Cox model for time to first confirmed or suspected acute IPF 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	87	21 (12/ 9)	24.1	19.70	87	12 (11/ 1)	13.8	10.67	0.63 (0.30, 1.32)	0.2231	
Age											0.4741
<65 years	17	4 (2/ 2)	23.5	19.13	20	2 (2/ 0)	10.0	7.31	0.36 (0.06, 2.03)	0.2476	
>=65 years	70	17 (10/ 7)	24.3	19.84	67	10 (9/ 1)	14.9	11.75	0.72 (0.32, 1.61)	0.4257	
Sex											0.5336
Male	68	17 (8/ 9)	25.0	20.34	68	7 (6/ 1)	10.3	7.85	0.53 (0.22, 1.31)	0.1711	
Female	19	4 (4/ 0)	21.1	17.37	19	5 (5/ 0)	26.3	21.43	0.89 (0.23, 3.40)	0.8625	
Baseline FVC percent predicted											0.0972
<=70%	24	13 (9/ 4)	54.2	56.22	19	4 (3/ 1)	21.1	18.32	0.29 (0.09, 0.95)	0.0411	
>70%	63	8 (3/ 5)	12.7	9.58	68	8 (8/ 0)	11.8	8.83	1.05 (0.39, 2.81)	0.9235	
Region											0.7937
Europe	14	4 (3/ 1)	28.6	22.61	12	1 (1/ 0)	8.3	6.31	0.59 (0.06, 5.46)	0.6426	
Asia	41	8 (5/ 3)	19.5	15.44	49	8 (7/ 1)	16.3	12.05	0.79 (0.29, 2.14)	0.6422	
Canada and USA	13	6 (2/ 4)	46.2	43.30	14	3 (3/ 0)	21.4	21.36	1.76 (0.42, 7.41)	0.4396	
Rest of the World	19	3 (2/ 1)	15.8	12.92	12	0 (0/ 0)	0.0	0.00	0.00 (NC, NC)	0.9913	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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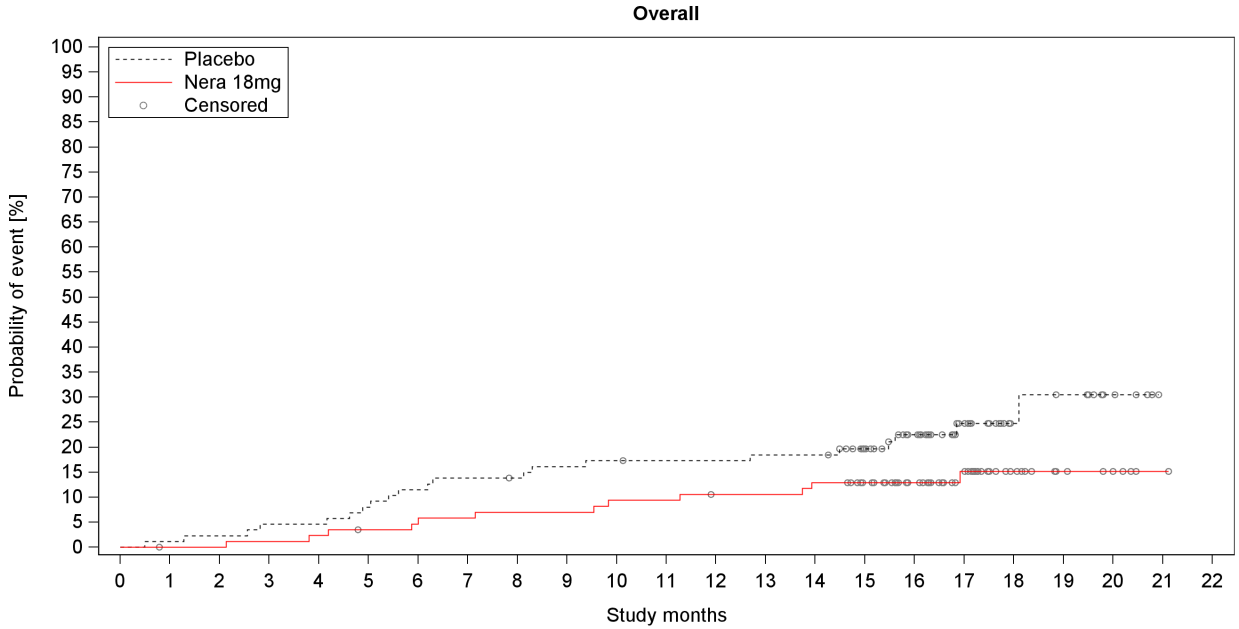

Number at risk (percentage relative to baseline)

Placebo	87	86	85	83	83	80	77	75	74	72	71	70	70	69	69	61	47	32	13	10	5	0	0
%	100.0	98.9	97.7	95.4	95.4	92.0	88.5	86.2	85.1	82.8	81.6	80.5	80.5	79.3	79.3	70.1	54.0	36.8	14.9	11.5	5.7	0.0	0.0
Nera 18mg	87	86	86	85	84	82	81	80	79	79	77	77	75	75	73	66	52	38	16	8	6	1	0
%	100.0	98.9	98.9	97.7	96.6	94.3	93.1	92.0	90.8	90.8	88.5	88.5	86.2	86.2	83.9	75.9	59.8	43.7	18.4	9.2	6.9	1.1	0.0

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

Placebo	0	0	0	0	0	0	0	0	1	1	1	2	2	2	2	9	21	35	54	56	61	66	66
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	2.3	2.3	2.3	2.3	10.3	24.1	40.2	62.1	64.4	70.1	75.9	75.9
Nera 18mg	0	1	1	1	1	2	2	2	2	2	2	2	3	3	3	10	24	37	59	67	69	74	75
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	2.3	2.3	3.4	3.4	3.4	11.5	27.6	42.5	67.8	77.0	79.3	85.1	86.2

Study: 1305-0014

Figure H.1.2.3.2: 2 Time to first confirmed or suspected acute IPF 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 H.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	87	12	13.8	10.53	87	3	3.4	2.48	0.25	(0.07,	0.93)	0.0380	
Age													0.9925
<65 years	17	2	11.8	9.08	20	0	0.0	0.00	0.00	(NC,	NC)	0.9920	
>=65 years	70	10	14.3	10.88	67	3	4.5	3.25	0.33	(0.09,	1.25)	0.1032	
Sex													0.9944
Male	68	10	14.7	11.37	68	3	4.4	3.23	0.36	(0.09,	1.39)	0.1369	
Female	19	2	10.5	7.68	19	0	0.0	0.00	0.00	(NC,	NC)	0.9940	
Baseline FVC percent predicted													
<=70%	24	7	29.2		19	2	10.5						
>70%	63	5	7.9		68	1	1.5						
Region													
Europe	14	2	14.3		12	0	0.0						
Asia	41	4	9.8		49	2	4.1						
Canada and USA	13	4	30.8		14	1	7.1						
Rest of the World	19	2	10.5		12	0	0.0						

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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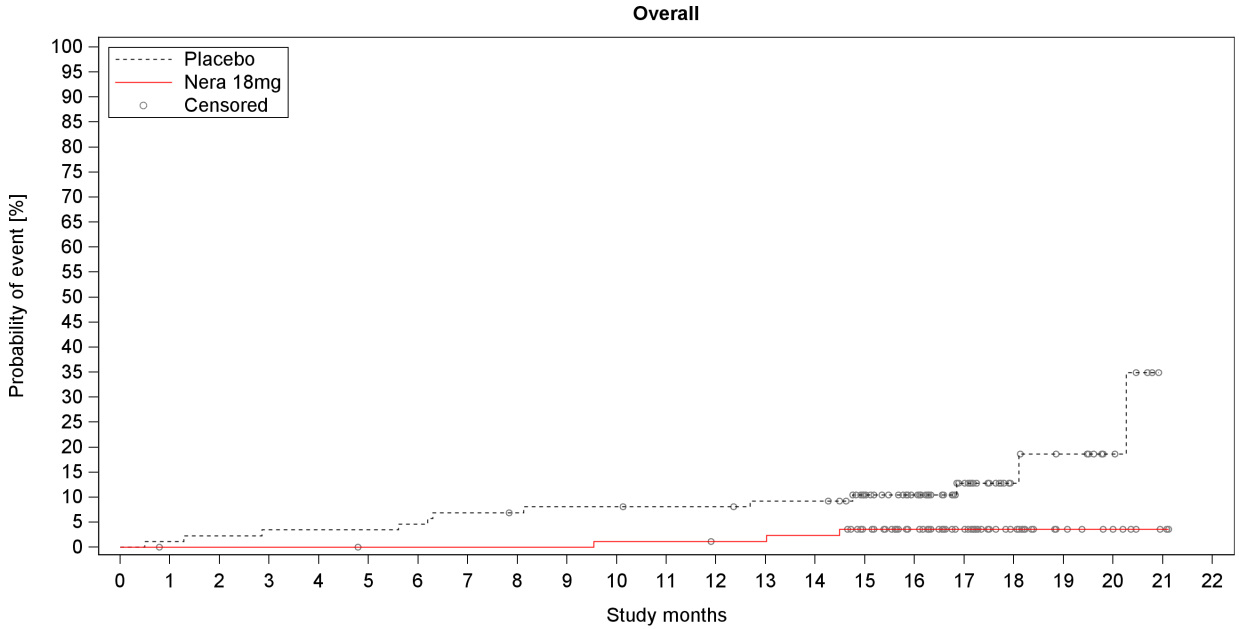

Number at risk (percentage relative to baseline)

Placebo	87	86	85	84	84	84	83	81	80	79	79	78	78	76	76	66	53	36	15	11	6	0	0
%	100.0	98.9	97.7	96.6	96.6	96.6	95.4	93.1	92.0	90.8	90.8	89.7	89.7	87.4	87.4	75.9	60.9	41.4	17.2	12.6	6.9	0.0	0.0
Nera 18mg	87	86	86	86	86	85	85	85	85	85	84	84	83	83	82	74	60	46	22	11	8	2	0
%	100.0	98.9	98.9	98.9	98.9	97.7	97.7	97.7	97.7	97.7	96.6	96.6	95.4	95.4	94.3	85.1	69.0	52.9	25.3	12.6	9.2	2.3	0.0

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

Placebo	0	0	0	0	0	0	0	0	1	1	1	2	2	3	3	12	25	41	62	65	70	75	75
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	2.3	2.3	3.4	3.4	13.8	28.7	47.1	71.3	74.7	80.5	86.2	86.2
Nera 18mg	0	1	1	1	1	2	2	2	2	2	2	2	3	3	3	10	24	38	62	73	76	82	84
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	2.3	2.3	3.4	3.4	3.4	11.5	27.6	43.7	71.3	83.9	87.4	94.3	96.6

Study: 1305-0014

Figure H.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 H.1.2.3.2: 4 Cox model for time to first confirmed acute IPF 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	87	8	9.2	7.32	87	8	9.2	6.98	1.15	(0.41, 3.23)	0.7967	
Age												0.5199
<65 years	17	2	11.8	9.56	20	2	10.0	7.31	0.64	(0.09, 4.78)	0.6637	
>=65 years	70	6	8.6	6.79	67	6	9.0	6.87	1.37	(0.41, 4.57)	0.6094	
Sex												0.9099
Male	68	6	8.8	7.10	68	5	7.4	5.56	1.08	(0.31, 3.82)	0.8992	
Female	19	2	10.5	8.10	19	3	15.8	12.12	1.23	(0.20, 7.47)	0.8217	
Baseline FVC percent predicted												
<=70%	24	6	25.0		19	2	10.5					
>70%	63	2	3.2		68	6	8.8					
Region												
Europe	14	1	7.1		12	1	8.3					
Asia	41	4	9.8		49	5	10.2					
Canada and USA	13	1	7.7		14	2	14.3					
Rest of the World	19	2	10.5		12	0	0.0					

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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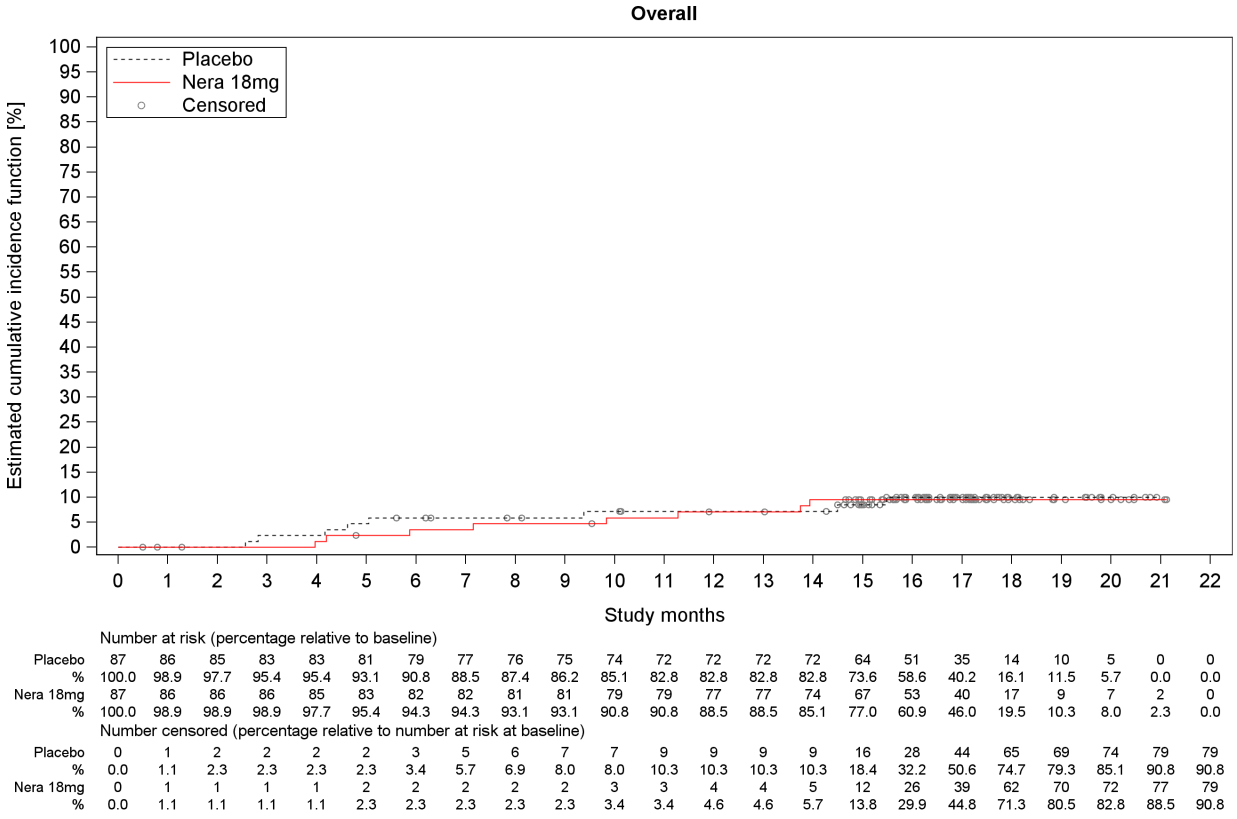

Number at risk (percentage relative to baseline)

Placebo	87	86	85	83	83	81	79	77	76	75	74	72	72	72	72	64	51	35	14	10	5	0	0
%	100.0	98.9	97.7	95.4	95.4	93.1	90.8	88.5	87.4	86.2	85.1	82.8	82.8	82.8	82.8	73.6	58.6	40.2	16.1	11.5	5.7	0.0	0.0
Nera 18mg	87	86	86	86	85	83	82	82	81	81	79	79	77	77	74	67	53	40	17	9	7	2	0
%	100.0	98.9	98.9	98.9	97.7	95.4	94.3	94.3	93.1	93.1	90.8	90.8	88.5	88.5	85.1	77.0	60.9	46.0	19.5	10.3	8.0	2.3	0.0

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

Placebo	0	1	2	2	2	2	3	5	6	7	7	9	9	9	9	16	28	44	65	69	74	79	79
%	0.0	1.1	2.3	2.3	2.3	2.3	3.4	5.7	6.9	8.0	8.0	10.3	10.3	10.3	10.3	18.4	32.2	50.6	74.7	79.3	85.1	90.8	90.8
Nera 18mg	0	1	1	1	1	2	2	2	2	2	3	3	4	4	5	12	26	39	62	70	72	77	79
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	3.4	3.4	4.6	4.6	5.7	13.8	29.9	44.8	71.3	80.5	82.8	88.5	90.8

Study: 1305-0014

Figure H.1.2.3.2: 4 Time to first confirmed acute IPF 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 H.1.2.3.2: 5 Cox model for time to first confirmed or suspected acute IPF 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	87	12	13.8	11.28	87	11	12.6	9.78	1.01	(0.43, 2.38)	0.9836	
Age												0.6859
<65 years	17	2	11.8	9.56	20	2	10.0	7.31	0.70	(0.10, 5.10)	0.7213	
>=65 years	70	10	14.3	11.70	67	9	13.4	10.58	1.09	(0.43, 2.79)	0.8520	
Sex												0.9041
Male	68	8	11.8	9.60	68	6	8.8	6.73	0.99	(0.33, 2.99)	0.9926	
Female	19	4	21.1	17.37	19	5	26.3	21.43	0.89	(0.23, 3.43)	0.8710	
Baseline FVC percent predicted												0.0229
<=70%	24	9	37.5	38.92	19	3	15.8	13.74	0.29	(0.07, 1.20)	0.0871	
>70%	63	3	4.8	3.60	68	8	11.8	8.83	2.72	(0.72, 10.30)	0.1399	
Region												0.4914
Europe	14	3	21.4	16.96	12	1	8.3	6.31	0.86	(0.09, 8.72)	0.9018	
Asia	41	5	12.2	9.65	49	7	14.3	10.55	1.00	(0.31, 3.24)	0.9956	
Canada and USA	13	2	15.4	14.66	14	3	21.4	21.36	5.18	(0.82, 32.83)	0.0807	
Rest of the World	19	2	10.5	8.61	12	0	0.0	0.00	0.00	(NC, NC)	0.9920	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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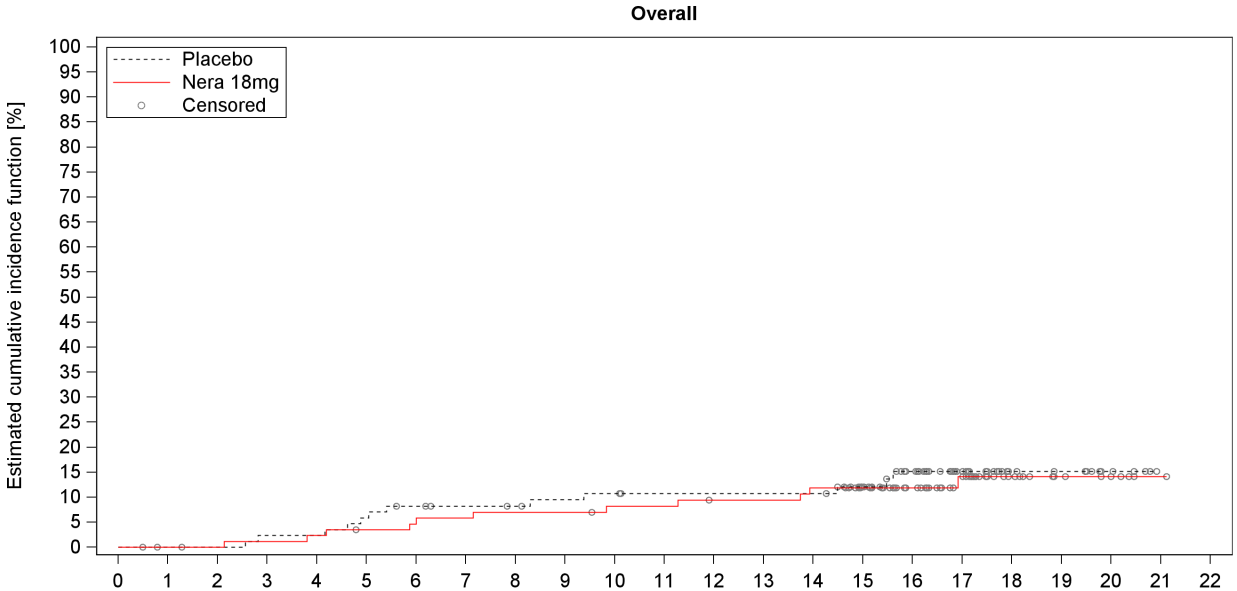

Number at risk (percentage relative to baseline)

Placebo	87	86	85	83	83	80	77	75	74	72	71	69	69	69	69	61	47	32	13	10	5	0	0
%	100.0	98.9	97.7	95.4	95.4	92.0	88.5	86.2	85.1	82.8	81.6	79.3	79.3	79.3	79.3	70.1	54.0	36.8	14.9	11.5	5.7	0.0	0.0
Nera 18mg	87	86	86	85	84	82	81	80	79	79	77	77	75	75	73	66	52	38	16	8	6	1	0
%	100.0	98.9	98.9	97.7	96.6	94.3	93.1	92.0	90.8	90.8	88.5	88.5	86.2	86.2	83.9	75.9	59.8	43.7	18.4	9.2	6.9	1.1	0.0

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

Placebo	0	1	2	2	2	2	3	5	6	7	7	9	9	9	9	16	28	43	62	65	70	75	75
%	0.0	1.1	2.3	2.3	2.3	2.3	3.4	5.7	6.9	8.0	8.0	10.3	10.3	10.3	10.3	18.4	32.2	49.4	71.3	74.7	80.5	86.2	86.2
Nera 18mg	0	1	1	1	1	2	2	2	2	2	3	3	4	4	4	11	25	38	60	68	70	75	76
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	3.4	3.4	4.6	4.6	4.6	12.6	28.7	43.7	69.0	78.2	80.5	86.2	87.4

Study: 1305-0014

Figure H.1.2.3.2: 5 Time to first confirmed or suspected acute IPF exacerbation - treatment policy approach to lung transplant - over the whole trial, estimated cumulative incidence function - 18mg - FAS (non-AF background)

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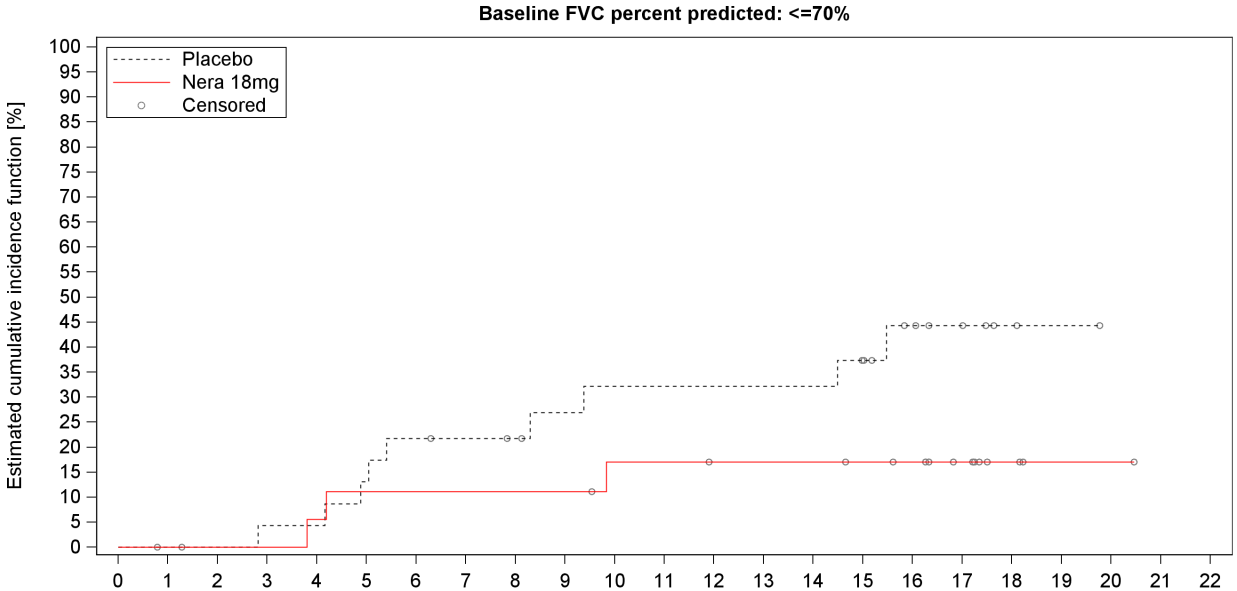

Number at risk (percentage relative to baseline)																						
Placebo	24	24	23	22	22	20	18	17	16	14	13	13	13	13	13	11	7	5	2	1	0	0	0
%	100.0	100.0	95.8	91.7	91.7	83.3	75.0	70.8	66.7	58.3	54.2	54.2	54.2	54.2	54.2	45.8	29.2	20.8	8.3	4.2	0.0	0.0	0.0
Nera 18mg	19	18	18	18	17	16	16	16	16	16	14	14	13	13	13	12	10	7	3	1	1	0	0
%	100.0	94.7	94.7	94.7	89.5	84.2	84.2	84.2	84.2	84.2	73.7	73.7	68.4	68.4	68.4	63.2	52.6	36.8	15.8	5.3	5.3	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																							
Placebo	0	0	1	1	1	1	1	2	3	4	4	4	4	4	4	5	8	10	13	14	15	15	15
%	0.0	0.0	4.2	4.2	4.2	4.2	4.2	8.3	12.5	16.7	16.7	16.7	16.7	16.7	16.7	20.8	33.3	41.7	54.2	58.3	62.5	62.5	62.5
Nera 18mg	0	1	1	1	1	1	1	1	1	1	2	2	3	3	3	4	6	9	13	15	15	16	16
%	0.0	5.3	5.3	5.3	5.3	5.3	5.3	5.3	5.3	5.3	10.5	10.5	15.8	15.8	15.8	21.1	31.6	47.4	68.4	78.9	78.9	84.2	84.2

Study: 1305-0014

Figure H.1.2.3.2: 5 Time to first confirmed or suspected acute IPF exacerbation - treatment policy approach to lung transplant - over the whole trial, estimated cumulative incidence function - 18mg - FAS (non-AF background)

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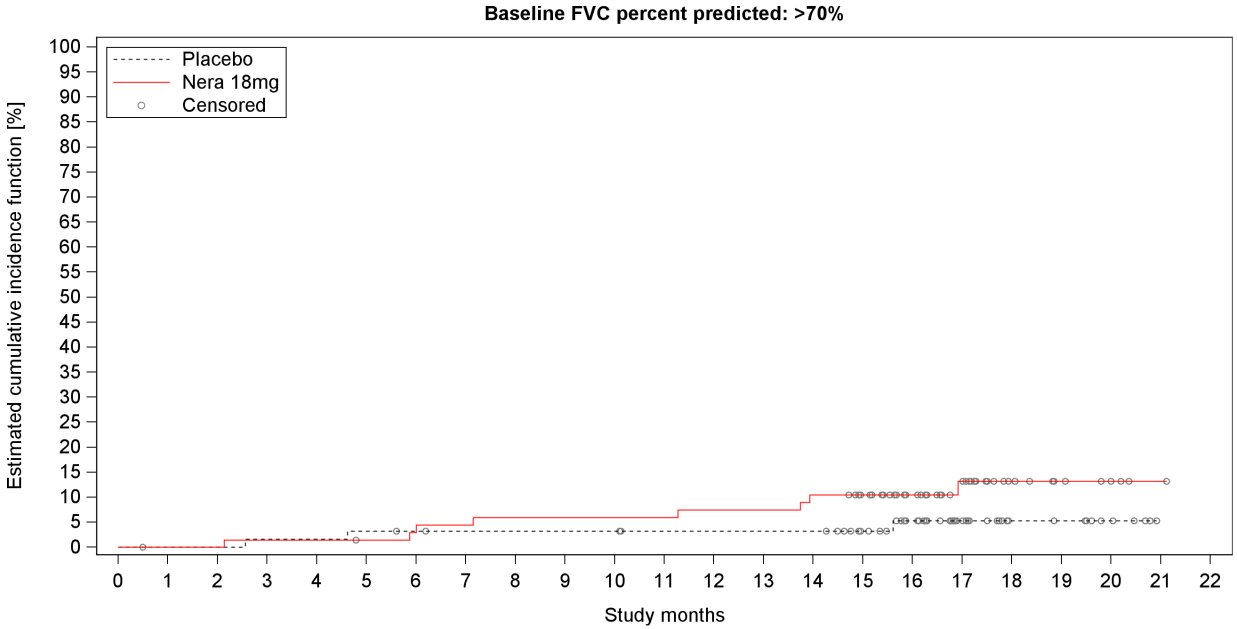

Number at risk (percentage relative to baseline)																						
Placebo	63	62	62	61	61	60	59	58	58	58	58	56	56	56	56	50	40	27	11	9	5	0	0
%	100.0	98.4	98.4	96.8	96.8	95.2	93.7	92.1	92.1	92.1	92.1	88.9	88.9	88.9	88.9	79.4	63.5	42.9	17.5	14.3	7.9	0.0	0.0
Nera 18mg	68	68	68	67	67	66	65	64	63	63	63	63	62	62	60	54	42	31	13	7	5	1	0
%	100.0	100.0	100.0	98.5	98.5	97.1	95.6	94.1	92.6	92.6	92.6	92.6	91.2	91.2	88.2	79.4	61.8	45.6	19.1	10.3	7.4	1.5	0.0
Number censored (percentage relative to number at risk at baseline)																							
Placebo	0	1	1	1	1	1	2	3	3	3	3	5	5	5	5	11	20	33	49	51	55	60	60
%	0.0	1.6	1.6	1.6	1.6	1.6	3.2	4.8	4.8	4.8	4.8	7.9	7.9	7.9	7.9	17.5	31.7	52.4	77.8	81.0	87.3	95.2	95.2
Nera 18mg	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	7	19	29	47	53	55	59	60
%	0.0	0.0	0.0	0.0	0.0	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	10.3	27.9	42.6	69.1	77.9	80.9	86.8	88.2

Study: 1305-0014

Figure H.1.2.3.2: 5 Time to first confirmed or suspected acute IPF exacerbation - treatment policy approach to lung transplant - over the whole trial, estimated cumulative incidence function - 18mg - FAS (non-AF background)

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H.2 Nerandomilast IPF HTA Analysis: DBL1 Analysis

H.2.1 Population with AF background

H.2.1.1 Efficacy Analysis

H.2.1.1.1 Time to event analyses

H.2.1.1.1.1 Analyses of composite endpoints

H.2.1.1.1.1.1 Time to first confirmed or suspected acute IPF exacerbation, respiratory hospitalisation or death

Table H.2.1.1.1.1.1: 1 Cox model for time to first confirmed or suspected acute IPF exacerbation, respiratory hospitalisation or death over the whole trial (DBL1) - 18mg - FAS (AF background)

Subgroup Category	Placebo N	n	(e/ h/ d)	%	Rate°	Nera 18mg N	n	(e/ h/ d)	%	Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	306	56	(20/ 30/ 6)	18.3	17.96	305	71	(27/ 38/ 6)	23.3	23.33	1.40	(0.98, 1.99)	0.0632	
Age														0.8196
<65 years	69	10	(3/ 6/ 1)	14.5	13.30	63	11	(3/ 8/ 0)	17.5	16.80	1.28	(0.54, 3.02)	0.5703	
>=65 years	237	46	(17/ 24/ 5)	19.4	19.44	242	60	(24/ 30/ 6)	24.8	25.11	1.43	(0.97, 2.10)	0.0689	
Sex														0.2395
Male	269	55	(20/ 29/ 6)	20.4	20.26	255	63	(24/ 33/ 6)	24.7	24.82	1.37	(0.95, 1.97)	0.0907	
Female	37	1	(0/ 1/ 0)	2.7	2.48	50	8	(3/ 5/ 0)	16.0	15.82	4.86	(0.61, 39.01)	0.1366	
Baseline FVC percent predicted														0.1037
<=70%	109	27	(10/ 14/ 3)	24.8	25.25	112	43	(16/ 22/ 5)	38.4	43.02	1.78	(1.10, 2.89)	0.0191	
>70%	197	29	(10/ 16/ 3)	14.7	14.15	193	28	(11/ 16/ 1)	14.5	13.70	0.99	(0.59, 1.67)	0.9683	
Type of AF therapy														0.9014
Nintedanib	173	30	(11/ 16/ 3)	17.3	16.87	178	41	(14/ 23/ 4)	23.0	23.25	1.38	(0.86, 2.21)	0.1832	
Pirfenidone	133	26	(9/ 14/ 3)	19.5	19.41	127	30	(13/ 15/ 2)	23.6	23.44	1.44	(0.85, 2.45)	0.1769	
Region														0.4524
Europe	136	17	(7/ 9/ 1)	12.5	12.37	136	31	(14/ 14/ 3)	22.8	23.20	1.81	(1.00, 3.27)	0.0506	
Asia	72	17	(7/ 9/ 1)	23.6	22.95	79	20	(6/ 12/ 2)	25.3	24.79	1.42	(0.74, 2.73)	0.2980	
Canada and USA	75	18	(6/ 9/ 3)	24.0	23.66	56	11	(3/ 7/ 1)	19.6	18.86	0.84	(0.40, 1.78)	0.6543	
Rest of the World	23	4	(0/ 3/ 1)	17.4	16.53	34	9	(4/ 5/ 0)	26.5	28.33	1.79	(0.55, 5.88)	0.3346	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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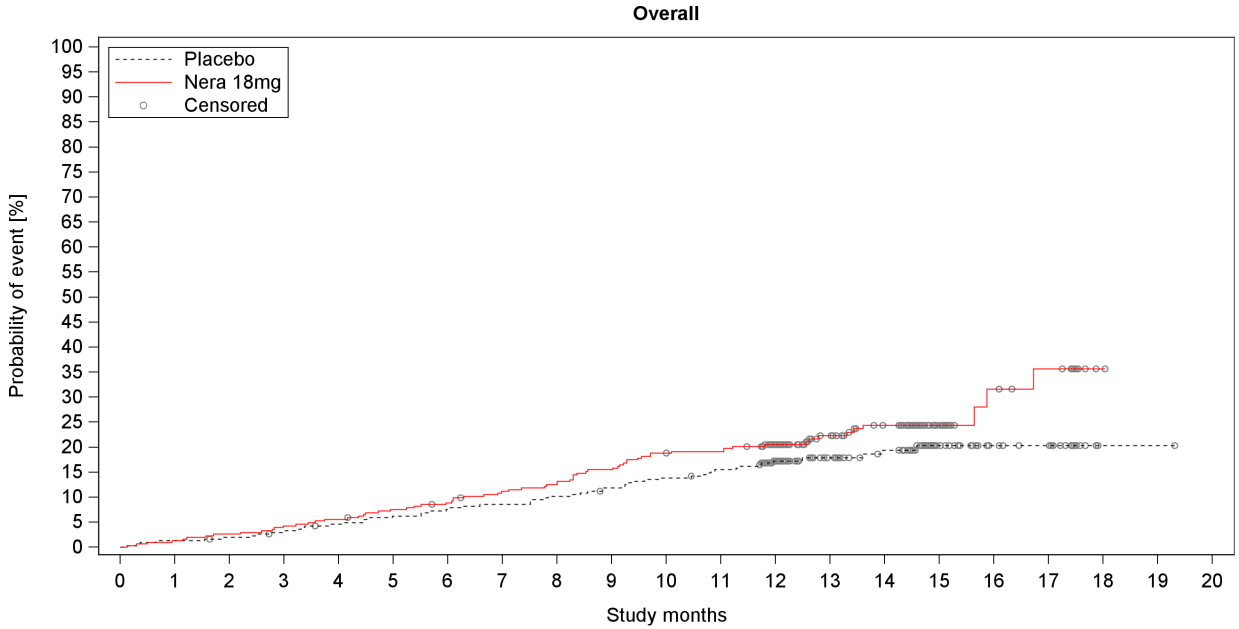

Number at risk (percentage relative to baseline)

Placebo	306	302	299	295	289	284	280	277	272	266	260	254	182	122	106	35	20	17	1	1	0
%	100.0	98.7	97.7	96.4	94.4	92.8	91.5	90.5	88.9	86.9	85.0	83.0	59.5	39.9	34.6	11.4	6.5	5.6	0.3	0.3	0.0
Nera 18mg	305	301	297	292	288	281	276	268	264	255	245	243	177	123	104	35	19	16	1	0	0
%	100.0	98.7	97.4	95.7	94.4	92.1	90.5	87.9	86.6	83.6	80.3	79.7	58.0	40.3	34.1	11.5	6.2	5.2	0.3	0.0	0.0

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

Placebo	0	0	1	2	3	3	3	3	3	4	4	5	72	131	145	215	230	233	249	249	250
%	0.0	0.0	0.3	0.7	1.0	1.0	1.0	1.0	1.0	1.3	1.3	1.6	23.5	42.8	47.4	70.3	75.2	76.1	81.4	81.4	81.7
Nera 18mg	0	0	0	0	0	1	2	3	3	3	3	4	66	117	133	202	216	218	233	234	234
%	0.0	0.0	0.0	0.0	0.0	0.3	0.7	1.0	1.0	1.0	1.0	1.3	21.6	38.4	43.6	66.2	70.8	71.5	76.4	76.7	76.7

Study: 1305-0014

Figure H.2.1.1.1.1.1: 1 Time to first confirmed or suspected acute IPF exacerbation, respiratory hospitalisation or death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (AF background)

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Figure H.2.1.1.1.1: 1

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H.2.1.1.1.1.2 Time to first confirmed acute IPF exacerbation or death

Table H.2.1.1.1.1.2: 1 Cox model for time to first confirmed acute IPF exacerbation or death over the whole trial (DBL1) - 18mg - FAS (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	306	31 (19/ 12)	10.1	9.48	305	37 (22/ 15)	12.1	11.42	1.26	(0.78, 2.03)	0.3531	
Age												0.8946
<65 years	69	5 (4/ 1)	7.2	6.49	63	5 (3/ 2)	7.9	7.34	1.16	(0.34, 4.02)	0.8140	
>=65 years	237	26 (15/ 11)	11.0	10.40	242	32 (19/ 13)	13.2	12.51	1.27	(0.76, 2.14)	0.3659	
Sex												0.9802
Male	269	31 (19/ 12)	11.5	10.84	255	32 (19/ 13)	12.5	11.81	1.18	(0.72, 1.93)	0.5188	
Female	37	0 (0/ 0)	0.0	0.00	50	5 (3/ 2)	10.0	9.43	>10	(NC, NC)	0.9799	
Baseline FVC percent predicted												0.4902
<=70%	109	16 (10/ 6)	14.7	14.09	112	22 (12/ 10)	19.6	19.75	1.42	(0.74, 2.72)	0.2846	
>70%	197	15 (9/ 6)	7.6	7.03	193	15 (10/ 5)	7.8	7.06	1.01	(0.49, 2.08)	0.9680	
Type of AF therapy												0.2841
Nintedanib	173	17 (11/ 6)	9.8	9.12	178	17 (11/ 6)	9.6	9.06	0.98	(0.50, 1.92)	0.9554	
Pirfenidone	133	14 (8/ 6)	10.5	9.95	127	20 (11/ 9)	15.7	14.66	1.66	(0.83, 3.30)	0.1497	
Region												0.3350
Europe	136	11 (7/ 4)	8.1	7.73	136	19 (11/ 8)	14.0	13.35	1.63	(0.77, 3.43)	0.2003	
Asia	72	10 (8/ 2)	13.9	13.08	79	7 (5/ 2)	8.9	8.10	0.71	(0.27, 1.89)	0.4959	
Canada and USA	75	9 (4/ 5)	12.0	10.96	56	6 (3/ 3)	10.7	9.78	0.91	(0.32, 2.56)	0.8612	
Rest of the World	23	1 (0/ 1)	4.3	3.81	34	5 (3/ 2)	14.7	14.76	4.42	(0.51, 38.06)	0.1760	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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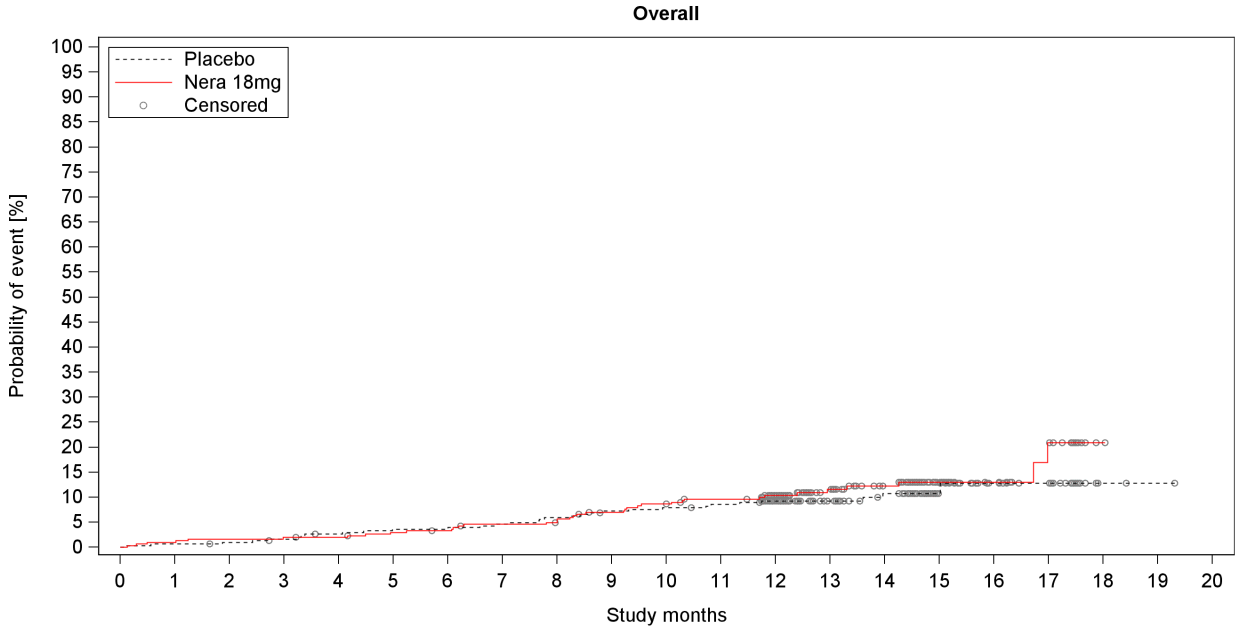

Number at risk (percentage relative to baseline)

Placebo	306	304	302	299	295	292	292	289	285	280	278	275	203	138	121	42	25	21	2	1	0
%	100.0	99.3	98.7	97.7	96.4	95.4	95.4	94.4	93.1	91.5	90.8	89.9	66.3	45.1	39.5	13.7	8.2	6.9	0.7	0.3	0.0
Nera 18mg	305	302	300	299	298	294	292	287	285	277	272	266	199	141	119	43	27	20	1	0	0
%	100.0	99.0	98.4	98.0	97.7	96.4	95.7	94.1	93.4	90.8	89.2	87.2	65.2	46.2	39.0	14.1	8.9	6.6	0.3	0.0	0.0

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

Placebo	0	0	1	2	3	3	3	3	3	4	4	5	75	140	155	234	250	254	273	274	275
%	0.0	0.0	0.3	0.7	1.0	1.0	1.0	1.0	1.0	1.3	1.3	1.6	24.5	45.8	50.7	76.5	81.7	83.0	89.2	89.5	89.9
Nera 18mg	0	0	0	0	1	2	3	4	5	7	7	10	75	131	152	227	243	248	267	268	268
%	0.0	0.0	0.0	0.0	0.3	0.7	1.0	1.3	1.6	2.3	2.3	3.3	24.6	43.0	49.8	74.4	79.7	81.3	87.5	87.9	87.9

Study: 1305-0014

Figure H.2.1.1.1.2: 1 Time to first confirmed acute IPF exacerbation or death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (AF background)

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Figure H.2.1.1.1.2: 1

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H.2.1.1.1.1.3 Time to first confirmed or suspected acute IPF exacerbation or death

Table H.2.1.1.1.1.3: 1 Cox model for time to first confirmed or suspected acute IPF exacerbation or death over the whole trial (DBL1) - 18mg - FAS (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	306	33 (22/ 11)	10.8	10.12	305	40 (29/ 11)	13.1	12.41	1.29	(0.81, 2.05)	0.2870	
Age												0.8431
<65 years	69	5 (4/ 1)	7.2	6.49	63	5 (3/ 2)	7.9	7.34	1.15	(0.33, 3.96)	0.8305	
>=65 years	237	28 (18/ 10)	11.8	11.25	242	35 (26/ 9)	14.5	13.77	1.31	(0.80, 2.16)	0.2886	
Sex												0.9796
Male	269	33 (22/ 11)	12.3	11.58	255	35 (26/ 9)	13.7	12.99	1.22	(0.76, 1.97)	0.4110	
Female	37	0 (0/ 0)	0.0	0.00	50	5 (3/ 2)	10.0	9.45	>10	(NC, NC)	0.9792	
Baseline FVC percent predicted												0.1891
<=70%	109	16 (10/ 6)	14.7	14.10	112	25 (18/ 7)	22.3	22.72	1.67	(0.89, 3.14)	0.1123	
>70%	197	17 (12/ 5)	8.6	8.00	193	15 (11/ 4)	7.8	7.06	0.89	(0.44, 1.79)	0.7451	
Type of AF therapy												0.3307
Nintedanib	173	18 (13/ 5)	10.4	9.71	178	19 (15/ 4)	10.7	10.16	1.04	(0.55, 1.98)	0.9037	
Pirfenidone	133	15 (9/ 6)	11.3	10.68	127	21 (14/ 7)	16.5	15.51	1.65	(0.85, 3.22)	0.1424	
Region												0.2964
Europe	136	12 (8/ 4)	8.8	8.45	136	20 (14/ 6)	14.7	14.15	1.58	(0.77, 3.25)	0.2097	
Asia	72	10 (8/ 2)	13.9	13.08	79	8 (6/ 2)	10.1	9.26	0.84	(0.33, 2.15)	0.7134	
Canada and USA	75	10 (6/ 4)	13.3	12.30	56	6 (3/ 3)	10.7	9.78	0.81	(0.29, 2.22)	0.6799	
Rest of the World	23	1 (0/ 1)	4.3	3.81	34	6 (6/ 0)	17.6	18.01	5.57	(0.67, 46.59)	0.1132	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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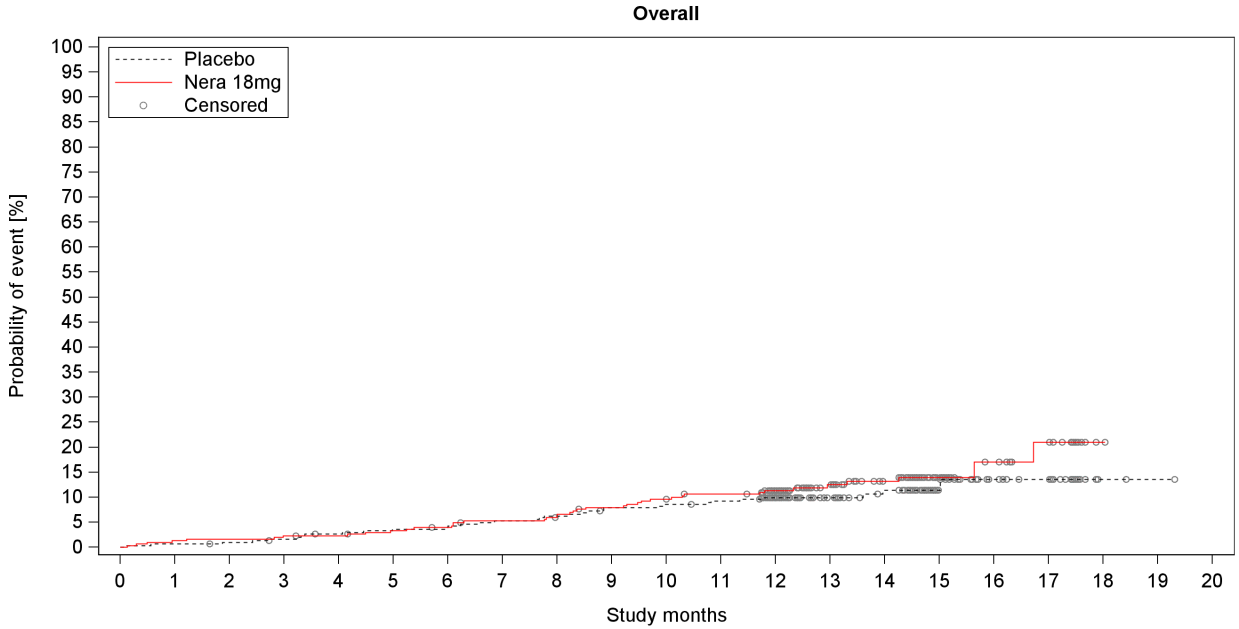

Number at risk (percentage relative to baseline)

Placebo	306	304	302	299	295	292	291	287	284	278	276	273	202	137	120	41	25	21	2	1	0
%	100.0	99.3	98.7	97.7	96.4	95.4	95.1	93.8	92.8	90.8	90.2	89.2	66.0	44.8	39.2	13.4	8.2	6.9	0.7	0.3	0.0
Nera 18mg	305	301	300	298	297	293	290	285	282	275	270	265	198	140	118	43	26	20	1	0	0
%	100.0	98.7	98.4	97.7	97.4	96.1	95.1	93.4	92.5	90.2	88.5	86.9	64.9	45.9	38.7	14.1	8.5	6.6	0.3	0.0	0.0

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

Placebo	0	0	1	2	3	3	3	3	3	4	4	5	74	139	154	233	248	252	271	272	273
%	0.0	0.0	0.3	0.7	1.0	1.0	1.0	1.0	1.0	1.3	1.3	1.6	24.2	45.4	50.3	76.1	81.0	82.4	88.6	88.9	89.2
Nera 18mg	0	0	0	0	1	2	3	4	5	6	6	8	73	129	150	224	240	245	264	265	265
%	0.0	0.0	0.0	0.0	0.3	0.7	1.0	1.3	1.6	2.0	2.0	2.6	23.9	42.3	49.2	73.4	78.7	80.3	86.6	86.9	86.9

Study: 1305-0014

Figure H.2.1.1.1.3: 1 Time to first confirmed or suspected acute IPF exacerbation or death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (AF background)

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H.2.1.1.1.1.4 Time to first respiratory hospitalisation or death

Table H.2.1.1.1.1.4: 1 Cox model for time to first respiratory hospitalisation or death over the whole trial (DBL1) - 18mg - FAS (AF 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	306	52 (44/ 8)	17.0	16.48	305	65 (59/ 6)	21.3	21.04	1.38	(0.95, 1.99)	0.0866	
Age												0.4661
<65 years	69	10 (9/ 1)	14.5	13.30	63	9 (9/ 0)	14.3	13.50	1.02	(0.42, 2.53)	0.9585	
>=65 years	237	42 (35/ 7)	17.7	17.47	242	56 (50/ 6)	23.1	23.12	1.48	(0.99, 2.21)	0.0564	
Sex												0.2383
Male	269	51 (43/ 8)	19.0	18.53	255	57 (51/ 6)	22.4	22.08	1.34	(0.92, 1.96)	0.1318	
Female	37	1 (1/ 0)	2.7	2.48	50	8 (8/ 0)	16.0	15.78	4.78	(0.60, 38.38)	0.1408	
Baseline FVC percent predicted												0.1834
<=70%	109	25 (21/ 4)	22.9	22.82	112	38 (33/ 5)	33.9	36.67	1.71	(1.03, 2.84)	0.0386	
>70%	197	27 (23/ 4)	13.7	13.11	193	27 (26/ 1)	14.0	13.16	1.04	(0.61, 1.77)	0.8948	
Type of AF therapy												0.9263
Nintedanib	173	29 (24/ 5)	16.8	16.11	178	39 (35/ 4)	21.9	21.86	1.36	(0.84, 2.20)	0.2095	
Pirfenidone	133	23 (20/ 3)	17.3	16.96	127	26 (24/ 2)	20.5	19.93	1.41	(0.80, 2.48)	0.2346	
Region												0.5075
Europe	136	16 (14/ 2)	11.8	11.55	136	28 (25/ 3)	20.6	20.63	1.70	(0.92, 3.15)	0.0898	
Asia	72	16 (15/ 1)	22.2	21.41	79	20 (18/ 2)	25.3	24.78	1.58	(0.81, 3.09)	0.1777	
Canada and USA	75	16 (12/ 4)	21.3	20.48	56	9 (8/ 1)	16.1	15.03	0.80	(0.35, 1.81)	0.5922	
Rest of the World	23	4 (3/ 1)	17.4	16.53	34	8 (8/ 0)	23.5	24.57	1.43	(0.43, 4.79)	0.5632	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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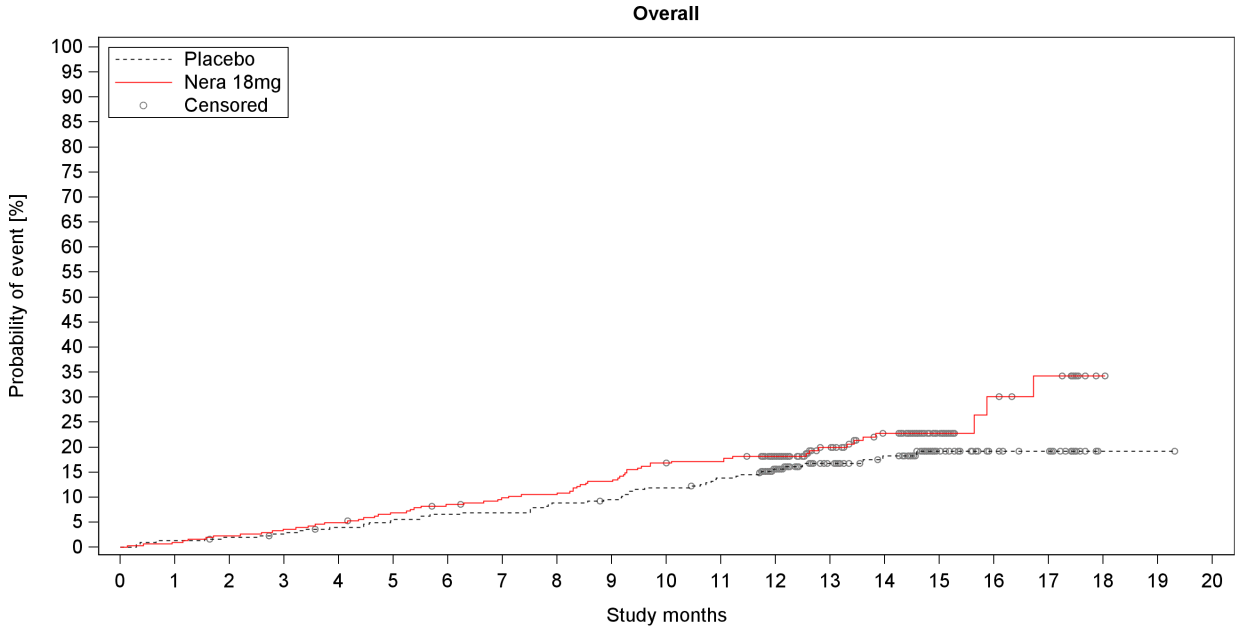

Number at risk (percentage relative to baseline)

Placebo	306	302	299	296	291	286	283	282	276	273	266	259	185	124	108	37	20	17	1	1	0
%	100.0	98.7	97.7	96.7	95.1	93.5	92.5	92.2	90.2	89.2	86.9	84.6	60.5	40.5	35.3	12.1	6.5	5.6	0.3	0.3	0.0
Nera 18mg	305	302	298	294	290	283	277	272	270	262	251	249	184	128	107	36	19	16	1	0	0
%	100.0	99.0	97.7	96.4	95.1	92.8	90.8	89.2	88.5	85.9	82.3	81.6	60.3	42.0	35.1	11.8	6.2	5.2	0.3	0.0	0.0

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

Placebo	0	0	1	2	3	3	3	3	3	4	4	5	74	133	147	217	234	237	253	253	254
%	0.0	0.0	0.3	0.7	1.0	1.0	1.0	1.0	1.0	1.3	1.3	1.6	24.2	43.5	48.0	70.9	76.5	77.5	82.7	82.7	83.0
Nera 18mg	0	0	0	0	0	1	2	3	3	3	3	4	66	119	136	207	222	224	239	240	240
%	0.0	0.0	0.0	0.0	0.0	0.3	0.7	1.0	1.0	1.0	1.0	1.3	21.6	39.0	44.6	67.9	72.8	73.4	78.4	78.7	78.7

Study: 1305-0014

Figure H.2.1.1.1.4: 1 Time to first respiratory hospitalisation or death
over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (AF background)

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Figure H.2.1.1.1.4: 1

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H.2.1.1.1.1.5 Time to first non-elective hospitalisation for any cause or death

Table H.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 (AF 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	306	80 (74/ 6)	26.1	27.36	305	89 (85/ 4)	29.2	30.37	1.14 (0.84, 1.54)	0.3958	
Age											0.3899
<65 years	69	15 (14/ 1)	21.7	21.51	63	12 (12/ 0)	19.0	18.59	0.85 (0.40, 1.81)	0.6676	
>=65 years	237	65 (60/ 5)	27.4	29.19	242	77 (73/ 4)	31.8	33.70	1.22 (0.87, 1.70)	0.2439	
Sex											0.2270
Male	269	77 (71/ 6)	28.6	30.34	255	77 (73/ 4)	30.2	31.48	1.10 (0.80, 1.52)	0.5392	
Female	37	3 (3/ 0)	8.1	7.77	50	12 (12/ 0)	24.0	24.76	2.47 (0.70, 8.80)	0.1619	
Baseline FVC percent predicted											0.1544
<=70%	109	33 (29/ 4)	30.3	32.40	112	45 (41/ 4)	40.2	46.19	1.43 (0.91, 2.25)	0.1186	
>70%	197	47 (45/ 2)	23.9	24.66	193	44 (44/ 0)	22.8	22.49	0.92 (0.61, 1.39)	0.6894	
Type of AF therapy											0.7688
Nintedanib	173	43 (39/ 4)	24.9	25.57	178	52 (50/ 2)	29.2	30.65	1.19 (0.79, 1.78)	0.4005	
Pirfenidone	133	37 (35/ 2)	27.8	29.78	127	37 (35/ 2)	29.1	29.98	1.09 (0.69, 1.72)	0.7255	
Region											0.0751
Europe	136	29 (27/ 2)	21.3	22.28	136	38 (36/ 2)	27.9	29.28	1.28 (0.79, 2.07)	0.3232	
Asia	72	20 (19/ 1)	27.8	28.23	79	30 (28/ 2)	38.0	41.26	1.64 (0.93, 2.91)	0.0892	
Canada and USA	75	26 (24/ 2)	34.7	37.91	56	11 (11/ 0)	19.6	18.77	0.51 (0.25, 1.04)	0.0631	
Rest of the World	23	5 (4/ 1)	21.7	21.92	34	10 (10/ 0)	29.4	31.31	1.46 (0.50, 4.29)	0.4938	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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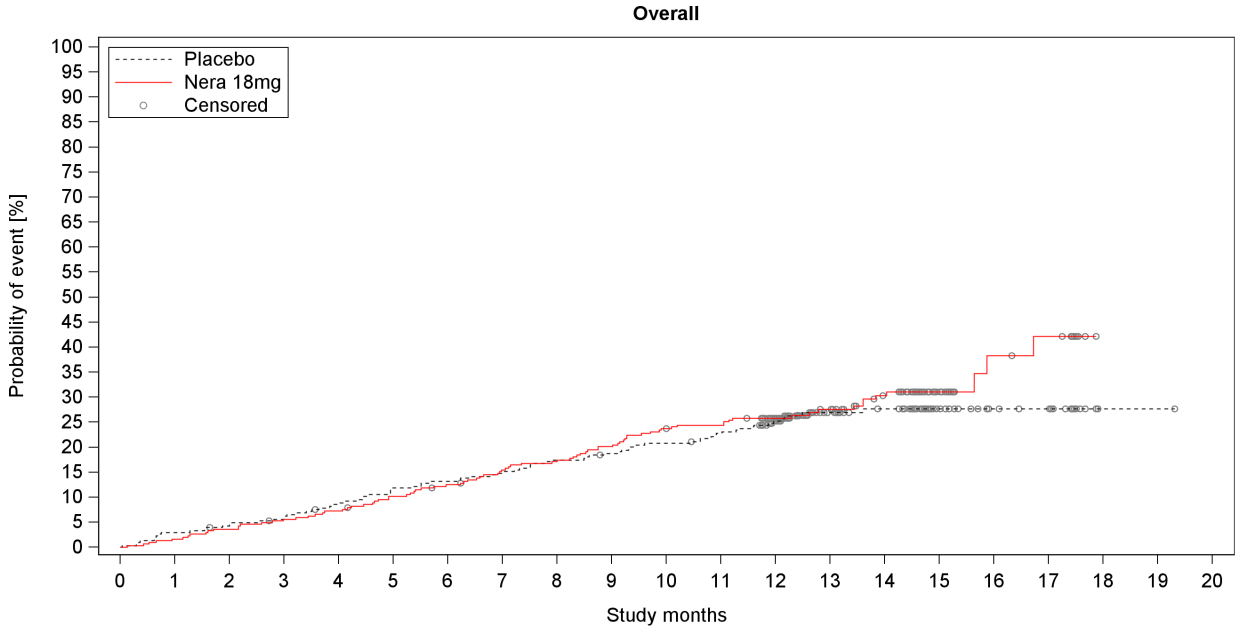

Number at risk (percentage relative to baseline)

Placebo	306	297	292	287	277	267	263	258	250	245	239	232	162	106	94	30	17	15	1	1	0
%	100.0	97.1	95.4	93.8	90.5	87.3	85.9	84.3	81.7	80.1	78.1	75.8	52.9	34.6	30.7	9.8	5.6	4.9	0.3	0.3	0.0
Nera 18mg	305	300	294	288	283	273	265	255	250	241	230	227	164	116	97	33	17	15	0	0	0
%	100.0	98.4	96.4	94.4	92.8	89.5	86.9	83.6	82.0	79.0	75.4	74.4	53.8	38.0	31.8	10.8	5.6	4.9	0.0	0.0	0.0

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

Placebo	0	0	1	2	3	3	3	3	3	4	4	5	68	121	132	196	209	211	225	225	226
%	0.0	0.0	0.3	0.7	1.0	1.0	1.0	1.0	1.0	1.3	1.3	1.6	22.2	39.5	43.1	64.1	68.3	69.0	73.5	73.5	73.9
Nera 18mg	0	0	0	0	0	1	2	3	3	3	3	4	63	108	123	186	200	201	216	216	216
%	0.0	0.0	0.0	0.0	0.0	0.3	0.7	1.0	1.0	1.0	1.0	1.3	20.7	35.4	40.3	61.0	65.6	65.9	70.8	70.8	70.8

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.2.1.1.1.5: 1

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H.2.1.1.1.2 Analyses of single endpoints

H.2.1.1.1.2.1 Time to death

Table H.2.1.1.1.2.1: 1 Cox model for time to death over the whole trial
(DBL1) - 18mg - FAS (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	306	19	6.2	5.64	305	20	6.6	5.96	1.14	(0.60, 2.14)	0.6914	
Age												0.9486
<65 years	69	2	2.9	2.56	63	2	3.2	2.85	1.21	(0.17, 8.62)	0.8484	
>=65 years	237	17	7.2	6.58	242	18	7.4	6.77	1.13	(0.58, 2.21)	0.7176	
Sex												0.9843
Male	269	19	7.1	6.43	255	15	5.9	5.32	0.93	(0.47, 1.83)	0.8247	
Female	37	0	0.0	0.00	50	5	10.0	9.28	>10	(NC, NC)	0.9844	
Baseline FVC percent predicted												0.3859
<=70%	109	10	9.2	8.40	112	13	11.6	11.01	1.48	(0.64, 3.42)	0.3588	
>70%	197	9	4.6	4.14	193	7	3.6	3.22	0.84	(0.31, 2.26)	0.7240	
Type of AF therapy												0.1599
Nintedanib	173	12	6.9	6.29	178	9	5.1	4.64	0.75	(0.32, 1.78)	0.5170	
Pirfenidone	133	7	5.3	4.80	127	11	8.7	7.76	1.89	(0.73, 4.93)	0.1921	
Region												0.4643
Europe	136	8	5.9	5.56	136	11	8.1	7.42	1.25	(0.50, 3.12)	0.6365	
Asia	72	4	5.6	4.89	79	2	2.5	2.23	0.54	(0.10, 3.01)	0.4855	
Canada and USA	75	6	8.0	7.08	56	3	5.4	4.76	0.71	(0.18, 2.86)	0.6353	
Rest of the World	23	1	4.3	3.81	34	4	11.8	11.55	4.33	(0.48, 39.30)	0.1929	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment,
continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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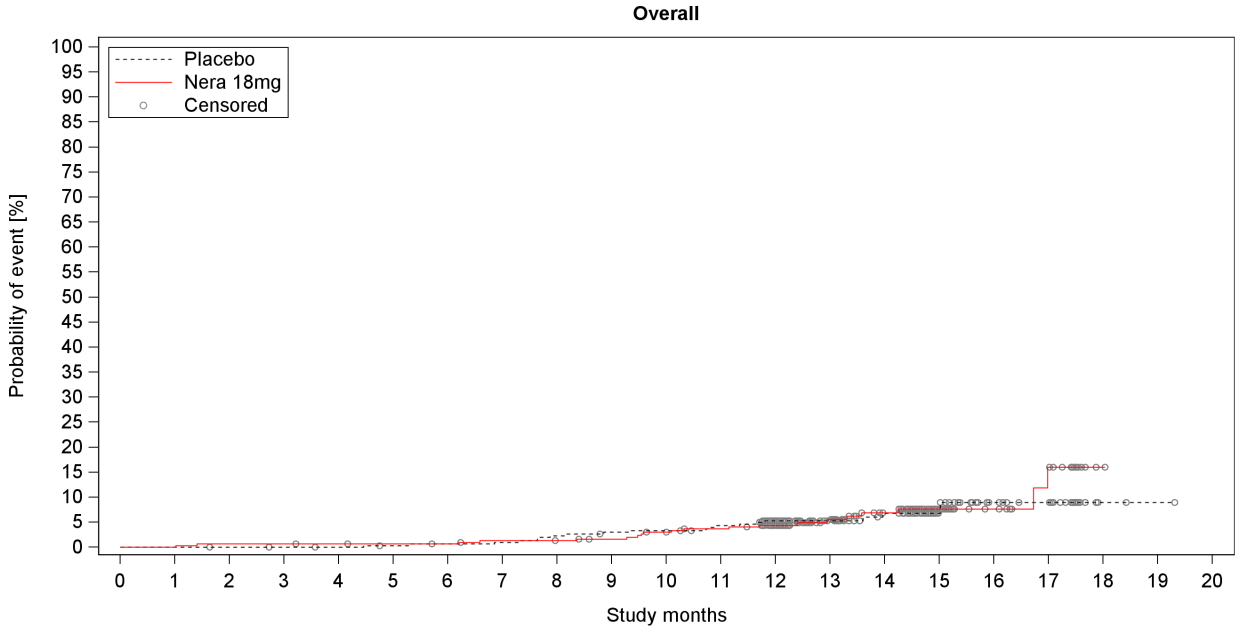

Number at risk (percentage relative to baseline)

Placebo	306	306	305	304	303	301	300	299	295	292	291	287	212	144	126	44	25	21	2	1	0
%	100.0	100.0	99.7	99.3	99.0	98.4	98.0	97.7	96.4	95.4	95.1	93.8	69.3	47.1	41.2	14.4	8.2	6.9	0.7	0.3	0.0
Nera 18mg	305	305	303	303	302	301	300	297	296	293	288	283	214	154	128	45	27	20	1	0	0
%	100.0	100.0	99.3	99.3	99.0	98.7	98.4	97.4	97.0	96.1	94.4	92.8	70.2	50.5	42.0	14.8	8.9	6.6	0.3	0.0	0.0

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

Placebo	0	0	1	2	3	4	4	4	4	5	5	6	78	146	162	244	262	266	285	286	287
%	0.0	0.0	0.3	0.7	1.0	1.3	1.3	1.3	1.3	1.6	1.6	2.0	25.5	47.7	52.9	79.7	85.6	86.9	93.1	93.5	93.8
Nera 18mg	0	0	0	0	1	2	3	4	5	7	8	11	78	136	160	242	260	265	284	285	285
%	0.0	0.0	0.0	0.0	0.3	0.7	1.0	1.3	1.6	2.3	2.6	3.6	25.6	44.6	52.5	79.3	85.2	86.9	93.1	93.4	93.4

Study: 1305-0014

Figure H.2.1.1.1.2.1: 1 Time to death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (AF background)

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Figure H.2.1.1.1.2.1: 1

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H.2.1.1.1.2.2 Time to first confirmed acute IPF exacerbation

Table H.2.1.1.1.2.2: 1 Cox model for time to first confirmed acute IPF exacerbation over the whole trial (DBL1) - 18mg - FAS (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	306	19	6.2	5.81	305	22	7.2	6.79	1.19	(0.65, 2.21)	0.5718	
Age												0.5699
<65 years	69	4	5.8	5.19	63	3	4.8	4.40	0.80	(0.18, 3.60)	0.7757	
>=65 years	237	15	6.3	6.00	242	19	7.9	7.43	1.30	(0.66, 2.55)	0.4554	
Sex												0.9846
Male	269	19	7.1	6.64	255	19	7.5	7.01	1.12	(0.59, 2.12)	0.7294	
Female	37	0	0.0	0.00	50	3	6.0	5.66	>10	(NC, NC)	0.9845	
Baseline FVC percent predicted												0.9164
<=70%	109	10	9.2	8.81	112	12	10.7	10.78	1.20	(0.51, 2.78)	0.6772	
>70%	197	9	4.6	4.22	193	10	5.2	4.70	1.12	(0.45, 2.76)	0.8059	
Type of AF therapy												0.4584
Nintedanib	173	11	6.4	5.90	178	11	6.2	5.87	0.97	(0.42, 2.24)	0.9416	
Pirfenidone	133	8	6.0	5.69	127	11	8.7	8.06	1.55	(0.62, 3.87)	0.3488	
Region												0.7129
Europe	136	7	5.1	4.92	136	11	8.1	7.73	1.49	(0.58, 3.84)	0.4132	
Asia	72	8	11.1	10.46	79	5	6.3	5.79	0.62	(0.20, 1.91)	0.4007	
Canada and USA	75	4	5.3	4.88	56	3	5.4	4.89	1.03	(0.23, 4.60)	0.9711	
Rest of the World	23	0	0.0	0.00	34	3	8.8	8.86	>10	(NC, NC)	0.9871	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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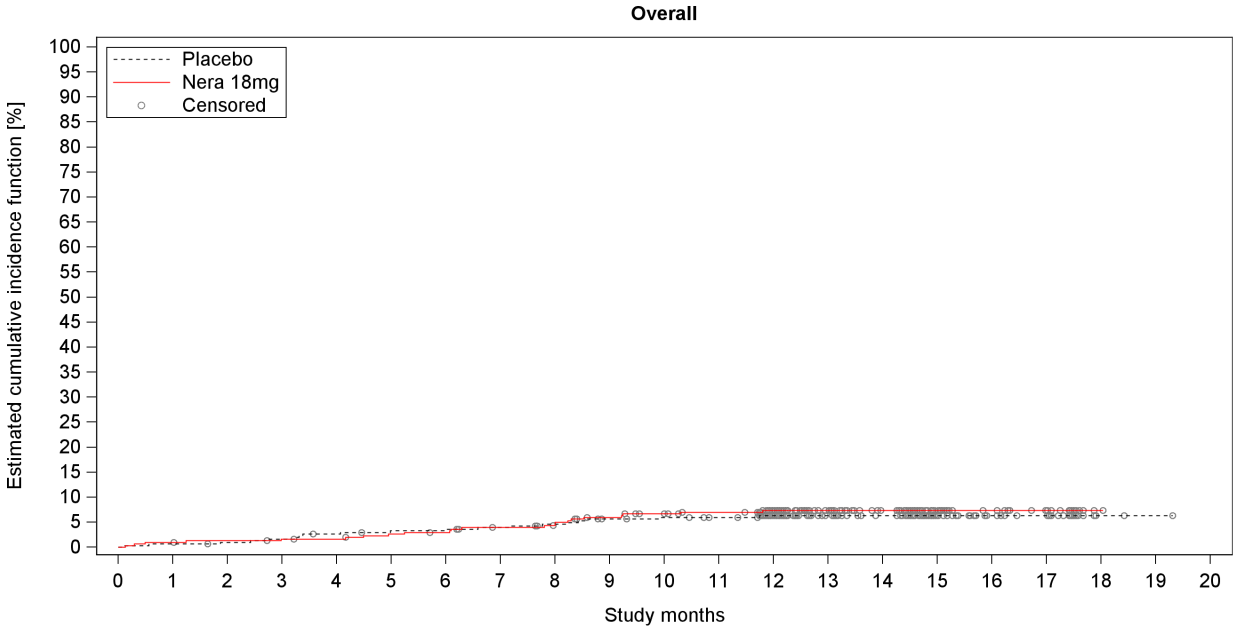

Number at risk (percentage relative to baseline)																					
Placebo	306	304	302	299	295	292	292	289	285	280	278	275	203	137	121	42	25	21	2	1	0
%	100.0	99.3	98.7	97.7	96.4	95.4	95.4	94.4	93.1	91.5	90.8	89.9	66.3	44.8	39.5	13.7	8.2	6.9	0.7	0.3	0.0
Nera 18mg	305	302	300	299	298	294	292	287	285	277	272	266	199	141	119	43	27	20	1	0	0
%	100.0	99.0	98.4	98.0	97.7	96.4	95.7	94.1	93.4	90.8	89.2	87.2	65.2	46.2	39.0	14.1	8.9	6.6	0.3	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																					
Placebo	0	0	1	2	3	4	4	5	7	9	10	13	84	150	166	245	262	266	285	286	287
%	0.0	0.0	0.3	0.7	1.0	1.3	1.3	1.6	2.3	2.9	3.3	4.2	27.5	49.0	54.2	80.1	85.6	86.9	93.1	93.5	93.8
Nera 18mg	0	0	1	1	2	3	4	6	7	10	13	18	84	142	164	240	256	263	282	283	283
%	0.0	0.0	0.3	0.3	0.7	1.0	1.3	2.0	2.3	3.3	4.3	5.9	27.5	46.6	53.8	78.7	83.9	86.2	92.5	92.8	92.8

Study: 1305-0014

Figure H.2.1.1.1.2.2: 1 Time to first confirmed acute IPF exacerbation over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (AF background)

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Figure H.2.1.1.1.2.2: 1

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H.2.1.1.1.2.3 Time to first confirmed or suspected acute IPF exacerbation

Table H.2.1.1.1.2.3: 1 Cox model for time to first confirmed or suspected acute IPF exacerbation over the whole trial (DBL1) - 18mg - FAS (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	306	22	7.2	6.75	305	29	9.5	9.00	1.37	(0.79, 2.39)	0.2673	
Age												0.4556
<65 years	69	4	5.8	5.19	63	3	4.8	4.40	0.81	(0.18, 3.62)	0.7820	
>=65 years	237	18	7.6	7.24	242	26	10.7	10.23	1.50	(0.82, 2.74)	0.1908	
Sex												0.9833
Male	269	22	8.2	7.72	255	26	10.2	9.65	1.33	(0.76, 2.36)	0.3203	
Female	37	0	0.0	0.00	50	3	6.0	5.67	>10	(NC, NC)	0.9830	
Baseline FVC percent predicted												0.2197
<=70%	109	10	9.2	8.81	112	18	16.1	16.36	1.85	(0.85, 4.03)	0.1194	
>70%	197	12	6.1	5.65	193	11	5.7	5.18	0.92	(0.40, 2.08)	0.8336	
Type of AF therapy												0.4182
Nintedanib	173	13	7.5	7.01	178	15	8.4	8.02	1.12	(0.53, 2.36)	0.7633	
Pirfenidone	133	9	6.8	6.41	127	14	11.0	10.34	1.78	(0.77, 4.14)	0.1788	
Region												0.6347
Europe	136	8	5.9	5.63	136	14	10.3	9.91	1.65	(0.69, 3.94)	0.2617	
Asia	72	8	11.1	10.46	79	6	7.6	6.95	0.77	(0.26, 2.24)	0.6298	
Canada and USA	75	6	8.0	7.39	56	3	5.4	4.89	0.68	(0.17, 2.72)	0.5871	
Rest of the World	23	0	0.0	0.00	34	6	17.6	18.01	>10	(NC, NC)	0.9854	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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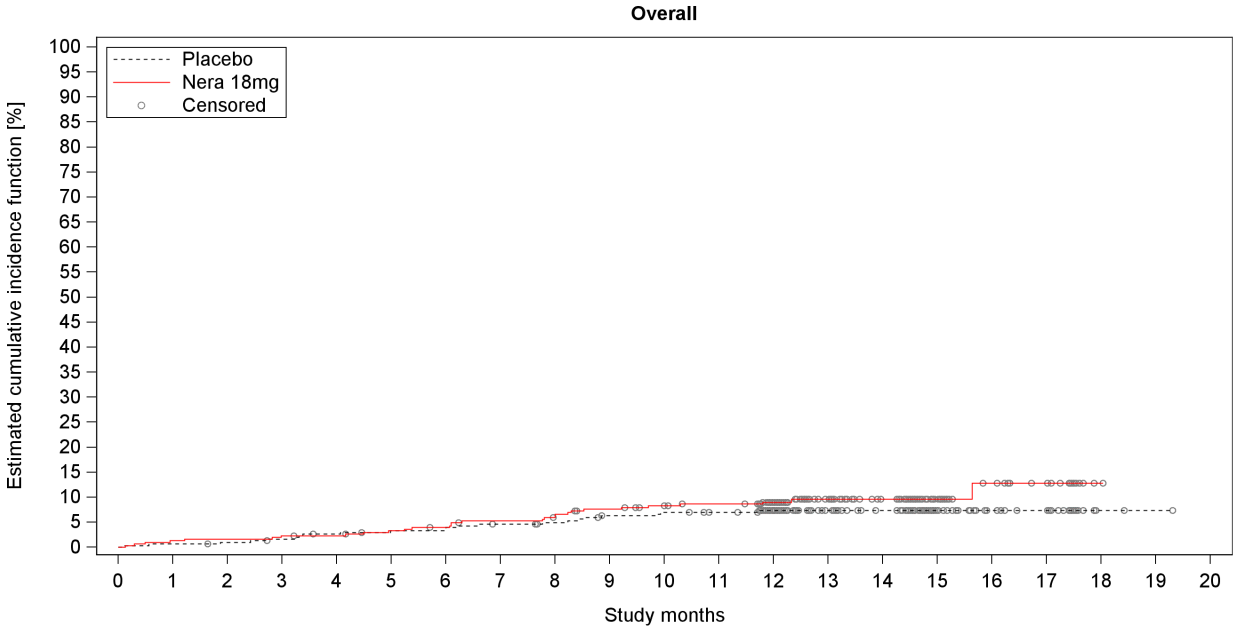

Number at risk (percentage relative to baseline)

Placebo	306	304	302	299	295	292	291	287	284	278	276	273	202	136	120	41	25	21	2	1	0
%	100.0	99.3	98.7	97.7	96.4	95.4	95.1	93.8	92.8	90.8	90.2	89.2	66.0	44.4	39.2	13.4	8.2	6.9	0.7	0.3	0.0
Nera 18mg	305	301	300	298	297	293	290	285	282	275	270	265	198	140	118	43	26	20	1	0	0
%	100.0	98.7	98.4	97.7	97.4	96.1	95.1	93.4	92.5	90.2	88.5	86.9	64.9	45.9	38.7	14.1	8.5	6.6	0.3	0.0	0.0

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

Placebo	0	0	1	2	3	4	4	5	7	9	9	12	82	148	164	243	259	263	282	283	284
%	0.0	0.0	0.3	0.7	1.0	1.3	1.3	1.6	2.3	2.9	2.9	3.9	26.8	48.4	53.6	79.4	84.6	85.9	92.2	92.5	92.8
Nera 18mg	0	0	0	0	1	2	3	4	5	7	10	14	80	137	159	234	250	256	275	276	276
%	0.0	0.0	0.0	0.0	0.3	0.7	1.0	1.3	1.6	2.3	3.3	4.6	26.2	44.9	52.1	76.7	82.0	83.9	90.2	90.5	90.5

Study: 1305-0014

Figure H.2.1.1.1.2.3: 1 Time to first confirmed or suspected acute IPF exacerbation over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (AF background)

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Figure H.2.1.1.1.2.3: 1

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H.2.1.1.1.2.4 Time to first respiratory hospitalisation

Table H.2.1.1.1.2.4: 1 Cox model for time to first respiratory hospitalisation over the whole trial (DBL1) - 18mg - FAS (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	306	44	14.4	13.95	305	59	19.3	19.10	1.46	(0.99, 2.16)	0.0585	
Age												0.5240
<65 years	69	9	13.0	11.97	63	9	14.3	13.50	1.13	(0.45, 2.84)	0.8029	
>=65 years	237	35	14.8	14.57	242	50	20.7	20.65	1.57	(1.02, 2.42)	0.0417	
Sex												0.2603
Male	269	43	16.0	15.63	255	51	20.0	19.76	1.41	(0.94, 2.11)	0.1010	
Female	37	1	2.7	2.48	50	8	16.0	15.78	4.75	(0.59, 38.07)	0.1422	
Baseline FVC percent predicted												0.3324
<=70%	109	21	19.3	19.17	112	33	29.5	31.85	1.73	(1.00, 2.99)	0.0511	
>70%	197	23	11.7	11.17	193	26	13.5	12.67	1.17	(0.67, 2.06)	0.5808	
Type of AF therapy												0.9472
Nintedanib	173	24	13.9	13.33	178	35	19.7	19.62	1.45	(0.86, 2.44)	0.1602	
Pirfenidone	133	20	15.0	14.77	127	24	18.9	18.40	1.49	(0.82, 2.71)	0.1905	
Region												0.7641
Europe	136	14	10.3	10.11	136	25	18.4	18.42	1.72	(0.90, 3.32)	0.1034	
Asia	72	15	20.8	20.07	79	18	22.8	22.31	1.51	(0.75, 3.02)	0.2478	
Canada and USA	75	12	16.0	15.38	56	8	14.3	13.36	0.96	(0.39, 2.35)	0.9293	
Rest of the World	23	3	13.0	12.40	34	8	23.5	24.57	1.72	(0.45, 6.57)	0.4244	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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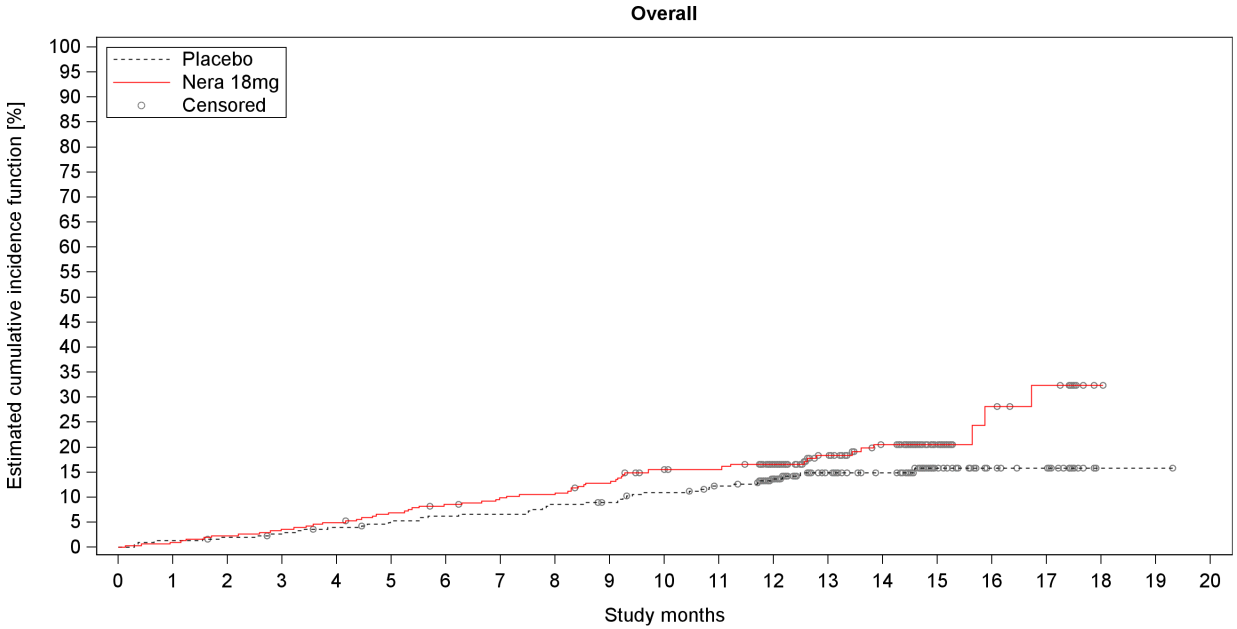

Number at risk (percentage relative to baseline)																				
Placebo	306	302	299	296	291	286	283	282	276	273	266	259	185	123	108	37	20	17	1	1	0
%	100.0	98.7	97.7	96.7	95.1	93.5	92.5	92.2	90.2	89.2	86.9	84.6	60.5	40.2	35.3	12.1	6.5	5.6	0.3	0.3	0.0
Nera 18mg	305	302	298	294	290	283	277	272	270	262	251	249	184	128	107	36	19	16	1	0	0
%	100.0	99.0	97.7	96.4	95.1	92.8	90.8	89.2	88.5	85.9	82.3	81.6	60.3	42.0	35.1	11.8	6.2	5.2	0.3	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																					
Placebo	0	0	1	2	3	4	4	4	4	6	7	10	80	140	155	225	242	245	261	261	262
%	0.0	0.0	0.3	0.7	1.0	1.3	1.3	1.3	1.3	2.0	2.3	3.3	26.1	45.8	50.7	73.5	79.1	80.1	85.3	85.3	85.6
Nera 18mg	0	0	0	0	0	1	2	3	3	4	7	9	71	124	142	213	228	230	245	246	246
%	0.0	0.0	0.0	0.0	0.0	0.3	0.7	1.0	1.0	1.3	2.3	3.0	23.3	40.7	46.6	69.8	74.8	75.4	80.3	80.7	80.7

Study: 1305-0014

Figure H.2.1.1.1.2.4: 1 Time to first respiratory hospitalisation over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (AF background)

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Figure H.2.1.1.1.2.4: 1

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H.2.1.1.1.2.5 Time to first non-elective hospitalisation for any cause

Table H.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 (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	306	74	24.2	25.31	305	85	27.9	29.01	1.17	(0.86,	1.60)	0.3281	
Age													0.4470
<65 years	69	14	20.3	20.08	63	12	19.0	18.59	0.90	(0.41,	1.94)	0.7807	
>=65 years	237	60	25.3	26.94	242	73	30.2	31.95	1.24	(0.88,	1.75)	0.2125	
Sex													0.2419
Male	269	71	26.4	27.97	255	73	28.6	29.85	1.13	(0.81,	1.56)	0.4717	
Female	37	3	8.1	7.77	50	12	24.0	24.76	2.47	(0.69,	8.77)	0.1631	
Baseline FVC percent predicted													0.1853
<=70%	109	29	26.6	28.48	112	41	36.6	42.08	1.47	(0.91,	2.37)	0.1121	
>70%	197	45	22.8	23.61	193	44	22.8	22.49	0.96	(0.63,	1.46)	0.8484	
Type of AF therapy													0.6457
Nintedanib	173	39	22.5	23.19	178	50	28.1	29.48	1.25	(0.82,	1.90)	0.2954	
Pirfenidone	133	35	26.3	28.17	127	35	27.6	28.36	1.08	(0.67,	1.73)	0.7511	
Region													0.1279
Europe	136	27	19.9	20.74	136	36	26.5	27.74	1.29	(0.78,	2.13)	0.3186	
Asia	72	19	26.4	26.82	79	28	35.4	38.51	1.59	(0.88,	2.87)	0.1223	
Canada and USA	75	24	32.0	35.00	56	11	19.6	18.77	0.56	(0.28,	1.15)	0.1137	
Rest of the World	23	4	17.4	17.53	34	10	29.4	31.31	1.74	(0.54,	5.60)	0.3493	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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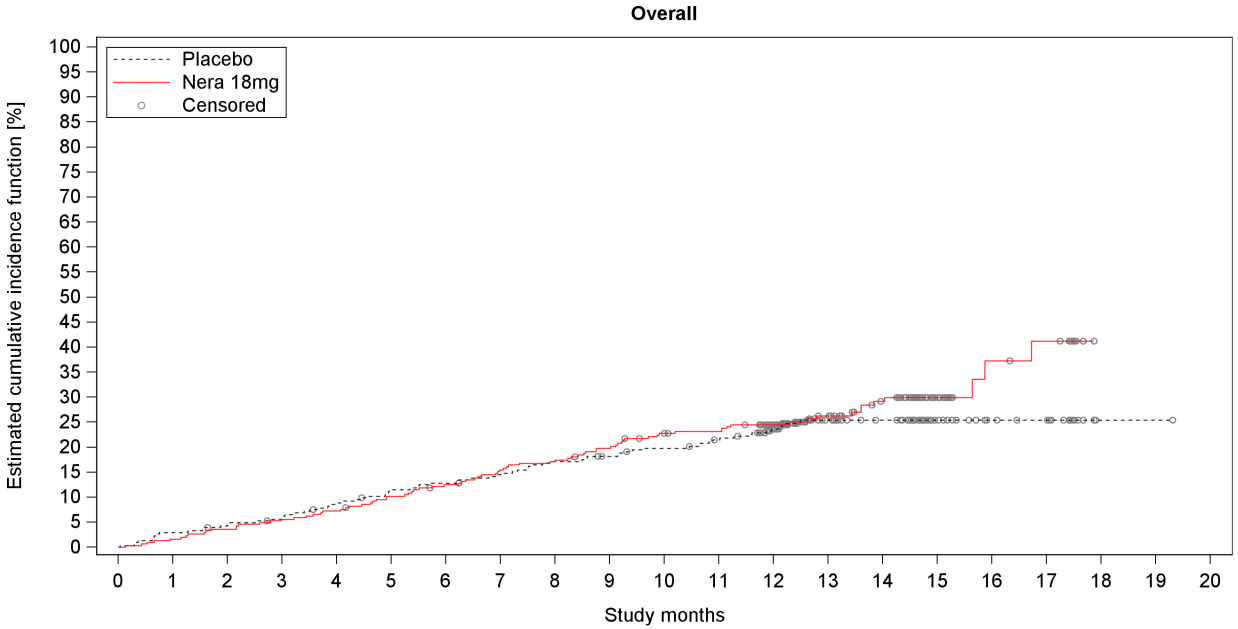

Number at risk (percentage relative to baseline)

Placebo	306	297	292	287	277	267	263	258	250	245	239	232	162	106	94	30	17	15	1	1	0
%	100.0	97.1	95.4	93.8	90.5	87.3	85.9	84.3	81.7	80.1	78.1	75.8	52.9	34.6	30.7	9.8	5.6	4.9	0.3	0.3	0.0
Nera 18mg	305	300	294	288	283	273	265	255	250	241	230	227	164	116	97	33	17	15	0	0	0
%	100.0	98.4	96.4	94.4	92.8	89.5	86.9	83.6	82.0	79.0	75.4	74.4	53.8	38.0	31.8	10.8	5.6	4.9	0.0	0.0	0.0

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

Placebo	0	0	1	2	3	4	4	4	4	6	7	9	73	126	138	202	215	217	231	231	232
%	0.0	0.0	0.3	0.7	1.0	1.3	1.3	1.3	1.3	2.0	2.3	2.9	23.9	41.2	45.1	66.0	70.3	70.9	75.5	75.5	75.8
Nera 18mg	0	0	0	0	0	1	2	3	3	4	6	8	67	112	127	190	204	205	220	220	220
%	0.0	0.0	0.0	0.0	0.0	0.3	0.7	1.0	1.0	1.3	2.0	2.6	22.0	36.7	41.6	62.3	66.9	67.2	72.1	72.1	72.1

Study: 1305-0014

Figure H.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 (AF background)

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H.2.1.1.1.3 Time to event analyses of quality of life

H.2.1.1.1.3.1 Living with Pulmonary Fibrosis (L-PF) total scores

Table H.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 (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	306	100	32.7	37.76	305	109	35.7	42.37	1.18	(0.90, 1.55)	0.2439	
Age												0.2649
<65 years	69	26	37.7	41.04	63	21	33.3	36.77	0.88	(0.50, 1.57)	0.6753	
>=65 years	237	74	31.2	36.72	242	88	36.4	43.97	1.28	(0.94, 1.75)	0.1165	
Sex												0.5814
Male	269	90	33.5	39.01	255	91	35.7	42.13	1.14	(0.85, 1.53)	0.3768	
Female	37	10	27.0	29.27	50	18	36.0	43.61	1.44	(0.66, 3.14)	0.3564	
Baseline FVC percent predicted												0.0423
<=70%	109	47	43.1	55.14	112	39	34.8	45.55	0.83	(0.54, 1.27)	0.3895	
>70%	197	53	26.9	29.51	193	70	36.3	40.78	1.48	(1.03, 2.11)	0.0340	
Type of AF therapy												0.2084
Nintedanib	173	58	33.5	38.58	178	55	30.9	37.63	1.00	(0.69, 1.45)	0.9857	
Pirfenidone	133	42	31.6	36.67	127	54	42.5	48.61	1.43	(0.95, 2.14)	0.0864	
Region												0.3912
Europe	136	39	28.7	31.92	136	51	37.5	44.47	1.42	(0.93, 2.16)	0.1015	
Asia	72	30	41.7	51.35	79	26	32.9	38.50	0.79	(0.46, 1.33)	0.3707	
Canada and USA	75	23	30.7	34.49	56	19	33.9	39.01	1.18	(0.64, 2.17)	0.5942	
Rest of the World	23	8	34.8	45.51	34	13	38.2	49.37	1.23	(0.51, 2.98)	0.6437	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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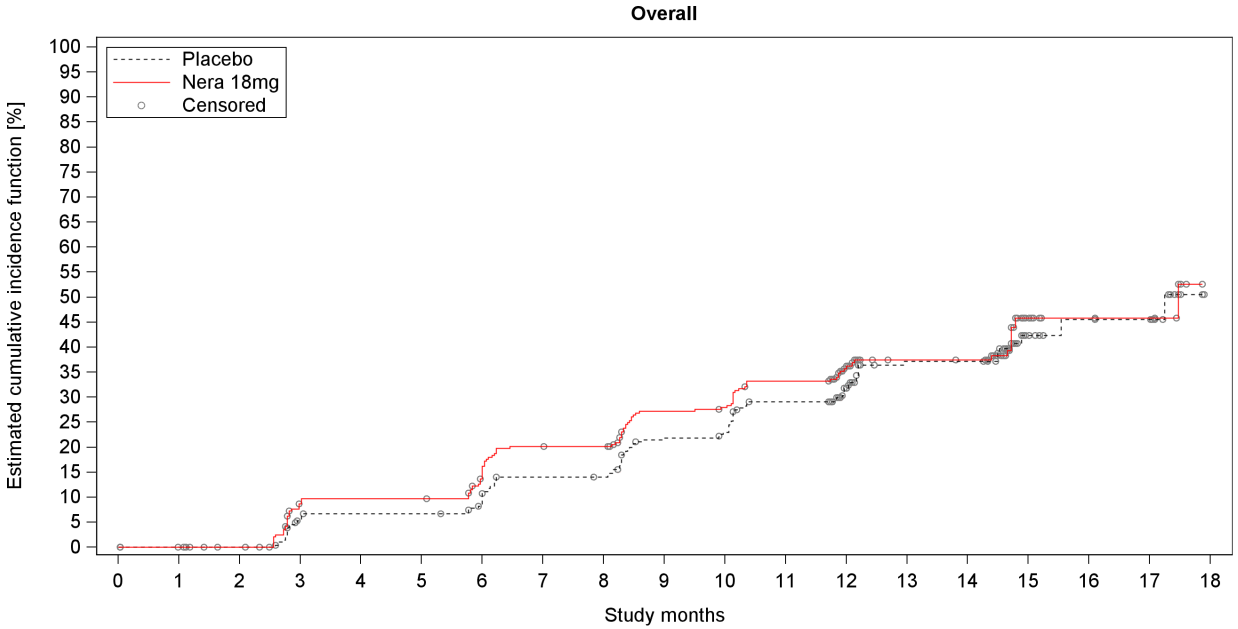

Number at risk (percentage relative to baseline)																			
Placebo	306	291	289	263	259	259	251	233	232	208	204	185	122	82	82	25	17	16	0
%	100.0	95.1	94.4	85.9	84.6	84.6	82.0	76.1	75.8	68.0	66.7	60.5	39.9	26.8	26.8	8.2	5.6	5.2	0.0
Nera 18mg	305	294	290	259	256	256	240	222	221	195	192	177	118	82	81	17	11	10	0
%	100.0	96.4	95.1	84.9	83.9	83.9	78.7	72.8	72.5	63.9	63.0	58.0	38.7	26.9	26.6	5.6	3.6	3.3	0.0
Number censored (percentage relative to number at risk at baseline)																			
Placebo	0	15	17	27	28	28	31	34	35	38	39	42	99	131	131	183	190	191	206
%	0.0	4.9	5.6	8.8	9.2	9.2	10.1	11.1	11.4	12.4	12.7	13.7	32.4	42.8	42.8	59.8	62.1	62.4	67.3
Nera 18mg	0	11	15	21	21	21	26	26	27	34	35	36	89	122	123	180	186	187	196
%	0.0	3.6	4.9	6.9	6.9	6.9	8.5	8.5	8.9	11.1	11.5	11.8	29.2	40.0	40.3	59.0	61.0	61.3	64.3

Study: 1305-0014

Figure H.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 (AF background)

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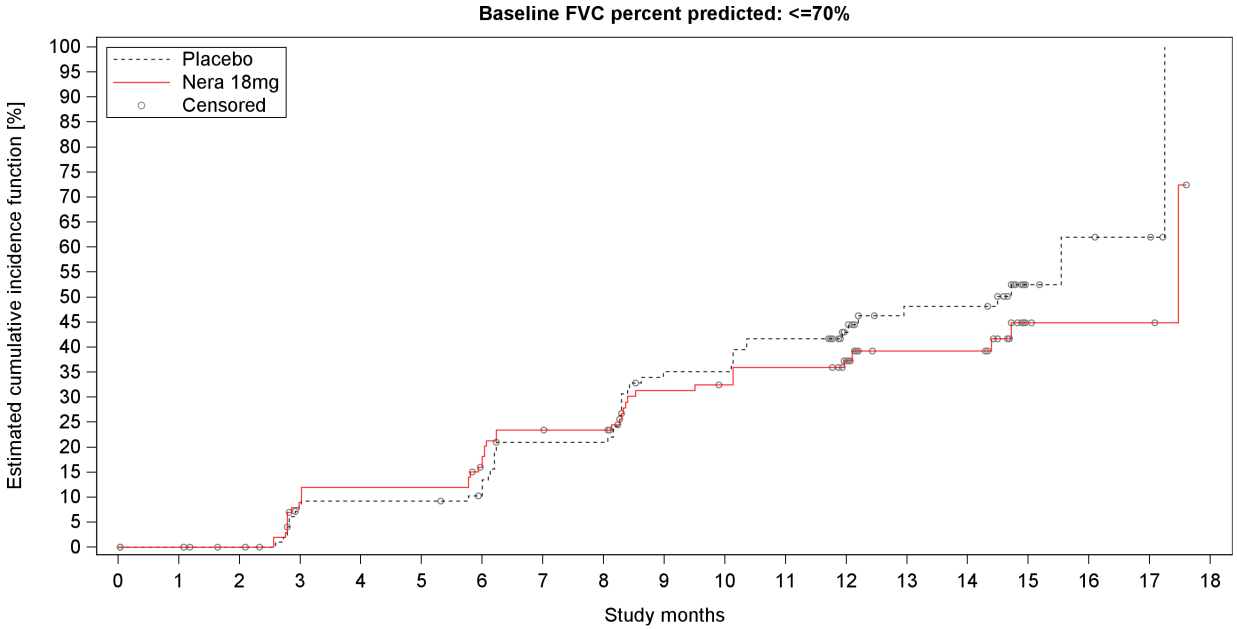

Number at risk (percentage relative to baseline)																			
Placebo	109	101	100	88	87	87	84	73	73	59	59	53	37	27	27	6	4	3	0
%	100.0	92.7	91.7	80.7	79.8	79.8	77.1	67.0	67.0	54.1	54.1	48.6	33.9	24.8	24.8	5.5	3.7	2.8	0.0
Nera 18mg	112	104	102	90	87	87	80	73	72	60	58	55	40	27	27	4	3	3	0
%	100.0	92.9	91.1	80.4	77.7	77.7	71.4	65.2	64.3	53.6	51.8	49.1	35.7	24.1	24.1	3.6	2.7	2.7	0.0
Number censored (percentage relative to number at risk at baseline)																			
Placebo	0	8	9	13	13	13	15	16	16	17	17	17	32	39	39	58	59	60	62
%	0.0	7.3	8.3	11.9	11.9	11.9	13.8	14.7	14.7	15.6	15.6	15.6	29.4	35.8	35.8	53.2	54.1	55.0	56.9
Nera 18mg	0	8	10	13	13	13	16	16	17	22	23	23	37	49	49	70	71	71	73
%	0.0	7.1	8.9	11.6	11.6	11.6	14.3	14.3	15.2	19.6	20.5	20.5	33.0	43.8	43.8	62.5	63.4	63.4	65.2

Study: 1305-0014

Figure H.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 (AF background)

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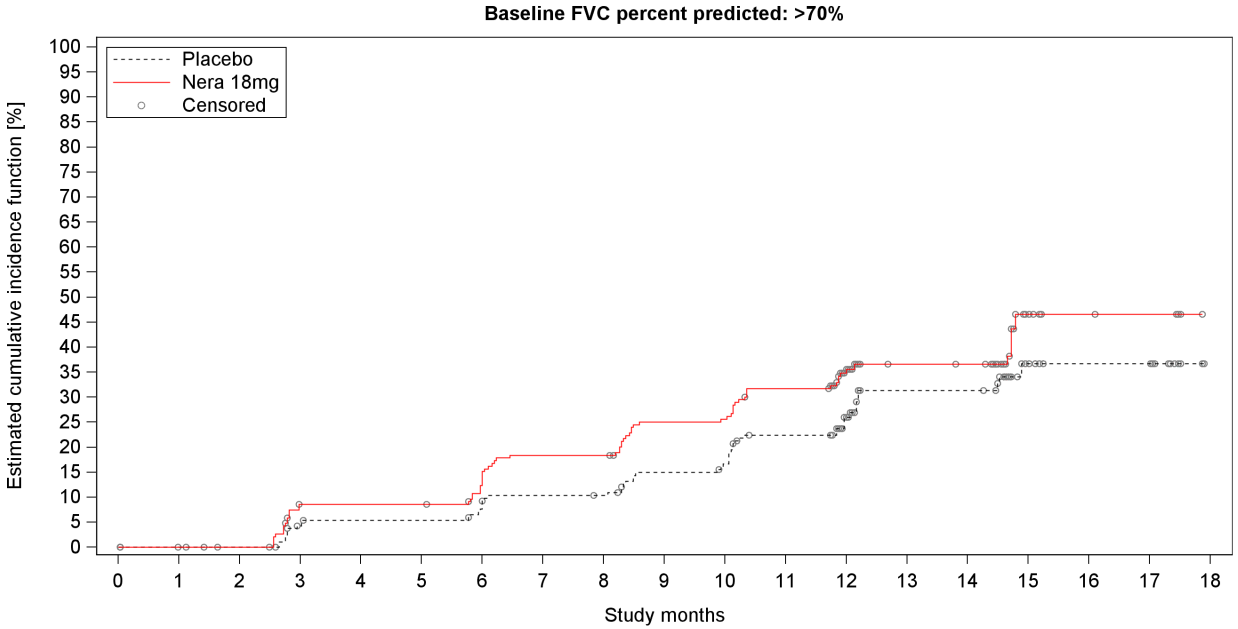

Number at risk (percentage relative to baseline)																			
Placebo	197	190	189	175	172	172	167	160	159	149	145	132	85	55	55	19	13	13	0
%	100.0	96.4	95.9	88.8	87.3	87.3	84.8	81.2	80.7	75.6	73.6	67.0	43.1	27.9	27.9	9.6	6.6	6.6	0.0
Nera 18mg	193	190	188	169	169	169	160	149	149	135	134	122	78	55	54	13	8	7	0
%	100.0	98.4	97.4	87.6	87.6	87.6	82.9	77.2	77.2	69.9	69.4	63.2	40.4	28.5	28.0	6.7	4.1	3.6	0.0
Number censored (percentage relative to number at risk at baseline)																			
Placebo	0	7	8	14	15	15	16	18	19	21	22	25	67	92	92	125	131	131	144
%	0.0	3.6	4.1	7.1	7.6	7.6	8.1	9.1	9.6	10.7	11.2	12.7	34.0	46.7	46.7	63.5	66.5	66.5	73.1
Nera 18mg	0	3	5	8	8	8	10	10	10	12	12	13	52	73	74	110	115	116	123
%	0.0	1.6	2.6	4.1	4.1	4.1	5.2	5.2	5.2	6.2	6.2	6.7	26.9	37.8	38.3	57.0	59.6	60.1	63.7

Study: 1305-0014

Figure H.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 (AF background)

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Table H.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 (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	306	123	40.2	48.61	305	119	39.0	47.58	1.03	(0.80,	1.33)	0.7963	
Age													0.5358
<65 years	69	26	37.7	42.10	63	21	33.3	37.44	0.88	(0.50,	1.58)	0.6774	
>=65 years	237	97	40.9	50.71	242	98	40.5	50.51	1.08	(0.82,	1.44)	0.5776	
Sex													0.6242
Male	269	111	41.3	50.45	255	99	38.8	46.99	1.01	(0.77,	1.32)	0.9670	
Female	37	12	32.4	36.37	50	20	40.0	50.70	1.22	(0.59,	2.51)	0.5887	
Baseline FVC percent predicted													0.9791
<=70%	109	50	45.9	60.13	112	47	42.0	58.87	1.04	(0.70,	1.55)	0.8574	
>70%	197	73	37.1	42.97	193	72	37.3	42.28	1.03	(0.74,	1.43)	0.8591	
Type of AF therapy													0.9314
Nintedanib	173	69	39.9	47.00	178	66	37.1	47.11	1.02	(0.73,	1.44)	0.8924	
Pirfenidone	133	54	40.6	50.84	127	53	41.7	48.18	1.05	(0.71,	1.53)	0.8141	
Region													0.7269
Europe	136	51	37.5	44.06	136	55	40.4	49.52	1.16	(0.79,	1.70)	0.4438	
Asia	72	34	47.2	60.86	79	30	38.0	45.88	0.81	(0.49,	1.32)	0.3964	
Canada and USA	75	29	38.7	45.91	56	23	41.1	48.52	1.03	(0.59,	1.80)	0.9064	
Rest of the World	23	9	39.1	49.34	34	11	32.4	41.89	1.04	(0.43,	2.51)	0.9330	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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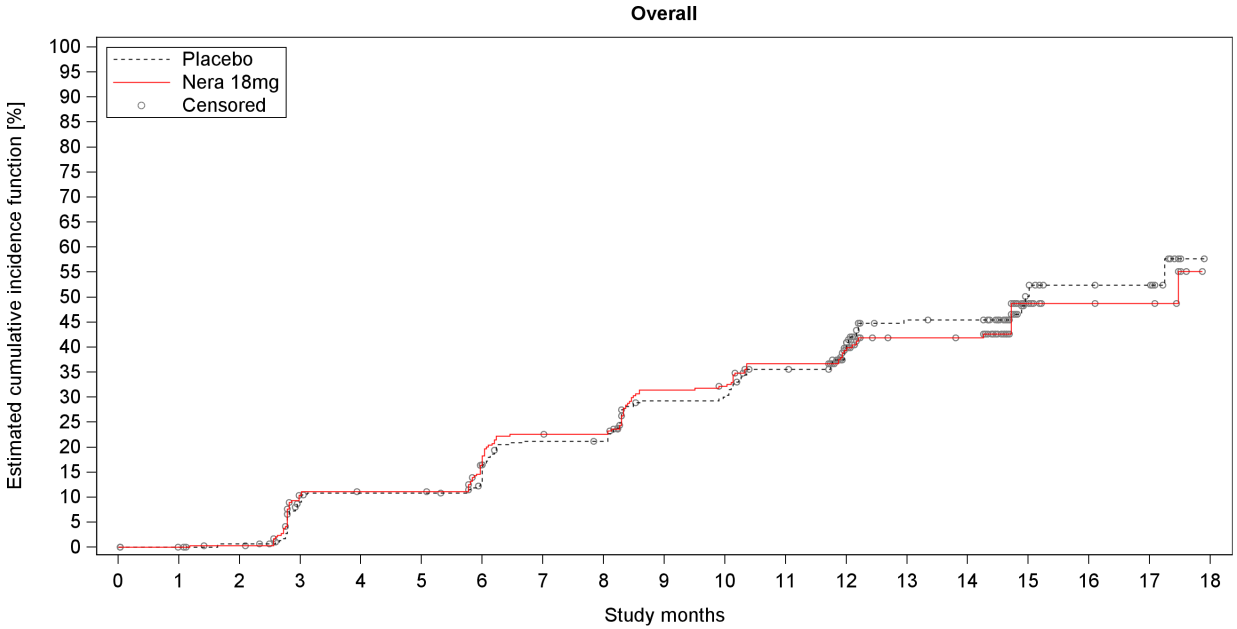

Number at risk (percentage relative to baseline)																			
Placebo	306	292	290	258	252	252	243	217	216	191	189	172	110	74	73	22	15	14	0
%	100.0	95.4	94.8	84.3	82.4	82.4	79.4	70.9	70.6	62.4	61.8	56.2	35.9	24.2	23.9	7.2	4.9	4.6	0.0
Nera 18mg	305	295	291	255	252	252	232	215	214	184	181	166	106	75	74	17	11	10	0
%	100.0	96.7	95.4	83.6	82.6	82.6	76.1	70.5	70.2	60.3	59.3	54.4	34.8	24.6	24.3	5.6	3.6	3.3	0.0
Number censored (percentage relative to number at risk at baseline)																			
Placebo	0	14	14	22	23	23	26	29	30	33	33	35	87	114	115	163	169	170	183
%	0.0	4.6	4.6	7.2	7.5	7.5	8.5	9.5	9.8	10.8	10.8	11.4	28.4	37.3	37.6	53.3	55.2	55.6	59.8
Nera 18mg	0	10	13	20	21	21	26	26	27	33	34	37	91	118	119	170	176	177	186
%	0.0	3.3	4.3	6.6	6.9	6.9	8.5	8.5	8.9	10.8	11.1	12.1	29.8	38.7	39.0	55.7	57.7	58.0	61.0

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.2.1.1.1.3.1: 2

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Table H.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 (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	306	111	36.3	42.00	305	128	42.0	51.08	1.27	(0.99, 1.64)	0.0648	
Age												0.7725
<65 years	69	27	39.1	42.14	63	27	42.9	50.26	1.18	(0.69, 2.02)	0.5347	
>=65 years	237	84	35.4	41.95	242	101	41.7	51.30	1.30	(0.97, 1.74)	0.0817	
Sex												0.7413
Male	269	97	36.1	42.22	255	106	41.6	50.26	1.25	(0.95, 1.65)	0.1169	
Female	37	14	37.8	40.56	50	22	44.0	55.44	1.41	(0.71, 2.83)	0.3254	
Baseline FVC percent predicted												0.4746
<=70%	109	45	41.3	51.88	112	49	43.8	59.17	1.12	(0.74, 1.68)	0.5907	
>70%	197	66	33.5	37.17	193	79	40.9	47.08	1.35	(0.97, 1.88)	0.0727	
Type of AF therapy												0.6452
Nintedanib	173	61	35.3	40.63	178	68	38.2	46.87	1.21	(0.85, 1.71)	0.2846	
Pirfenidone	133	50	37.6	43.80	127	60	47.2	56.85	1.36	(0.93, 1.99)	0.1076	
Region												0.7894
Europe	136	47	34.6	39.34	136	58	42.6	52.79	1.40	(0.95, 2.06)	0.0925	
Asia	72	27	37.5	44.70	79	33	41.8	49.97	1.16	(0.70, 1.94)	0.5664	
Canada and USA	75	25	33.3	37.27	56	22	39.3	45.06	1.24	(0.70, 2.20)	0.4616	
Rest of the World	23	12	52.2	69.17	34	15	44.1	57.96	0.91	(0.42, 1.95)	0.8094	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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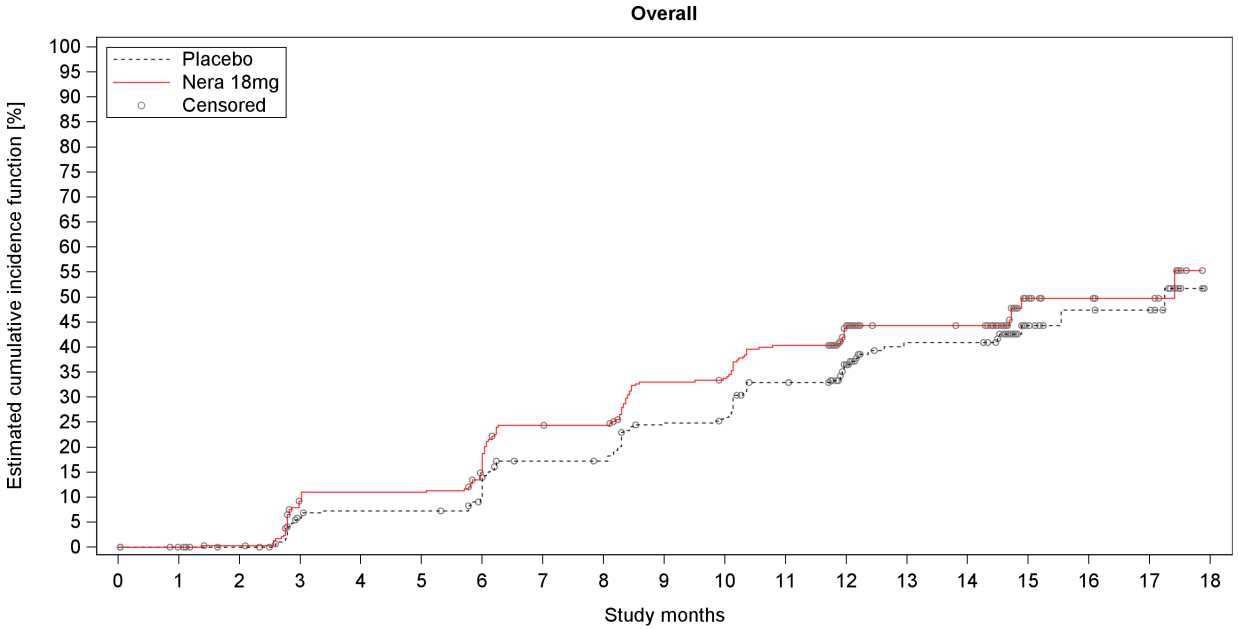

Number at risk (percentage relative to baseline)																			
Placebo	306	298	296	269	264	264	253	229	228	205	201	179	113	76	76	25	17	16	0
%	100.0	97.4	96.7	87.9	86.3	86.3	82.7	74.8	74.5	67.0	65.7	58.5	36.9	24.8	24.8	8.2	5.6	5.2	0.0
Nera 18mg	305	298	293	261	256	256	241	213	212	185	182	164	99	70	69	18	13	11	0
%	100.0	97.7	96.1	85.6	83.9	83.9	79.0	69.8	69.5	60.7	59.7	53.8	32.5	23.0	22.6	5.9	4.3	3.6	0.0
Number censored (percentage relative to number at risk at baseline)																			
Placebo	0	8	10	20	21	21	24	28	29	31	32	35	93	124	124	172	179	180	195
%	0.0	2.6	3.3	6.5	6.9	6.9	7.8	9.2	9.5	10.1	10.5	11.4	30.4	40.5	40.5	56.2	58.5	58.8	63.7
Nera 18mg	0	7	11	17	17	17	21	22	23	26	27	27	84	112	113	160	165	167	177
%	0.0	2.3	3.6	5.6	5.6	5.6	6.9	7.2	7.5	8.5	8.9	8.9	27.5	36.7	37.0	52.5	54.1	54.8	58.0

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.2.1.1.1.3.1: 3

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H.2.1.1.1.3.2 Living with Pulmonary Fibrosis (L-PF) domain scores

Table H.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 (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	306	151	49.3	64.93	305	159	52.1	71.30	1.13	(0.90,	1.41)	0.2828	
Age													0.5265
<65 years	69	38	55.1	69.28	63	32	50.8	68.03	0.98	(0.61,	1.57)	0.9390	
>=65 years	237	113	47.7	63.59	242	127	52.5	72.17	1.17	(0.90,	1.51)	0.2351	
Sex													0.3377
Male	269	132	49.1	65.79	255	129	50.6	68.54	1.08	(0.84,	1.37)	0.5530	
Female	37	19	51.4	59.57	50	30	60.0	86.23	1.47	(0.81,	2.67)	0.2011	
Baseline FVC percent predicted													0.4434
<=70%	109	58	53.2	75.04	112	57	50.9	75.52	1.00	(0.70,	1.45)	0.9829	
>70%	197	93	47.2	59.90	193	102	52.8	69.14	1.20	(0.91,	1.60)	0.2003	
Type of AF therapy													0.3606
Nintedanib	173	86	49.7	66.67	178	85	47.8	66.70	1.03	(0.76,	1.39)	0.8453	
Pirfenidone	133	65	48.9	62.77	127	74	58.3	77.43	1.27	(0.91,	1.78)	0.1603	
Region													0.4447
Europe	136	61	44.9	57.87	136	73	53.7	75.00	1.36	(0.97,	1.92)	0.0770	
Asia	72	34	47.2	61.31	79	38	48.1	63.04	1.00	(0.63,	1.59)	0.9944	
Canada and USA	75	42	56.0	75.21	56	28	50.0	62.00	0.86	(0.53,	1.39)	0.5403	
Rest of the World	23	14	60.9	88.38	34	20	58.8	98.85	1.19	(0.60,	2.36)	0.6208	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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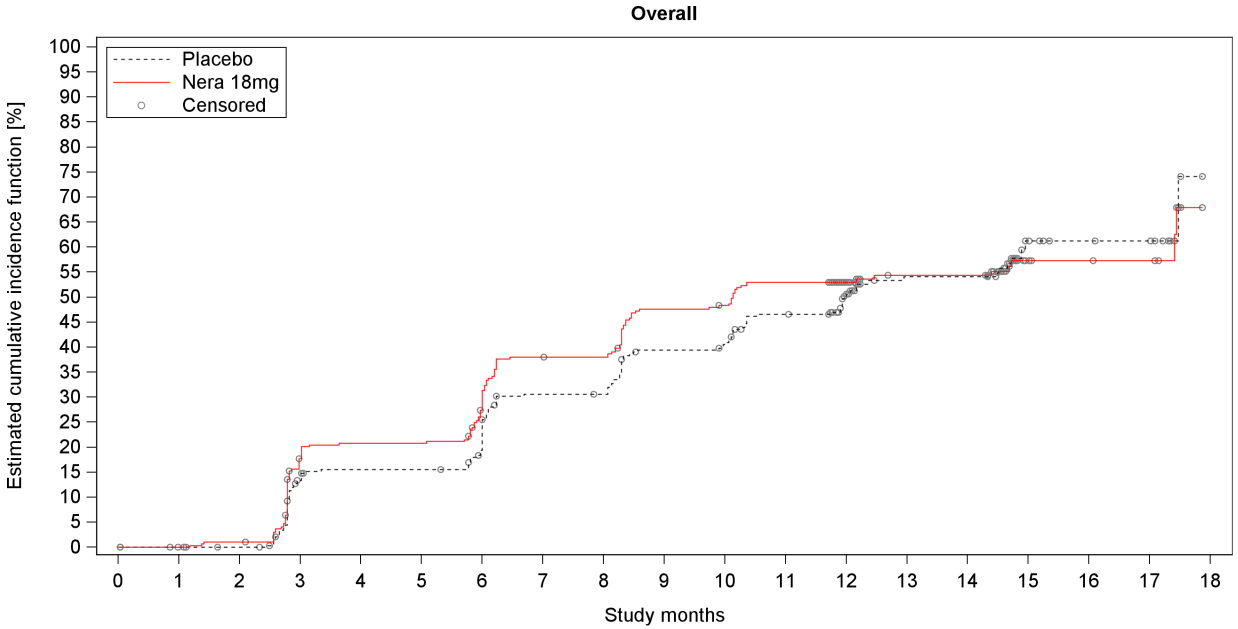

Number at risk (percentage relative to baseline)																			
Placebo	306	298	296	247	239	239	225	190	189	163	159	140	93	59	59	18	12	11	0
%	100.0	97.4	96.7	80.7	78.1	78.1	73.5	62.1	61.8	53.3	52.0	45.8	30.4	19.3	19.3	5.9	3.9	3.6	0.0
Nera 18mg	305	298	293	238	229	229	206	176	175	147	144	131	88	61	61	14	11	10	0
%	100.0	97.7	96.1	78.0	75.1	75.1	67.5	57.7	57.4	48.2	47.2	43.0	28.9	20.0	20.0	4.6	3.6	3.3	0.0
Number censored (percentage relative to number at risk at baseline)																			
Placebo	0	8	10	20	22	22	25	29	30	32	33	36	75	103	103	138	144	145	155
%	0.0	2.6	3.3	6.5	7.2	7.2	8.2	9.5	9.8	10.5	10.8	11.8	24.5	33.7	33.7	45.1	47.1	47.4	50.7
Nera 18mg	0	7	9	15	15	15	19	19	20	21	22	22	65	90	90	134	137	138	146
%	0.0	2.3	3.0	4.9	4.9	4.9	6.2	6.2	6.6	6.9	7.2	7.2	21.3	29.5	29.5	43.9	44.9	45.2	47.9

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.2.1.1.1.3.2: 1

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Table H.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 (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	306	100	32.7	36.87	305	93	30.5	33.63	0.93	(0.70,	1.23)	0.5968	
Age													0.6962
<65 years	69	22	31.9	32.55	63	21	33.3	34.70	1.03	(0.57,	1.88)	0.9120	
>=65 years	237	78	32.9	38.30	242	72	29.8	33.33	0.90	(0.65,	1.25)	0.5375	
Sex													0.5771
Male	269	88	32.7	37.29	255	75	29.4	32.03	0.89	(0.65,	1.21)	0.4515	
Female	37	12	32.4	34.06	50	18	36.0	42.47	1.11	(0.53,	2.33)	0.7734	
Baseline FVC percent predicted													0.8763
<=70%	109	43	39.4	48.45	112	43	38.4	46.54	0.95	(0.62,	1.46)	0.8241	
>70%	197	57	28.9	31.23	193	50	25.9	27.15	0.91	(0.62,	1.34)	0.6323	
Type of AF therapy													0.5497
Nintedanib	173	56	32.4	36.42	178	48	27.0	30.65	0.86	(0.58,	1.26)	0.4290	
Pirfenidone	133	44	33.1	37.45	127	45	35.4	37.52	1.02	(0.67,	1.54)	0.9375	
Region													0.8957
Europe	136	41	30.1	33.33	136	39	28.7	31.39	0.89	(0.57,	1.39)	0.6108	
Asia	72	27	37.5	42.81	79	24	30.4	33.19	0.83	(0.48,	1.45)	0.5236	
Canada and USA	75	25	33.3	37.74	56	21	37.5	41.24	1.13	(0.63,	2.02)	0.6885	
Rest of the World	23	7	30.4	36.97	34	9	26.5	30.96	0.91	(0.34,	2.44)	0.8452	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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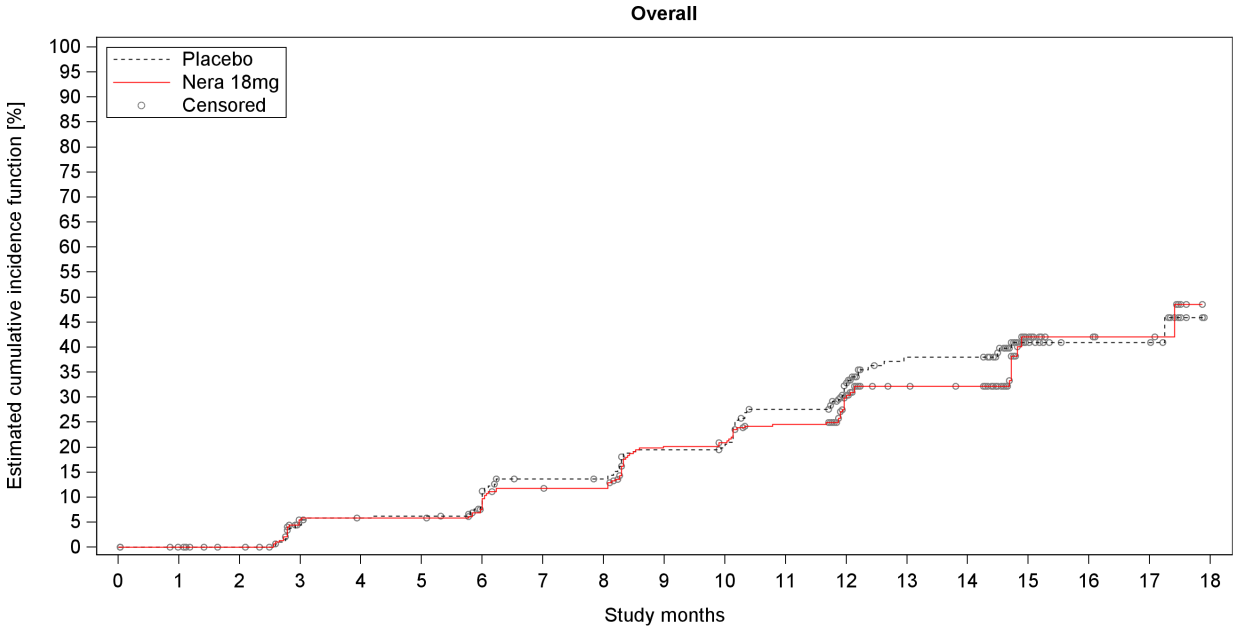

Number at risk (percentage relative to baseline)

Placebo	306	298	296	273	268	267	259	238	237	220	217	195	124	75	75	24	15	15	0
%	100.0	97.4	96.7	89.2	87.6	87.3	84.6	77.8	77.5	71.9	70.9	63.7	40.5	24.5	24.5	7.8	4.9	4.9	0.0
Nera 18mg	305	299	295	274	272	272	261	248	247	218	215	202	126	88	86	20	12	10	0
%	100.0	98.0	96.7	89.8	89.2	89.2	85.6	81.3	81.0	71.5	70.5	66.2	41.3	28.9	28.2	6.6	3.9	3.3	0.0

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

Placebo	0	8	10	20	21	21	24	29	30	31	32	34	94	135	135	183	192	192	206
%	0.0	2.6	3.3	6.5	6.9	6.9	7.8	9.5	9.8	10.1	10.5	11.1	30.7	44.1	44.1	59.8	62.7	62.7	67.3
Nera 18mg	0	6	10	15	16	16	22	23	24	30	31	34	98	132	134	193	201	203	212
%	0.0	2.0	3.3	4.9	5.2	5.2	7.2	7.5	7.9	9.8	10.2	11.1	32.1	43.3	43.9	63.3	65.9	66.6	69.5

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.2.1.1.1.3.2: 2

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Table H.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 (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	306	162	52.9	70.26	305	179	58.7	81.59	1.20	(0.97,	1.49)	0.0951	
Age													0.8600
<65 years	69	37	53.6	63.76	63	36	57.1	73.23	1.15	(0.73,	1.83)	0.5484	
>=65 years	237	125	52.7	72.45	242	143	59.1	84.01	1.21	(0.95,	1.54)	0.1273	
Sex													0.9807
Male	269	143	53.2	71.55	255	149	58.4	81.31	1.19	(0.95,	1.50)	0.1299	
Female	37	19	51.4	61.86	50	30	60.0	83.04	1.20	(0.67,	2.17)	0.5367	
Baseline FVC percent predicted													0.4910
<=70%	109	61	56.0	78.55	112	65	58.0	83.65	1.09	(0.76,	1.54)	0.6445	
>70%	197	101	51.3	66.05	193	114	59.1	80.46	1.27	(0.97,	1.66)	0.0835	
Type of AF therapy													0.2185
Nintedanib	173	87	50.3	64.88	178	102	57.3	83.42	1.35	(1.01,	1.80)	0.0404	
Pirfenidone	133	75	56.4	77.73	127	77	60.6	79.29	1.03	(0.75,	1.42)	0.8473	
Region													0.8336
Europe	136	72	52.9	70.05	136	75	55.1	75.22	1.08	(0.78,	1.50)	0.6362	
Asia	72	38	52.8	71.33	79	47	59.5	83.21	1.18	(0.77,	1.81)	0.4597	
Canada and USA	75	38	50.7	65.64	56	35	62.5	83.30	1.31	(0.83,	2.08)	0.2443	
Rest of the World	23	14	60.9	84.28	34	22	64.7	103.88	1.46	(0.74,	2.86)	0.2710	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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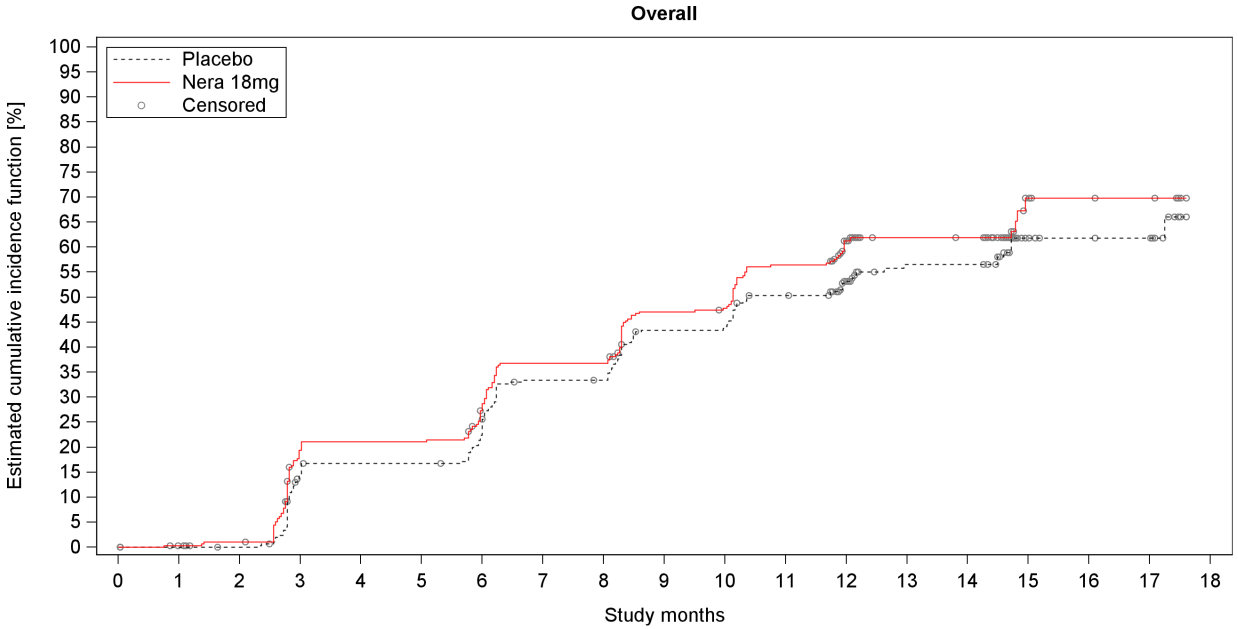

Number at risk (percentage relative to baseline)																			
Placebo	306	298	296	246	238	238	221	187	186	156	155	135	85	60	60	19	14	13	0
%	100.0	97.4	96.7	80.4	77.8	77.8	72.2	61.1	60.8	51.0	50.7	44.1	27.8	19.6	19.6	6.2	4.6	4.2	0.0
Nera 18mg	305	298	293	235	230	230	208	181	181	148	145	121	72	50	49	11	8	7	0
%	100.0	97.7	96.1	77.0	75.4	75.4	68.2	59.3	59.3	48.5	47.5	39.7	23.6	16.4	16.1	3.6	2.6	2.3	0.0
Number censored (percentage relative to number at risk at baseline)																			
Placebo	0	8	10	18	19	19	20	23	24	26	26	28	71	91	91	126	131	132	144
%	0.0	2.6	3.3	5.9	6.2	6.2	6.5	7.5	7.8	8.5	8.5	9.2	23.2	29.7	29.7	41.2	42.8	43.1	47.1
Nera 18mg	0	6	9	13	13	13	17	17	17	21	22	22	59	80	81	115	118	119	126
%	0.0	2.0	3.0	4.3	4.3	4.3	5.6	5.6	5.6	6.9	7.2	7.2	19.3	26.2	26.6	37.7	38.7	39.0	41.3

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.2.1.1.1.3.2: 3

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H.2.1.1.1.3.3 Patient Global Impression of Severity (PGI-S) scores

Table H.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 (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	306	185	60.5	92.73	305	180	59.0	91.60	1.08	(0.88, 1.33)	0.4817	
Age												0.4869
<65 years	69	42	60.9	84.34	63	34	54.0	77.65	0.93	(0.59, 1.47)	0.7664	
>=65 years	237	143	60.3	95.52	242	146	60.3	95.59	1.12	(0.89, 1.42)	0.3434	
Sex												0.1741
Male	269	162	60.2	93.23	255	147	57.6	87.11	1.01	(0.81, 1.27)	0.9182	
Female	37	23	62.2	89.35	50	33	66.0	118.86	1.52	(0.88, 2.63)	0.1295	
Baseline FVC percent predicted												0.2826
<=70%	109	63	57.8	89.80	112	70	62.5	107.43	1.25	(0.89, 1.76)	0.2028	
>70%	197	122	61.9	94.32	193	110	57.0	83.74	0.99	(0.76, 1.28)	0.9169	
Type of AF therapy												0.7921
Nintedanib	173	107	61.8	92.23	178	98	55.1	89.32	1.05	(0.80, 1.38)	0.7271	
Pirfenidone	133	78	58.6	93.43	127	82	64.6	94.47	1.11	(0.81, 1.52)	0.5094	
Region												0.0252
Europe	136	81	59.6	88.10	136	73	53.7	81.33	1.05	(0.77, 1.45)	0.7424	
Asia	72	46	63.9	112.93	79	44	55.7	80.24	0.66	(0.44, 1.00)	0.0526	
Canada and USA	75	45	60.0	88.03	56	41	73.2	127.18	1.58	(1.03, 2.42)	0.0374	
Rest of the World	23	13	56.5	82.77	34	22	64.7	111.76	1.54	(0.77, 3.06)	0.2207	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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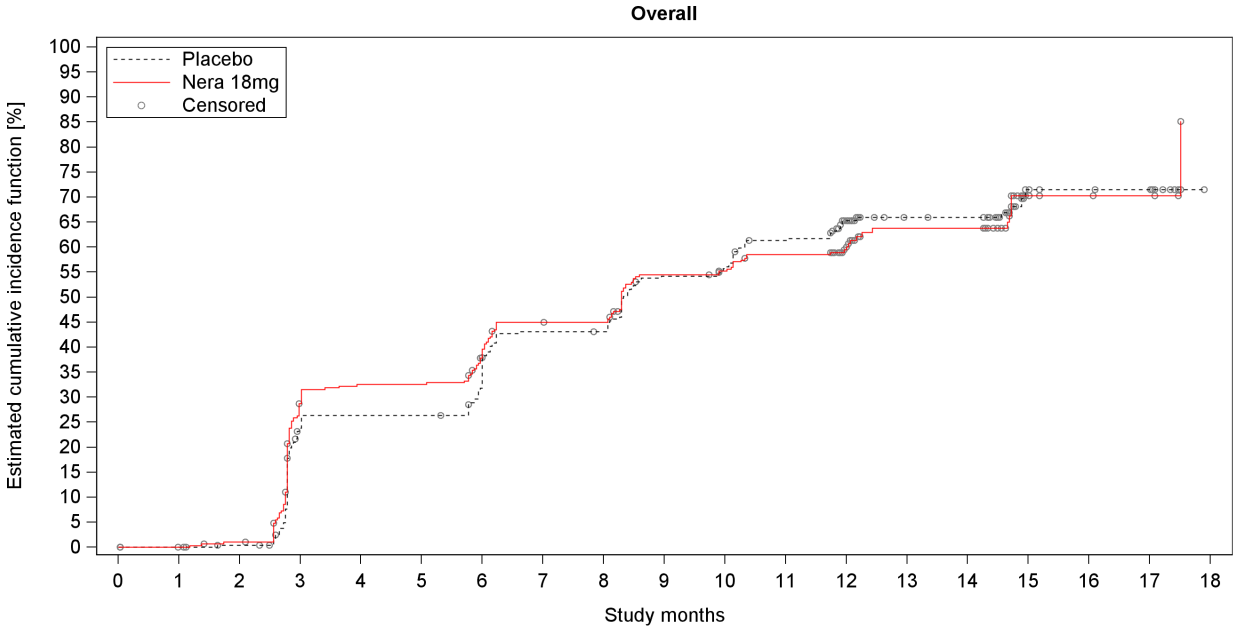

Number at risk (percentage relative to baseline)																			
Placebo	306	291	289	212	205	205	188	155	154	123	118	101	68	46	45	14	11	10	0
%	100.0	95.1	94.4	69.3	67.0	67.0	61.4	50.7	50.3	40.2	38.6	33.0	22.2	15.0	14.7	4.6	3.6	3.3	0.0
Nera 18mg	305	295	289	204	193	193	175	154	153	124	120	110	68	44	44	9	7	6	0
%	100.0	96.7	94.8	66.9	63.3	63.3	57.4	50.5	50.2	40.7	39.3	36.1	22.3	14.4	14.4	3.0	2.3	2.0	0.0
Number censored (percentage relative to number at risk at baseline)																			
Placebo	0	15	16	26	26	26	28	30	31	32	33	35	58	79	80	107	110	111	121
%	0.0	4.9	5.2	8.5	8.5	8.5	9.2	9.8	10.1	10.5	10.8	11.4	19.0	25.8	26.1	35.0	35.9	36.3	39.5
Nera 18mg	0	10	13	18	18	18	21	22	23	26	28	29	69	87	87	117	119	120	125
%	0.0	3.3	4.3	5.9	5.9	5.9	6.9	7.2	7.5	8.5	9.2	9.5	22.6	28.5	28.5	38.4	39.0	39.3	41.0

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.2.1.1.1.3.3: 1

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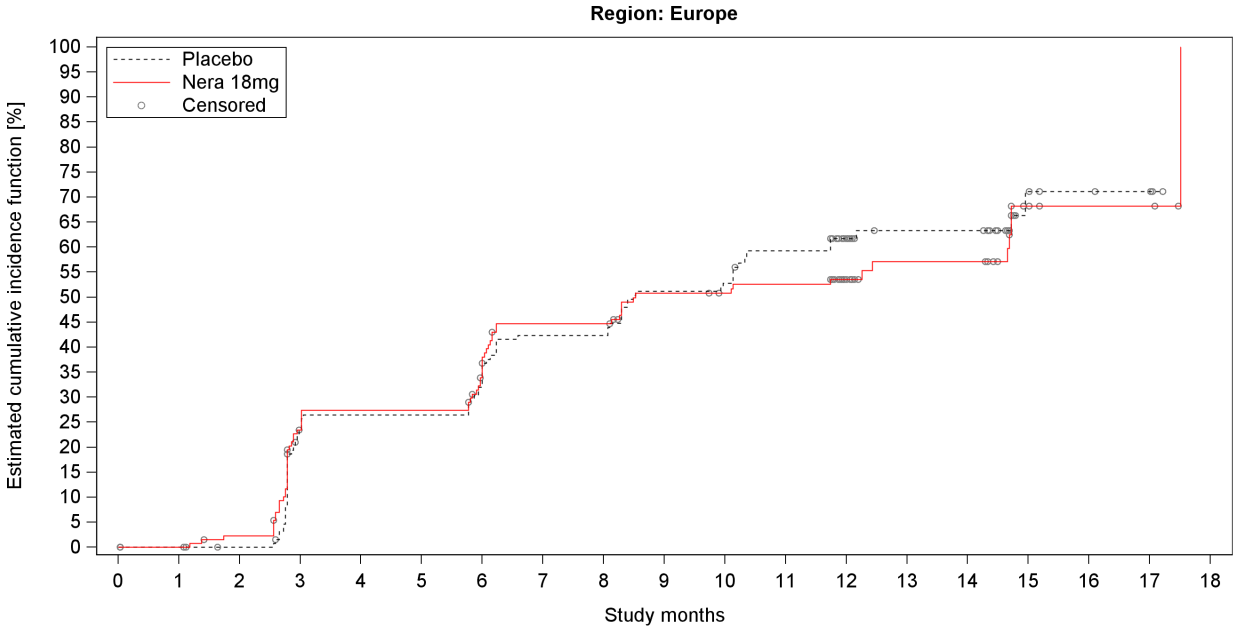

Number at risk (percentage relative to baseline)																			
Placebo	136	131	130	97	93	93	86	72	72	61	59	50	31	22	22	6	4	3	0
%	100.0	96.3	95.6	71.3	68.4	68.4	63.2	52.9	52.9	44.9	43.4	36.8	22.8	16.2	16.2	4.4	2.9	2.2	0.0
Nera 18mg	136	132	126	96	91	91	80	66	66	56	54	52	32	24	24	6	4	4	0
%	100.0	97.1	92.6	70.6	66.9	66.9	58.8	48.5	48.5	41.2	39.7	38.2	23.5	17.6	17.6	4.4	2.9	2.9	0.0
Number censored (percentage relative to number at risk at baseline)																			
Placebo	0	5	6	9	9	9	9	10	10	10	10	11	27	35	35	49	51	52	55
%	0.0	3.7	4.4	6.6	6.6	6.6	6.6	7.4	7.4	7.4	7.4	8.1	19.9	25.7	25.7	36.0	37.5	38.2	40.4
Nera 18mg	0	4	7	10	10	10	13	14	14	17	19	19	38	44	44	58	60	60	63
%	0.0	2.9	5.1	7.4	7.4	7.4	9.6	10.3	10.3	12.5	14.0	14.0	27.9	32.4	32.4	42.6	44.1	44.1	46.3

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.2.1.1.1.3.3: 1

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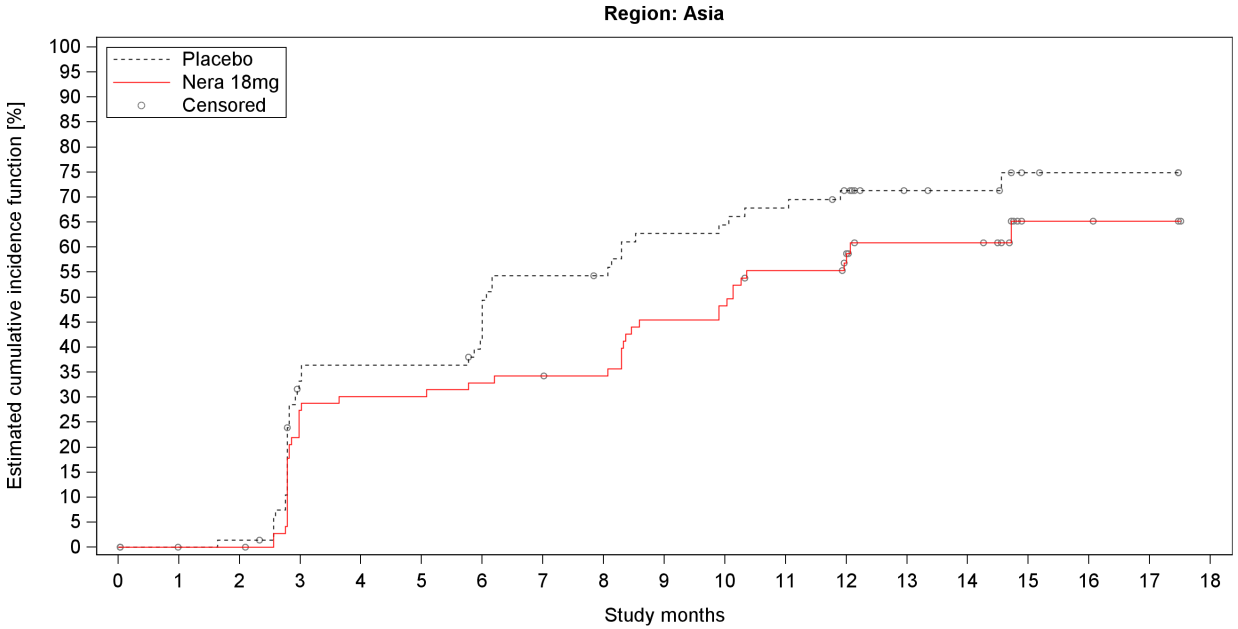

Number at risk (percentage relative to baseline)

Placebo	72	68	67	42	40	40	36	28	27	22	21	19	15	10	9	3	2	2	0
%	100.0	94.4	93.1	58.3	55.6	55.6	50.0	38.9	37.5	30.6	29.2	26.4	20.8	13.9	12.5	4.2	2.8	2.8	0.0
Nera 18mg	79	74	74	53	51	51	49	48	47	39	37	31	23	15	15	3	3	2	0
%	100.0	93.7	93.7	67.1	64.6	64.6	62.0	60.8	59.5	49.4	46.8	39.2	29.1	19.0	19.0	3.8	3.8	2.5	0.0

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

Placebo	0	4	4	8	8	8	9	9	10	10	10	10	12	17	18	23	24	24	26
%	0.0	5.6	5.6	11.1	11.1	11.1	12.5	12.5	13.9	13.9	13.9	13.9	16.7	23.6	25.0	31.9	33.3	33.3	36.1
Nera 18mg	0	5	5	6	6	6	6	6	7	7	7	8	15	21	21	32	32	33	35
%	0.0	6.3	6.3	7.6	7.6	7.6	7.6	7.6	8.9	8.9	8.9	10.1	19.0	26.6	26.6	40.5	40.5	41.8	44.3

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.2.1.1.1.3.3: 1

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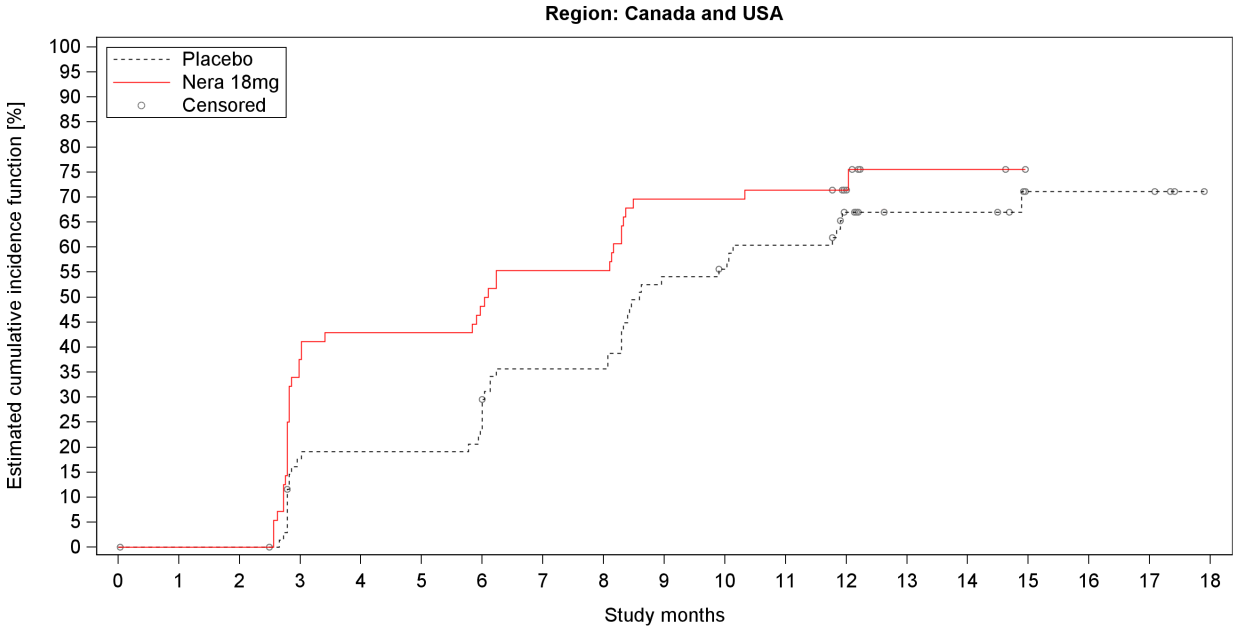

Number at risk (percentage relative to baseline)																			
Placebo	75	70	70	55	54	54	51	42	42	30	28	25	18	12	12	4	4	4	0
%	100.0	93.3	93.3	73.3	72.0	72.0	68.0	56.0	56.0	40.0	37.3	33.3	24.0	16.0	16.0	5.3	5.3	5.3	0.0
Nera 18mg	56	56	56	35	32	32	29	25	25	17	17	16	8	3	3	0	0	0	0
%	100.0	100.0	100.0	62.5	57.1	57.1	51.8	44.6	44.6	30.4	30.4	28.6	14.3	5.4	5.4	0.0	0.0	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																			
Placebo	0	5	5	8	8	8	8	9	9	9	10	10	13	19	19	26	26	26	30
%	0.0	6.7	6.7	10.7	10.7	10.7	10.7	12.0	12.0	12.0	13.3	13.3	17.3	25.3	25.3	34.7	34.7	34.7	40.0
Nera 18mg	0	0	0	0	0	0	0	0	0	0	0	0	8	12	12	15	15	15	15
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	14.3	21.4	21.4	26.8	26.8	26.8	26.8

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.2.1.1.1.3.3: 1

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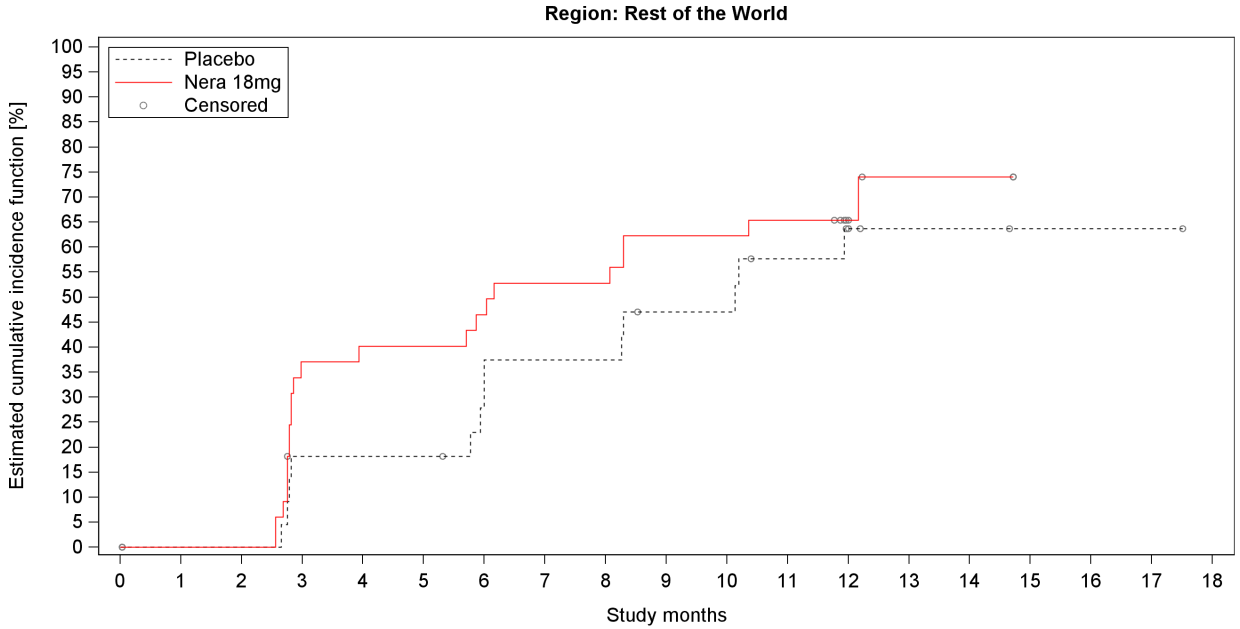

Number at risk (percentage relative to baseline)

Placebo	23	22	22	18	18	18	15	13	13	10	10	7	4	2	2	1	1	1	0
%	100.0	95.7	95.7	78.3	78.3	78.3	65.2	56.5	56.5	43.5	43.5	30.4	17.4	8.7	8.7	4.3	4.3	4.3	0.0
Nera 18mg	34	33	33	20	19	19	17	15	15	12	12	11	5	2	2	0	0	0	0
%	100.0	97.1	97.1	58.8	55.9	55.9	50.0	44.1	44.1	35.3	35.3	32.4	14.7	5.9	5.9	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	2	2	2	3	3	4	6	8	8	9	9	9	10
%	0.0	4.3	4.3	4.3	4.3	4.3	8.7	8.7	8.7	13.0	13.0	17.4	26.1	34.8	34.8	39.1	39.1	39.1	43.5
Nera 18mg	0	1	1	2	2	2	2	2	2	2	2	2	8	10	10	12	12	12	12
%	0.0	2.9	2.9	5.9	5.9	5.9	5.9	5.9	5.9	5.9	5.9	5.9	23.5	29.4	29.4	35.3	35.3	35.3	35.3

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.2.1.1.1.3.3: 1

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Table H.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 (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	306	180	58.8	91.36	305	164	53.8	81.39	0.94	(0.76,	1.17)	0.5818	
Age													0.2877
<65 years	69	48	69.6	106.86	63	34	54.0	78.63	0.76	(0.49,	1.19)	0.2304	
>=65 years	237	132	55.7	86.79	242	130	53.7	82.15	1.00	(0.79,	1.28)	0.9785	
Sex													0.2871
Male	269	156	58.0	90.66	255	139	54.5	82.25	0.98	(0.78,	1.24)	0.8831	
Female	37	24	64.9	96.22	50	25	50.0	76.90	0.70	(0.40,	1.24)	0.2270	
Baseline FVC percent predicted													0.0690
<=70%	109	70	64.2	109.42	112	55	49.1	76.04	0.73	(0.51,	1.04)	0.0771	
>70%	197	110	55.8	82.68	193	109	56.5	84.38	1.10	(0.84,	1.43)	0.5051	
Type of AF therapy													0.6904
Nintedanib	173	100	57.8	87.11	178	91	51.1	82.00	0.98	(0.73,	1.30)	0.8842	
Pirfenidone	133	80	60.2	97.31	127	73	57.5	80.64	0.90	(0.65,	1.23)	0.5051	
Region													0.9685
Europe	136	78	57.4	87.44	136	69	50.7	78.83	0.93	(0.67,	1.29)	0.6754	
Asia	72	44	61.1	98.34	79	44	55.7	83.20	0.92	(0.60,	1.40)	0.6872	
Canada and USA	75	44	58.7	88.85	56	31	55.4	74.59	0.89	(0.56,	1.41)	0.6106	
Rest of the World	23	14	60.9	103.37	34	20	58.8	102.40	1.09	(0.55,	2.16)	0.8043	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, 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 will only be 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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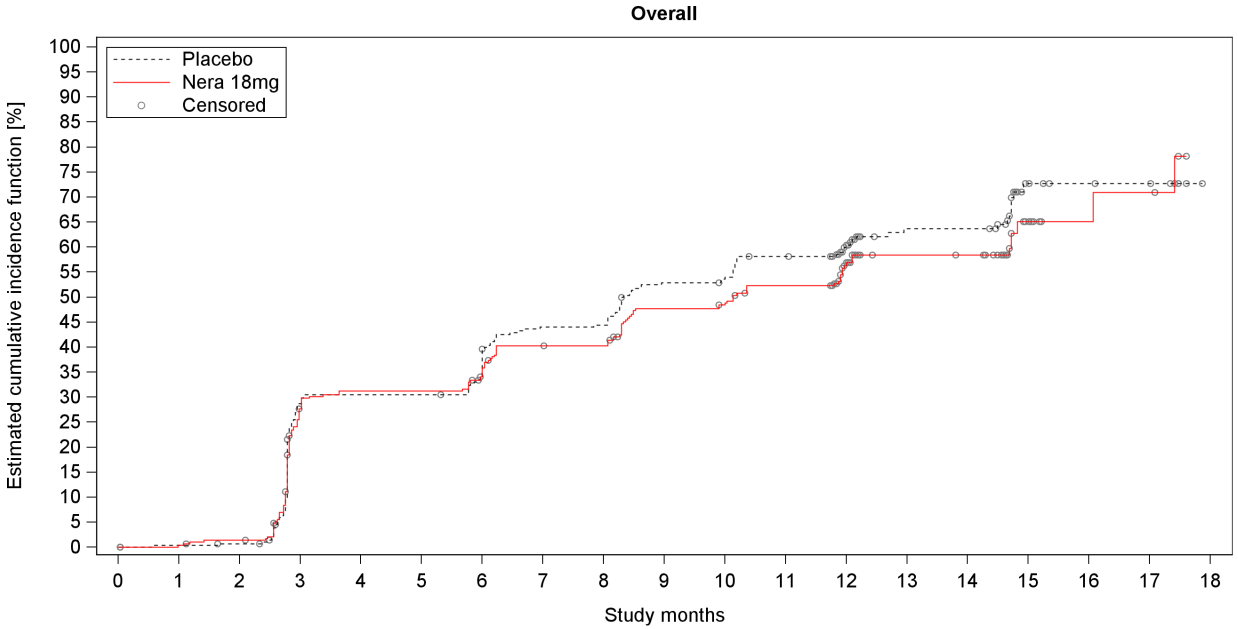

Number at risk (percentage relative to baseline)

Placebo	306	286	284	198	193	193	181	152	151	127	124	111	78	47	47	12	9	8	0
%	100.0	93.5	92.8	64.7	63.1	63.1	59.2	49.7	49.3	41.5	40.5	36.3	25.5	15.4	15.4	3.9	2.9	2.6	0.0
Nera 18mg	305	289	285	203	193	193	182	164	163	139	136	124	69	43	42	11	6	5	0
%	100.0	94.8	93.4	66.6	63.3	63.3	59.7	53.8	53.4	45.6	44.6	40.7	22.6	14.1	13.8	3.6	2.0	1.6	0.0

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

Placebo	0	19	20	27	27	27	29	31	31	32	33	34	63	88	88	114	117	118	126
%	0.0	6.2	6.5	8.8	8.8	8.8	9.5	10.1	10.1	10.5	10.8	11.1	20.6	28.8	28.8	37.3	38.2	38.6	41.2
Nera 18mg	0	15	16	23	23	23	26	27	28	32	33	35	81	104	105	132	137	137	141
%	0.0	4.9	5.2	7.5	7.5	7.5	8.5	8.9	9.2	10.5	10.8	11.5	26.6	34.1	34.4	43.3	44.9	44.9	46.2

Study: 1305-0014

Figure H.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 (AF background)

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Figure H.2.1.1.1.3.3: 2

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H.2.1.1.1.4 Time to event analyses of supplemental oxygen use

Table H.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 (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	229	45	19.7	20.67	227	41	18.1	18.31	1.02	(0.67, 1.57)	0.9247	
Age												0.9517
<65 years	56	8	14.3	14.13	56	8	14.3	13.97	1.00	(0.37, 2.67)	0.9998	
>=65 years	173	37	21.4	22.97	171	33	19.3	19.80	1.03	(0.64, 1.67)	0.8903	
Sex												0.1535
Male	196	39	19.9	21.10	188	37	19.7	20.17	1.16	(0.74, 1.83)	0.5195	
Female	33	6	18.2	18.26	39	4	10.3	9.87	0.43	(0.12, 1.55)	0.1983	
Baseline FVC percent predicted												0.3965
<=70%	74	24	32.4	37.49	71	16	22.5	25.22	0.83	(0.44, 1.58)	0.5752	
>70%	155	21	13.5	13.66	156	25	16.0	15.58	1.21	(0.67, 2.17)	0.5218	
Type of AF therapy												0.1383
Nintedanib	133	25	18.8	20.09	128	18	14.1	14.33	0.75	(0.41, 1.37)	0.3461	
Pirfenidone	96	20	20.8	21.44	99	23	23.2	23.41	1.43	(0.78, 2.63)	0.2524	
Region												0.9128
Europe	102	14	13.7	14.33	97	15	15.5	15.54	1.15	(0.56, 2.39)	0.7023	
Asia	59	13	22.0	22.99	62	13	21.0	20.85	1.18	(0.54, 2.57)	0.6850	
Canada and USA	47	14	29.8	32.68	40	9	22.5	22.74	0.81	(0.35, 1.89)	0.6267	
Rest of the World	21	4	19.0	19.40	28	4	14.3	15.72	0.94	(0.23, 3.80)	0.9364	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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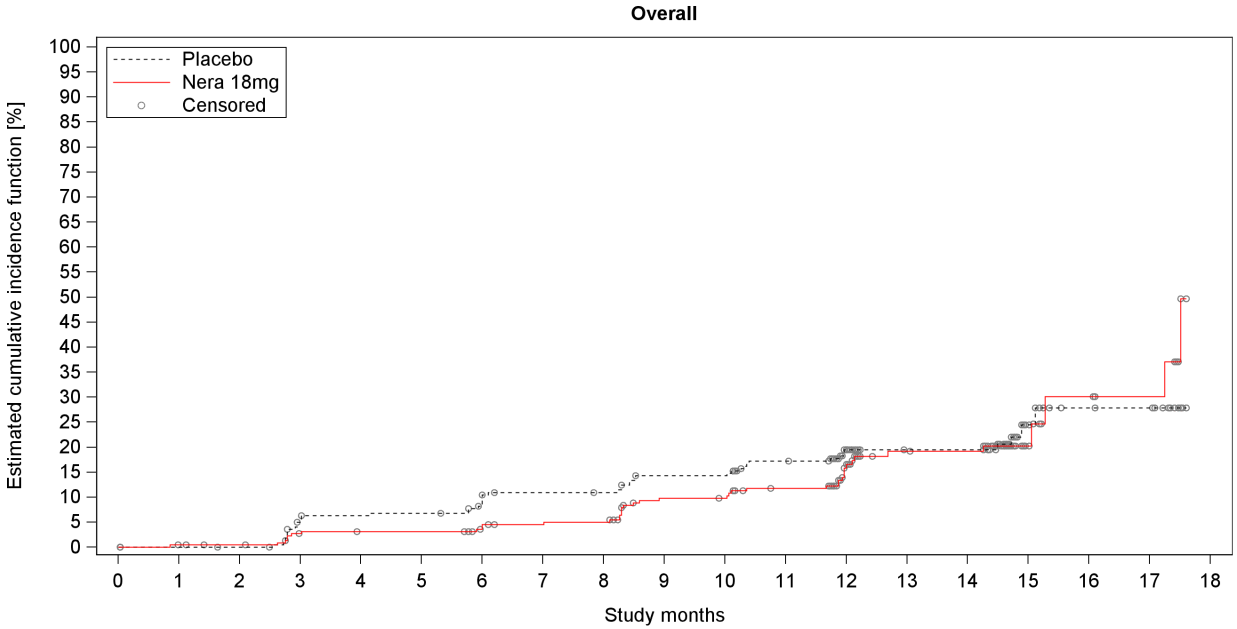

Number at risk (percentage relative to baseline)																			
Placebo	229	225	224	208	204	203	196	189	188	179	179	169	117	77	77	24	15	14	0
%	100.0	98.3	97.8	90.8	89.1	88.6	85.6	82.5	82.1	78.2	78.2	73.8	51.1	33.6	33.6	10.5	6.6	6.1	0.0
Nera 18mg	227	224	222	214	212	212	207	203	202	186	185	177	113	78	77	21	13	10	0
%	100.0	98.7	97.8	94.3	93.4	93.4	91.2	89.4	89.0	81.9	81.5	78.0	49.8	34.4	33.9	9.3	5.7	4.4	0.0
Number censored (percentage relative to number at risk at baseline)																			
Placebo	0	4	5	10	11	11	14	16	17	19	19	23	71	111	111	161	169	170	184
%	0.0	1.7	2.2	4.4	4.8	4.8	6.1	7.0	7.4	8.3	8.3	10.0	31.0	48.5	48.5	70.3	73.8	74.2	80.3
Nera 18mg	0	2	4	7	8	8	12	14	14	20	21	25	82	113	114	169	175	178	186
%	0.0	0.9	1.8	3.1	3.5	3.5	5.3	6.2	6.2	8.8	9.3	11.0	36.1	49.8	50.2	74.4	77.1	78.4	81.9

Study: 1305-0014

Figure H.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 (AF background)

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Table H.2.1.1.1.4: 2 Cox model for time to increase of supplemental oxygen use over the whole trial (DBL1) - 18mg - FAS (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	306	101	33.0	39.08	305	91	29.8	33.62	0.89	(0.67, 1.18)	0.4265	
Age												0.1172
<65 years	69	19	27.5	29.64	63	10	15.9	16.33	0.51	(0.24, 1.10)	0.0869	
>=65 years	237	82	34.6	42.20	242	81	33.5	38.68	0.99	(0.73, 1.35)	0.9520	
Sex												0.1863
Male	269	93	34.6	41.59	255	83	32.5	37.31	0.98	(0.73, 1.31)	0.8737	
Female	37	8	21.6	22.97	50	8	16.0	16.60	0.49	(0.18, 1.31)	0.1533	
Baseline FVC percent predicted												0.5932
<=70%	109	51	46.8	63.44	112	43	38.4	49.87	0.82	(0.55, 1.23)	0.3378	
>70%	197	50	25.4	28.09	193	48	24.9	26.03	0.96	(0.64, 1.43)	0.8281	
Type of AF therapy												0.6177
Nintedanib	173	54	31.2	37.69	178	51	28.7	32.91	0.84	(0.57, 1.23)	0.3661	
Pirfenidone	133	47	35.3	40.82	127	40	31.5	34.58	0.97	(0.63, 1.48)	0.8851	
Region												0.3395
Europe	136	36	26.5	30.11	136	39	28.7	32.33	1.05	(0.66, 1.65)	0.8431	
Asia	72	25	34.7	40.91	79	24	30.4	33.64	0.96	(0.55, 1.70)	0.8981	
Canada and USA	75	36	48.0	63.04	56	19	33.9	37.44	0.61	(0.35, 1.06)	0.0779	
Rest of the World	23	4	17.4	19.40	34	9	26.5	32.22	1.62	(0.50, 5.29)	0.4228	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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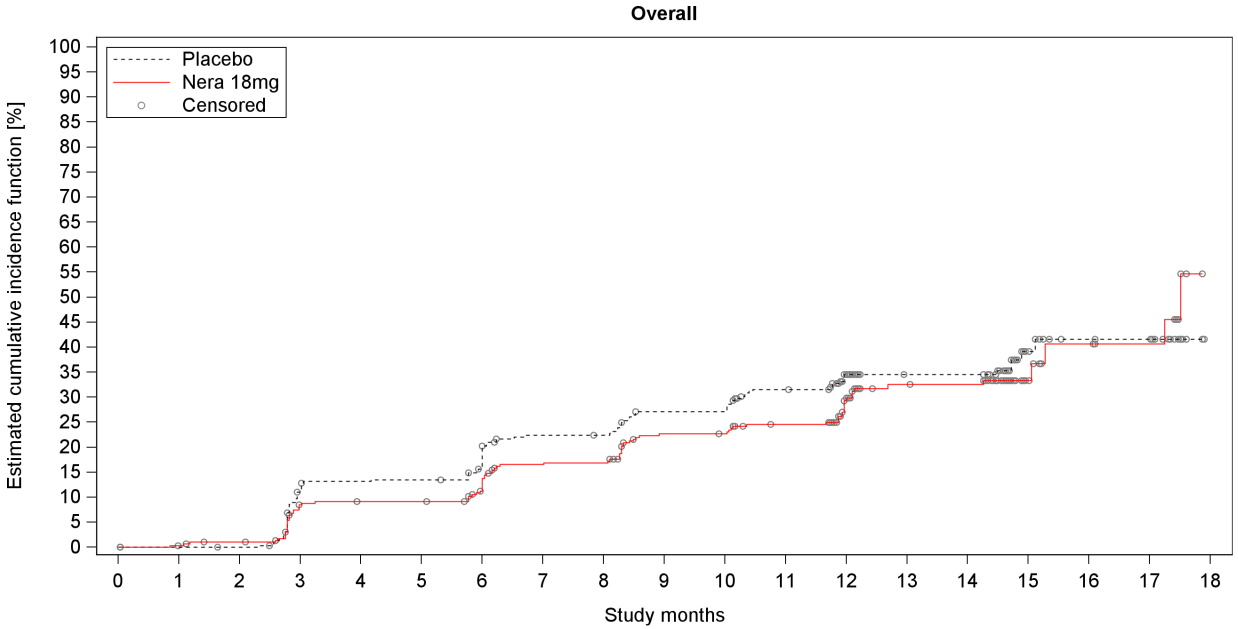

Number at risk (percentage relative to baseline)

Placebo	306	294	293	254	247	246	236	215	214	199	199	183	127	86	86	27	18	17	0
%	100.0	96.1	95.8	83.0	80.7	80.4	77.1	70.3	69.9	65.0	65.0	59.8	41.5	28.1	28.1	8.8	5.9	5.6	0.0
Nera 18mg	305	298	294	267	264	264	252	234	233	211	210	201	126	86	85	23	15	12	0
%	100.0	97.7	96.4	87.5	86.6	86.6	82.6	76.7	76.4	69.2	68.9	65.9	41.3	28.2	27.9	7.5	4.9	3.9	0.0

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

Placebo	0	12	13	20	21	21	24	27	28	30	30	34	83	124	124	179	187	188	205
%	0.0	3.9	4.2	6.5	6.9	6.9	7.8	8.8	9.2	9.8	9.8	11.1	27.1	40.5	40.5	58.5	61.1	61.4	67.0
Nera 18mg	0	6	8	13	14	14	20	23	23	29	30	34	98	133	134	195	201	204	214
%	0.0	2.0	2.6	4.3	4.6	4.6	6.6	7.5	7.5	9.5	9.8	11.1	32.1	43.6	43.9	63.9	65.9	66.9	70.2

Study: 1305-0014

Figure H.2.1.1.1.4: 2 Time to increase of supplemental oxygen use over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (AF background)

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H.2.1.2 Safety analysis

H.2.1.2.1 Safety analysis over the whole trial

H.2.1.2.1.1 Adverse events overall over the whole trial

Table H.2.1.2.1.1: 1 Proportion of patients with any adverse events over the whole trial (DBL1) - 18mg - TS (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	306	291	95.1	305	295	96.7	0.3112	1.02 (0.98, 1.05)	1.52 (0.67, 3.44)	1.62 (-1.64, 5.00)	
Age											0.7466
<65 years	69	65	94.2	63	61	96.8	0.4700	1.03 (0.95, 1.11)	1.88 (0.33, 10.62)	2.62 (-5.83, 11.12)	
>=65 years	237	226	95.4	242	234	96.7	0.4540	1.01 (0.98, 1.05)	1.42 (0.56, 3.60)	1.34 (-2.35, 5.17)	
Sex											0.6489
Male	269	256	95.2	255	246	96.5	0.4572	1.01 (0.98, 1.05)	1.39 (0.58, 3.31)	1.30 (-2.33, 4.96)	
Female	37	35	94.6	50	49	98.0	0.3894	1.04 (0.95, 1.13)	2.80 (0.24, 32.10)	3.41 (-5.95, 15.81)	
Baseline FVC percent predicted											0.7337
<=70%	109	106	97.2	112	110	98.2	0.6290	1.01 (0.97, 1.05)	1.56 (0.26, 9.50)	0.97 (-3.88, 6.16)	
>70%	197	185	93.9	193	185	95.9	0.3836	1.02 (0.97, 1.07)	1.50 (0.60, 3.75)	1.95 (-2.66, 6.66)	
Type of AF therapy											0.5871
Nintedanib	173	165	95.4	178	174	97.8	0.2205	1.02 (0.99, 1.07)	2.11 (0.62, 7.14)	2.38 (-1.70, 6.83)	
Pirfenidone	133	126	94.7	127	121	95.3	0.8421	1.01 (0.95, 1.06)	1.12 (0.37, 3.43)	0.54 (-5.32, 6.33)	
Region											0.2867
Europe	136	128	94.1	136	132	97.1	0.2376	1.03 (0.98, 1.09)	2.06 (0.61, 7.02)	2.94 (-2.29, 8.53)	
Asia	72	67	93.1	79	77	97.5	0.1977	1.05 (0.97, 1.13)	2.87 (0.54, 15.30)	4.41 (-2.97, 12.92)	
Canada and USA	75	74	98.7	56	53	94.6	0.1854	0.96 (0.90, 1.03)	0.24 (0.02, 2.36)	-4.02 (-13.34, 2.79)	
Rest of the World	23	22	95.7	34	33	97.1	0.7771	1.01 (0.91, 1.13)	1.50 (0.09, 25.26)	1.41 (-11.09, 18.23)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.1: 2 Proportion of patients with any adverse events (excluding disease-related events) over the whole trial (DBL1) - 18mg - TS (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	306	291	95.1	305	293	96.1	0.5607	1.01 (0.98, 1.05)	1.26 (0.58, 2.74)	0.97 (-2.43, 4.42)	
Age											0.9770
<65 years	69	65	94.2	63	60	95.2	0.7909	1.01 (0.93, 1.10)	1.23 (0.26, 5.73)	1.04 (-8.01, 9.80)	
>=65 years	237	226	95.4	242	233	96.3	0.6139	1.01 (0.97, 1.05)	1.26 (0.51, 3.10)	0.92 (-2.86, 4.82)	
Sex											0.5342
Male	269	256	95.2	255	244	95.7	0.7764	1.01 (0.97, 1.04)	1.13 (0.50, 2.56)	0.52 (-3.29, 4.29)	
Female	37	35	94.6	50	49	98.0	0.3894	1.04 (0.95, 1.13)	2.80 (0.24, 32.10)	3.41 (-5.95, 15.81)	
Baseline FVC percent predicted											0.3916
<=70%	109	106	97.2	112	108	96.4	0.7281	0.99 (0.95, 1.04)	0.76 (0.17, 3.50)	-0.82 (-6.38, 4.66)	
>70%	197	185	93.9	193	185	95.9	0.3836	1.02 (0.97, 1.07)	1.50 (0.60, 3.75)	1.95 (-2.66, 6.66)	
Type of AF therapy											0.5543
Nintedanib	173	165	95.4	178	173	97.2	0.3679	1.02 (0.98, 1.06)	1.68 (0.54, 5.23)	1.82 (-2.43, 6.34)	
Pirfenidone	133	126	94.7	127	120	94.5	0.9292	1.00 (0.94, 1.06)	0.95 (0.32, 2.80)	-0.25 (-6.31, 5.67)	
Region											0.3345
Europe	136	128	94.1	136	132	97.1	0.2376	1.03 (0.98, 1.09)	2.06 (0.61, 7.02)	2.94 (-2.29, 8.53)	
Asia	72	67	93.1	79	76	96.2	0.3885	1.03 (0.96, 1.12)	1.89 (0.44, 8.21)	3.15 (-4.70, 11.82)	
Canada and USA	75	74	98.7	56	53	94.6	0.1854	0.96 (0.90, 1.03)	0.24 (0.02, 2.36)	-4.02 (-13.34, 2.79)	
Rest of the World	23	22	95.7	34	32	94.1	0.7991	0.98 (0.87, 1.11)	0.73 (0.06, 8.52)	-1.53 (-15.22, 15.64)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.1: 3 Proportion of patients with serious adverse events over the whole trial (DBL1) - 18mg - TS (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	306	112	36.6	305	118	38.7	0.5944	1.06 (0.86, 1.30)	1.09 (0.79, 1.52)	2.09 (-5.57, 9.71)	
Age											0.7887
<65 years	69	19	27.5	63	17	27.0	0.9433	0.98 (0.56, 1.71)	0.97 (0.45, 2.09)	-0.55 (-15.41, 14.57)	
>=65 years	237	93	39.2	242	101	41.7	0.5781	1.06 (0.86, 1.32)	1.11 (0.77, 1.60)	2.50 (-6.26, 11.19)	
Sex											0.1843
Male	269	106	39.4	255	103	40.4	0.8176	1.03 (0.83, 1.26)	1.04 (0.73, 1.48)	0.99 (-7.35, 9.32)	
Female	37	6	16.2	50	15	30.0	0.1374	1.85 (0.79, 4.31)	2.21 (0.76, 6.41)	13.78 (-4.69, 29.98)	
Baseline FVC percent predicted											0.2294
<=70%	109	45	41.3	112	56	50.0	0.1935	1.21 (0.91, 1.62)	1.42 (0.84, 2.42)	8.72 (-4.36, 21.37)	
>70%	197	67	34.0	193	62	32.1	0.6923	0.94 (0.71, 1.25)	0.92 (0.60, 1.40)	-1.89 (-11.13, 7.41)	
Type of AF therapy											0.0737
Nintedanib	173	53	30.6	178	69	38.8	0.1099	1.27 (0.95, 1.69)	1.43 (0.92, 2.23)	8.13 (-1.83, 17.84)	
Pirfenidone	133	59	44.4	127	49	38.6	0.3446	0.87 (0.65, 1.16)	0.79 (0.48, 1.29)	-5.78 (-17.45, 6.14)	
Region											0.1070
Europe	136	40	29.4	136	55	40.4	0.0564	1.38 (0.99, 1.91)	1.63 (0.99, 2.70)	11.03 (-0.30, 21.97)	
Asia	72	30	41.7	79	34	43.0	0.8648	1.03 (0.71, 1.50)	1.06 (0.55, 2.02)	1.37 (-14.12, 16.70)	
Canada and USA	75	32	42.7	56	16	28.6	0.0976	0.67 (0.41, 1.09)	0.54 (0.26, 1.12)	-14.10 (-29.27, 2.58)	
Rest of the World	23	10	43.5	34	13	38.2	0.6922	0.88 (0.47, 1.65)	0.80 (0.27, 2.36)	-5.24 (-29.61, 19.21)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.1: 4 Proportion of patients with serious adverse events (excluding disease-related events) over the whole trial (DBL1) - 18mg - TS (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	306	109	35.6	305	109	35.7	0.9760	1.00 (0.81, 1.24)	1.01 (0.72, 1.40)	0.12 (-7.44, 7.67)	
Age											0.9306
<65 years	69	18	26.1	63	16	25.4	0.9278	0.97 (0.54, 1.74)	0.96 (0.44, 2.11)	-0.69 (-15.31, 14.21)	
>=65 years	237	91	38.4	242	93	38.4	0.9941	1.00 (0.80, 1.26)	1.00 (0.69, 1.45)	0.03 (-8.62, 8.68)	
Sex											0.2037
Male	269	103	38.3	255	95	37.3	0.8070	0.97 (0.78, 1.21)	0.96 (0.67, 1.36)	-1.04 (-9.27, 7.24)	
Female	37	6	16.2	50	14	28.0	0.1965	1.73 (0.73, 4.07)	2.01 (0.69, 5.86)	11.78 (-6.48, 27.91)	
Baseline FVC percent predicted											0.4137
<=70%	109	45	41.3	112	51	45.5	0.5238	1.10 (0.82, 1.49)	1.19 (0.70, 2.03)	4.25 (-8.70, 16.99)	
>70%	197	64	32.5	193	58	30.1	0.6040	0.93 (0.69, 1.24)	0.89 (0.58, 1.37)	-2.44 (-11.54, 6.74)	
Type of AF therapy											0.1766
Nintedanib	173	52	30.1	178	62	34.8	0.3397	1.16 (0.86, 1.57)	1.24 (0.79, 1.95)	4.77 (-5.01, 14.41)	
Pirfenidone	133	57	42.9	127	47	37.0	0.3359	0.86 (0.64, 1.17)	0.78 (0.48, 1.29)	-5.85 (-17.45, 6.01)	
Region											0.1649
Europe	136	40	29.4	136	50	36.8	0.1975	1.25 (0.89, 1.76)	1.40 (0.84, 2.32)	7.35 (-3.81, 18.26)	
Asia	72	27	37.5	79	32	40.5	0.7053	1.08 (0.72, 1.61)	1.13 (0.59, 2.19)	3.01 (-12.36, 18.08)	
Canada and USA	75	32	42.7	56	16	28.6	0.0976	0.67 (0.41, 1.09)	0.54 (0.26, 1.12)	-14.10 (-29.27, 2.58)	
Rest of the World	23	10	43.5	34	11	32.4	0.3930	0.74 (0.38, 1.46)	0.62 (0.21, 1.86)	-11.13 (-34.86, 13.39)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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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H.2.1.2.1.2 Adverse events by intensity over the whole trial

Table H.2.1.2.1.2: 1 Proportion of patients with any adverse events with CTCAE grade >=3 over the whole trial (DBL1) - 18mg - TS (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	306	89	29.1	305	108	35.4	0.0944	1.22 (0.97, 1.53)	1.34 (0.95, 1.88)	6.32 (-1.09, 13.64)	
Age											0.5421
<65 years	69	18	26.1	63	17	27.0	0.9071	1.03 (0.59, 1.83)	1.05 (0.48, 2.27)	0.90 (-13.90, 15.88)	
>=65 years	237	71	30.0	242	91	37.6	0.0770	1.26 (0.97, 1.62)	1.41 (0.96, 2.06)	7.65 (-0.83, 15.96)	
Sex											0.1849
Male	269	84	31.2	255	93	36.5	0.2046	1.17 (0.92, 1.49)	1.26 (0.88, 1.82)	5.24 (-2.84, 13.26)	
Female	37	5	13.5	50	15	30.0	0.0708	2.22 (0.89, 5.56)	2.74 (0.90, 8.41)	16.49 (-1.62, 32.20)	
Baseline FVC percent predicted											0.6234
<=70%	109	36	33.0	112	48	42.9	0.1323	1.30 (0.92, 1.83)	1.52 (0.88, 2.63)	9.83 (-2.94, 22.14)	
>70%	197	53	26.9	193	60	31.1	0.3624	1.16 (0.85, 1.58)	1.23 (0.79, 1.90)	4.18 (-4.80, 13.10)	
Type of AF therapy											0.0808
Nintedanib	173	47	27.2	178	70	39.3	0.0157	1.45 (1.07, 1.96)	1.74 (1.11, 2.73)	12.16 (2.29, 21.68)	
Pirfenidone	133	42	31.6	127	38	29.9	0.7722	0.95 (0.66, 1.37)	0.93 (0.55, 1.57)	-1.66 (-12.71, 9.51)	
Region											0.0854
Europe	136	34	25.0	136	52	38.2	0.0189	1.53 (1.07, 2.19)	1.86 (1.10, 3.12)	13.24 (2.18, 23.86)	
Asia	72	21	29.2	79	31	39.2	0.1932	1.35 (0.86, 2.12)	1.57 (0.79, 3.10)	10.07 (-5.06, 24.45)	
Canada and USA	75	27	36.0	56	13	23.2	0.1160	0.64 (0.37, 1.13)	0.54 (0.25, 1.17)	-12.79 (-27.30, 3.22)	
Rest of the World	23	7	30.4	34	12	35.3	0.7026	1.16 (0.54, 2.50)	1.25 (0.40, 3.87)	4.86 (-19.80, 27.26)	

Study: 1305-0014. MedDRA version: 27.0. 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 H.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 (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	306	85	27.8	305	100	32.8	0.1778	1.18 (0.93, 1.50)	1.27 (0.90, 1.79)	5.01 (-2.27, 12.22)	
Age											0.6281
<65 years	69	17	24.6	63	16	25.4	0.9199	1.03 (0.57, 1.86)	1.04 (0.47, 2.29)	0.76 (-13.78, 15.51)	
>=65 years	237	68	28.7	242	84	34.7	0.1571	1.21 (0.93, 1.58)	1.32 (0.90, 1.94)	6.02 (-2.31, 14.23)	
Sex											0.2194
Male	269	80	29.7	255	86	33.7	0.3270	1.13 (0.88, 1.46)	1.20 (0.83, 1.74)	3.99 (-3.96, 11.89)	
Female	37	5	13.5	50	14	28.0	0.1059	2.07 (0.82, 5.24)	2.49 (0.81, 7.68)	14.49 (-3.40, 30.12)	
Baseline FVC percent predicted											0.7832
<=70%	109	35	32.1	112	44	39.3	0.2658	1.22 (0.86, 1.75)	1.37 (0.79, 2.38)	7.18 (-5.41, 19.43)	
>70%	197	50	25.4	193	56	29.0	0.4198	1.14 (0.83, 1.58)	1.20 (0.77, 1.88)	3.63 (-5.18, 12.39)	
Type of AF therapy											0.1296
Nintedanib	173	45	26.0	178	64	36.0	0.0441	1.38 (1.00, 1.90)	1.60 (1.01, 2.52)	9.94 (0.26, 19.35)	
Pirfenidone	133	40	30.1	127	36	28.3	0.7593	0.94 (0.65, 1.38)	0.92 (0.54, 1.57)	-1.73 (-12.63, 9.29)	
Region											0.0848
Europe	136	34	25.0	136	49	36.0	0.0482	1.44 (1.00, 2.08)	1.69 (1.00, 2.85)	11.03 (0.08, 21.63)	
Asia	72	17	23.6	79	28	35.4	0.1124	1.50 (0.90, 2.50)	1.78 (0.87, 3.62)	11.83 (-2.79, 25.62)	
Canada and USA	75	27	36.0	56	13	23.2	0.1160	0.64 (0.37, 1.13)	0.54 (0.25, 1.17)	-12.79 (-27.30, 3.22)	
Rest of the World	23	7	30.4	34	10	29.4	0.9340	0.97 (0.43, 2.17)	0.95 (0.30, 3.02)	-1.02 (-25.01, 21.35)	

Study: 1305-0014. MedDRA version: 27.0. 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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H.2.1.2.1.3 Adverse events leading to treatment discontinuation over the whole trial

Table H.2.1.2.1.3: 1 Proportion of patients with any adverse events leading to treatment discontinuation over the whole trial (DBL1) - 18mg - TS (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	306	40	13.1	305	54	17.7	0.1125	1.35 (0.93, 1.97)	1.43 (0.92, 2.23)	4.63 (-1.11, 10.37)	
Age											0.5948
<65 years	69	5	7.2	63	8	12.7	0.2937	1.75 (0.60, 5.08)	1.86 (0.58, 6.02)	5.45 (-5.12, 16.64)	
>=65 years	237	35	14.8	242	46	19.0	0.2158	1.29 (0.86, 1.92)	1.35 (0.84, 2.19)	4.24 (-2.51, 10.94)	
Sex											0.0302
Male	269	40	14.9	255	39	15.3	0.8921	1.03 (0.69, 1.54)	1.03 (0.64, 1.67)	0.42 (-5.72, 6.62)	
Female	37	0	0.0	50	15	30.0	0.0004	>10 (1.43, >99)	NC (NC, NC)	30.00 (15.61, 43.75)	
Baseline FVC percent predicted											0.4809
<=70%	109	17	15.6	112	20	17.9	0.6527	1.14 (0.63, 2.07)	1.18 (0.58, 2.39)	2.26 (-7.71, 12.14)	
>70%	197	23	11.7	193	34	17.6	0.0968	1.51 (0.92, 2.46)	1.62 (0.91, 2.86)	5.94 (-1.11, 13.02)	
Type of AF therapy											0.2688
Nintedanib	173	25	14.5	178	40	22.5	0.0531	1.56 (0.99, 2.45)	1.72 (0.99, 2.98)	8.02 (-0.14, 16.05)	
Pirfenidone	133	15	11.3	127	14	11.0	0.9480	0.98 (0.49, 1.94)	0.97 (0.45, 2.11)	-0.25 (-8.07, 7.66)	
Region											0.1773
Europe	136	13	9.6	136	27	19.9	0.0165	2.08 (1.12, 3.85)	2.34 (1.15, 4.77)	10.29 (1.85, 18.73)	
Asia	72	13	18.1	79	13	16.5	0.7948	0.91 (0.45, 1.83)	0.89 (0.38, 2.08)	-1.60 (-13.93, 10.47)	
Canada and USA	75	10	13.3	56	5	8.9	0.4335	0.67 (0.24, 1.85)	0.64 (0.20, 1.98)	-4.40 (-15.17, 7.50)	
Rest of the World	23	4	17.4	34	9	26.5	0.4229	1.52 (0.53, 4.36)	1.71 (0.46, 6.40)	9.08 (-13.96, 28.71)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	35	11.4	305	51	16.7	0.0604	1.46 (0.98, 2.18)	1.55 (0.98, 2.47)	5.28 (-0.25, 10.83)	
Age											0.4453
<65 years	69	4	5.8	63	8	12.7	0.1683	2.19 (0.69, 6.92)	2.36 (0.68, 8.27)	6.90 (-3.32, 17.89)	
>=65 years	237	31	13.1	242	43	17.8	0.1558	1.36 (0.89, 2.08)	1.44 (0.87, 2.37)	4.69 (-1.82, 11.16)	
Sex											0.0394
Male	269	35	13.0	255	37	14.5	0.6184	1.12 (0.73, 1.71)	1.13 (0.69, 1.87)	1.50 (-4.42, 7.48)	
Female	37	0	0.0	50	14	28.0	0.0007	>10 (1.33, >99)	NC (NC, NC)	28.00 (13.88, 41.67)	
Baseline FVC percent predicted											0.6956
<=70%	109	14	12.8	112	19	17.0	0.3902	1.32 (0.70, 2.50)	1.39 (0.66, 2.93)	4.12 (-5.43, 13.59)	
>70%	197	21	10.7	193	32	16.6	0.0880	1.56 (0.93, 2.60)	1.67 (0.92, 3.01)	5.92 (-0.93, 12.81)	
Type of AF therapy											0.0406
Nintedanib	173	20	11.6	178	40	22.5	0.0066	1.94 (1.19, 3.19)	2.22 (1.24, 3.98)	10.91 (3.04, 18.67)	
Pirfenidone	133	15	11.3	127	11	8.7	0.4820	0.77 (0.37, 1.61)	0.75 (0.33, 1.69)	-2.62 (-10.12, 4.93)	
Region											0.1580
Europe	136	10	7.4	136	25	18.4	0.0066	2.50 (1.25, 5.00)	2.84 (1.31, 6.17)	11.03 (3.07, 19.09)	
Asia	72	11	15.3	79	13	16.5	0.8433	1.08 (0.52, 2.25)	1.09 (0.46, 2.62)	1.18 (-10.83, 12.86)	
Canada and USA	75	10	13.3	56	5	8.9	0.4335	0.67 (0.24, 1.85)	0.64 (0.20, 1.98)	-4.40 (-15.17, 7.50)	
Rest of the World	23	4	17.4	34	8	23.5	0.5771	1.35 (0.46, 3.97)	1.46 (0.38, 5.57)	6.14 (-16.51, 25.62)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)

Primary System Organ Class Preferred Term	Placebo N	Placebo n	Placebo %	Nera 18mg N	Nera 18mg n	Nera 18mg %
Overall	306	40	13.1	305	54	17.7
Gastrointestinal disorders		4	1.3		28	9.2
Diarrhoea		2	0.7		23	7.5
Nausea		2	0.7		4	1.3
Abdominal pain		0	0.0		2	0.7
Abdominal discomfort		0	0.0		1	0.3
Flatulence		1	0.3		0	0.0
Gastric dilatation		1	0.3		0	0.0
Gastrointestinal disorder		1	0.3		0	0.0
Gastrooesophageal reflux disease		1	0.3		0	0.0
Paraesthesia oral		0	0.0		1	0.3
General disorders and administration site conditions		12	3.9		10	3.3
Condition aggravated		8	2.6		6	2.0
Asthenia		0	0.0		3	1.0
Fatigue		3	1.0		0	0.0
Chest pain		0	0.0		1	0.3
Death		1	0.3		0	0.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		12	3.9		6	2.0
Lung neoplasm malignant		2	0.7		1	0.3
Squamous cell carcinoma of skin		2	0.7		1	0.3
Lung adenocarcinoma		2	0.7		0	0.0
Prostate cancer		2	0.7		0	0.0
Acute leukaemia		0	0.0		1	0.3
Chronic myeloid leukaemia		1	0.3		0	0.0
Hodgkin’s disease		1	0.3		0	0.0
Lung neoplasm		0	0.0		1	0.3
Neuroendocrine carcinoma of the skin		1	0.3		0	0.0
Sarcomatoid carcinoma		0	0.0		1	0.3
Squamous cell carcinoma of lung		0	0.0		1	0.3
Transitional cell carcinoma		1	0.3		0	0.0
Respiratory, thoracic and mediastinal disorders		6	2.0		1	0.3
Dyspnoea		3	1.0		0	0.0
Cough		1	0.3		0	0.0
Hepatopulmonary syndrome		1	0.3		0	0.0
Pneumothorax		0	0.0		1	0.3
Respiratory failure		1	0.3		0	0.0

Study: 1305-0014. MedDRA version: 27.0
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 H.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 (AF background)

Primary System Organ Class Preferred Term	Placebo N	 n	 %	Nera 18mg N	 n	 %
Infections and infestations		1	0.3		4	1.3
Bacterial infection		1	0.3		0	0.0
Bronchitis bacterial		0	0.0		1	0.3
Herpes zoster		0	0.0		1	0.3
Pneumonia bacterial		0	0.0		1	0.3
Septic shock		0	0.0		1	0.3
Skin infection		0	0.0		1	0.3
Nervous system disorders		3	1.0		2	0.7
Cerebral haemorrhage		1	0.3		0	0.0
Dizziness		1	0.3		0	0.0
Dysgeusia		0	0.0		1	0.3
Encephalopathy		1	0.3		0	0.0
Hypoaesthesia		0	0.0		1	0.3
Psychiatric disorders		0	0.0		5	1.6
Anxiety		0	0.0		3	1.0
Suicidal ideation		0	0.0		2	0.7
Vascular disorders		1	0.3		3	1.0
Vasculitis		0	0.0		3	1.0
Granulomatosis with polyangiitis		1	0.3		0	0.0
Cardiac disorders		1	0.3		2	0.7
Coronary artery disease		0	0.0		1	0.3
Heart failure with reduced ejection fraction		0	0.0		1	0.3
Palpitations		1	0.3		0	0.0
Investigations		0	0.0		3	1.0
Weight decreased		0	0.0		2	0.7
Blast cell count increased		0	0.0		1	0.3
Metabolism and nutrition disorders		1	0.3		2	0.7
Abnormal loss of weight		0	0.0		1	0.3
Decreased appetite		0	0.0		1	0.3
Hyponatraemia		1	0.3		0	0.0
Hepatobiliary disorders		2	0.7		0	0.0
Hepatic function abnormal		1	0.3		0	0.0
Suspected drug-induced liver injury		1	0.3		0	0.0
Musculoskeletal and connective tissue disorders		1	0.3		1	0.3

Study: 1305-0014. MedDRA version: 27.0
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 H.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 (AF background)

Primary System Organ Class Preferred Term	Placebo N	 n	 %	Nera 18mg N	 n	 %
Arthralgia		1	0.3		1	0.3
Myalgia		1	0.3		0	0.0
Blood and lymphatic system disorders		1	0.3		0	0.0
Anaemia		1	0.3		0	0.0
Immune system disorders		0	0.0		1	0.3
Multiple allergies		0	0.0		1	0.3
Injury, poisoning and procedural complications		1	0.3		0	0.0
Cervical vertebral fracture		1	0.3		0	0.0
Skin and subcutaneous tissue disorders		0	0.0		1	0.3
Rash		0	0.0		1	0.3

Study: 1305-0014. MedDRA version: 27.0
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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H.2.1.2.1.4 Adverse events on SOC level over the whole trial

Table H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (AF 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	306	11	3.6	305	6	2.0	0.2213	0.55 (0.20, 1.46)	0.54 (0.20, 1.47)	-1.63 (-4.55, 1.13)	
Age											
<65 years	69	3	4.3	63	0	0.0					
>=65 years	237	8	3.4	242	6	2.5					
Sex											
Male	269	8	3.0	255	6	2.4					
Female	37	3	8.1	50	0	0.0					
Baseline FVC percent predicted											
<=70%	109	5	4.6	112	1	0.9					
>70%	197	6	3.0	193	5	2.6					
Type of AF therapy											
Nintedanib	173	6	3.5	178	4	2.2					
Pirfenidone	133	5	3.8	127	2	1.6					
Region											
Europe	136	5	3.7	136	1	0.7					
Asia	72	1	1.4	79	1	1.3					
Canada and USA	75	4	5.3	56	4	7.1					
Rest of the World	23	1	4.3	34	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	33	10.8	305	32	10.5	0.9067	0.97 (0.61, 1.54)	0.97 (0.58, 1.62)	-0.29 (-5.25, 4.66)	
Age											
<65 years	69	9	13.0	63	4	6.3					
>=65 years	237	24	10.1	242	28	11.6					
Sex											
Male	269	31	11.5	255	28	11.0					
Female	37	2	5.4	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	15	13.8	112	14	12.5					
>70%	197	18	9.1	193	18	9.3					
Type of AF therapy											
Nintedanib	173	21	12.1	178	20	11.2					
Pirfenidone	133	12	9.0	127	12	9.4					
Region											
Europe	136	12	8.8	136	18	13.2					
Asia	72	7	9.7	79	5	6.3					
Canada and USA	75	9	12.0	56	6	10.7					
Rest of the World	23	5	21.7	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	13	4.2	305	13	4.3	0.9932	1.00 (0.47, 2.13)	1.00 (0.46, 2.20)	0.01 (-3.36, 3.39)	
Age											
<65 years	69	2	2.9	63	0	0.0					
>=65 years	237	11	4.6	242	13	5.4					
Sex											
Male	269	12	4.5	255	8	3.1					
Female	37	1	2.7	50	5	10.0					
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	5	4.5					
>70%	197	11	5.6	193	8	4.1					
Type of AF therapy											
Nintedanib	173	7	4.0	178	6	3.4					
Pirfenidone	133	6	4.5	127	7	5.5					
Region											
Europe	136	4	2.9	136	7	5.1					
Asia	72	1	1.4	79	2	2.5					
Canada and USA	75	7	9.3	56	2	3.6					
Rest of the World	23	1	4.3	34	2	5.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	19	6.2	305	14	4.6	0.3760	0.74 (0.38, 1.45)	0.73 (0.36, 1.48)	-1.62 (-5.38, 2.07)	
Age											
<65 years	69	4	5.8	63	5	7.9					
>=65 years	237	15	6.3	242	9	3.7					
Sex											
Male	269	17	6.3	255	13	5.1					
Female	37	2	5.4	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	9	8.3	112	5	4.5					
>70%	197	10	5.1	193	9	4.7					
Type of AF therapy											
Nintedanib	173	9	5.2	178	8	4.5					
Pirfenidone	133	10	7.5	127	6	4.7					
Region											
Europe	136	13	9.6	136	9	6.6					
Asia	72	3	4.2	79	2	2.5					
Canada and USA	75	1	1.3	56	1	1.8					
Rest of the World	23	2	8.7	34	2	5.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (AF background)
SOC: Gastrointestinal 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	306	127	41.5	305	185	60.7	<.0001	1.46 (1.24, 1.72)	2.17 (1.57, 3.00)	19.15 (11.25, 26.72)	
Age											0.7405
<65 years	69	27	39.1	63	34	54.0	0.0877	1.38 (0.95, 2.00)	1.82 (0.91, 3.64)	14.84 (-2.12, 30.68)	
>=65 years	237	100	42.2	242	151	62.4	<.0001	1.48 (1.24, 1.77)	2.27 (1.58, 3.28)	20.20 (11.28, 28.67)	
Sex											0.1160
Male	269	113	42.0	255	147	57.6	0.0003	1.37 (1.15, 1.64)	1.88 (1.33, 2.66)	15.64 (7.08, 23.88)	
Female	37	14	37.8	50	38	76.0	0.0003	2.01 (1.29, 3.12)	5.20 (2.06, 13.17)	38.16 (17.24, 55.01)	
Baseline FVC percent predicted											0.1007
<=70%	109	48	44.0	112	60	53.6	0.1563	1.22 (0.93, 1.60)	1.47 (0.86, 2.49)	9.53 (-3.59, 22.21)	
>70%	197	79	40.1	193	125	64.8	<.0001	1.62 (1.32, 1.97)	2.75 (1.82, 4.14)	24.67 (14.81, 33.85)	
Type of AF therapy											0.4597
Nintedanib	173	82	47.4	178	128	71.9	<.0001	1.52 (1.26, 1.82)	2.84 (1.82, 4.42)	24.51 (14.31, 34.02)	
Pirfenidone	133	45	33.8	127	57	44.9	0.0682	1.33 (0.98, 1.80)	1.59 (0.96, 2.63)	11.05 (-0.81, 22.51)	
Region											0.6706
Europe	136	60	44.1	136	87	64.0	0.0010	1.45 (1.16, 1.82)	2.25 (1.38, 3.66)	19.85 (8.01, 30.93)	
Asia	72	20	27.8	79	40	50.6	0.0042	1.82 (1.18, 2.81)	2.67 (1.35, 5.26)	22.86 (7.25, 36.88)	
Canada and USA	75	36	48.0	56	35	62.5	0.0994	1.30 (0.95, 1.78)	1.81 (0.89, 3.66)	14.50 (-2.68, 30.36)	
Rest of the World	23	11	47.8	34	23	67.6	0.1345	1.41 (0.87, 2.30)	2.28 (0.77, 6.78)	19.82 (-5.70, 42.63)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	77	25.2	305	90	29.5	0.2282	1.17 (0.90, 1.52)	1.24 (0.87, 1.78)	4.34 (-2.72, 11.36)	
Age											
<65 years	69	16	23.2	63	12	19.0					
>=65 years	237	61	25.7	242	78	32.2					
Sex											
Male	269	74	27.5	255	75	29.4					
Female	37	3	8.1	50	15	30.0					
Baseline FVC percent predicted											
<=70%	109	29	26.6	112	38	33.9					
>70%	197	48	24.4	193	52	26.9					
Type of AF therapy											
Nintedanib	173	44	25.4	178	50	28.1					
Pirfenidone	133	33	24.8	127	40	31.5					
Region											
Europe	136	33	24.3	136	45	33.1					
Asia	72	17	23.6	79	14	17.7					
Canada and USA	75	26	34.7	56	20	35.7					
Rest of the World	23	1	4.3	34	11	32.4					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	13	4.2	305	9	3.0	0.3894	0.69 (0.30, 1.60)	0.69 (0.29, 1.63)	-1.30 (-4.50, 1.80)	
Age											
<65 years	69	3	4.3	63	2	3.2					
>=65 years	237	10	4.2	242	7	2.9					
Sex											
Male	269	12	4.5	255	6	2.4					
Female	37	1	2.7	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	1	0.9	112	3	2.7					
>70%	197	12	6.1	193	6	3.1					
Type of AF therapy											
Nintedanib	173	10	5.8	178	7	3.9					
Pirfenidone	133	3	2.3	127	2	1.6					
Region											
Europe	136	3	2.2	136	4	2.9					
Asia	72	6	8.3	79	4	5.1					
Canada and USA	75	2	2.7	56	0	0.0					
Rest of the World	23	2	8.7	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	192	62.7	305	190	62.3	0.9085	0.99 (0.88, 1.12)	0.98 (0.71, 1.36)	-0.45 (-8.08, 7.19)	
Age											
<65 years	69	46	66.7	63	42	66.7					
>=65 years	237	146	61.6	242	148	61.2					
Sex											
Male	269	167	62.1	255	157	61.6					
Female	37	25	67.6	50	33	66.0					
Baseline FVC percent predicted											
<=70%	109	68	62.4	112	62	55.4					
>70%	197	124	62.9	193	128	66.3					
Type of AF therapy											
Nintedanib	173	108	62.4	178	102	57.3					
Pirfenidone	133	84	63.2	127	88	69.3					
Region											
Europe	136	86	63.2	136	88	64.7					
Asia	72	47	65.3	79	48	60.8					
Canada and USA	75	44	58.7	56	34	60.7					
Rest of the World	23	15	65.2	34	20	58.8					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	39	12.7	305	36	11.8	0.7228	0.93 (0.61, 1.42)	0.92 (0.56, 1.49)	-0.94 (-6.20, 4.31)	
Age											
<65 years	69	7	10.1	63	5	7.9					
>=65 years	237	32	13.5	242	31	12.8					
Sex											
Male	269	34	12.6	255	28	11.0					
Female	37	5	13.5	50	8	16.0					
Baseline FVC percent predicted											
<=70%	109	14	12.8	112	10	8.9					
>70%	197	25	12.7	193	26	13.5					
Type of AF therapy											
Nintedanib	173	21	12.1	178	27	15.2					
Pirfenidone	133	18	13.5	127	9	7.1					
Region											
Europe	136	17	12.5	136	15	11.0					
Asia	72	3	4.2	79	8	10.1					
Canada and USA	75	13	17.3	56	9	16.1					
Rest of the World	23	6	26.1	34	4	11.8					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	60	19.6	305	77	25.2	0.0948	1.29 (0.96, 1.73)	1.38 (0.94, 2.03)	5.64 (-0.98, 12.21)	
Age											
<65 years	69	10	14.5	63	13	20.6					
>=65 years	237	50	21.1	242	64	26.4					
Sex											
Male	269	52	19.3	255	66	25.9					
Female	37	8	21.6	50	11	22.0					
Baseline FVC percent predicted											
<=70%	109	19	17.4	112	29	25.9					
>70%	197	41	20.8	193	48	24.9					
Type of AF therapy											
Nintedanib	173	37	21.4	178	55	30.9					
Pirfenidone	133	23	17.3	127	22	17.3					
Region											
Europe	136	22	16.2	136	39	28.7					
Asia	72	12	16.7	79	20	25.3					
Canada and USA	75	20	26.7	56	13	23.2					
Rest of the World	23	6	26.1	34	5	14.7					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	49	16.0	305	44	14.4	0.5851	0.90 (0.62, 1.31)	0.88 (0.57, 1.38)	-1.59 (-7.31, 4.14)	
Age											
<65 years	69	8	11.6	63	5	7.9					
>=65 years	237	41	17.3	242	39	16.1					
Sex											
Male	269	41	15.2	255	37	14.5					
Female	37	8	21.6	50	7	14.0					
Baseline FVC percent predicted											
<=70%	109	22	20.2	112	20	17.9					
>70%	197	27	13.7	193	24	12.4					
Type of AF therapy											
Nintedanib	173	25	14.5	178	22	12.4					
Pirfenidone	133	24	18.0	127	22	17.3					
Region											
Europe	136	19	14.0	136	19	14.0					
Asia	72	15	20.8	79	17	21.5					
Canada and USA	75	12	16.0	56	6	10.7					
Rest of the World	23	3	13.0	34	2	5.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	65	21.2	305	78	25.6	0.2060	1.20 (0.90, 1.61)	1.27 (0.87, 1.86)	4.33 (-2.39, 11.01)	
Age											
<65 years	69	16	23.2	63	14	22.2					
>=65 years	237	49	20.7	242	64	26.4					
Sex											
Male	269	57	21.2	255	58	22.7					
Female	37	8	21.6	50	20	40.0					
Baseline FVC percent predicted											
<=70%	109	19	17.4	112	20	17.9					
>70%	197	46	23.4	193	58	30.1					
Type of AF therapy											
Nintedanib	173	37	21.4	178	42	23.6					
Pirfenidone	133	28	21.1	127	36	28.3					
Region											
Europe	136	32	23.5	136	39	28.7					
Asia	72	11	15.3	79	13	16.5					
Canada and USA	75	15	20.0	56	20	35.7					
Rest of the World	23	7	30.4	34	6	17.6					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	19	6.2	305	10	3.3	0.0885	0.53 (0.25, 1.12)	0.51 (0.23, 1.12)	-2.93 (-6.54, 0.51)	
Age											
<65 years	69	1	1.4	63	2	3.2					
>=65 years	237	18	7.6	242	8	3.3					
Sex											
Male	269	18	6.7	255	8	3.1					
Female	37	1	2.7	50	2	4.0					
Baseline FVC percent predicted											
<=70%	109	7	6.4	112	2	1.8					
>70%	197	12	6.1	193	8	4.1					
Type of AF therapy											
Nintedanib	173	9	5.2	178	5	2.8					
Pirfenidone	133	10	7.5	127	5	3.9					
Region											
Europe	136	5	3.7	136	4	2.9					
Asia	72	6	8.3	79	3	3.8					
Canada and USA	75	4	5.3	56	1	1.8					
Rest of the World	23	4	17.4	34	2	5.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	54	17.6	305	60	19.7	0.5206	1.11 (0.80, 1.55)	1.14 (0.76, 1.72)	2.03 (-4.17, 8.21)	
Age											
<65 years	69	11	15.9	63	8	12.7					
>=65 years	237	43	18.1	242	52	21.5					
Sex											
Male	269	48	17.8	255	49	19.2					
Female	37	6	16.2	50	11	22.0					
Baseline FVC percent predicted											
<=70%	109	17	15.6	112	28	25.0					
>70%	197	37	18.8	193	32	16.6					
Type of AF therapy											
Nintedanib	173	30	17.3	178	32	18.0					
Pirfenidone	133	24	18.0	127	28	22.0					
Region											
Europe	136	28	20.6	136	27	19.9					
Asia	72	5	6.9	79	11	13.9					
Canada and USA	75	18	24.0	56	13	23.2					
Rest of the World	23	3	13.0	34	9	26.5					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	57	18.6	305	57	18.7	0.9845	1.00 (0.72, 1.40)	1.00 (0.67, 1.51)	0.06 (-6.13, 6.25)	
Age											
<65 years	69	11	15.9	63	10	15.9					
>=65 years	237	46	19.4	242	47	19.4					
Sex											
Male	269	47	17.5	255	42	16.5					
Female	37	10	27.0	50	15	30.0					
Baseline FVC percent predicted											
<=70%	109	22	20.2	112	23	20.5					
>70%	197	35	17.8	193	34	17.6					
Type of AF therapy											
Nintedanib	173	27	15.6	178	33	18.5					
Pirfenidone	133	30	22.6	127	24	18.9					
Region											
Europe	136	26	19.1	136	28	20.6					
Asia	72	17	23.6	79	14	17.7					
Canada and USA	75	10	13.3	56	11	19.6					
Rest of the World	23	4	17.4	34	4	11.8					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	16	5.2	305	18	5.9	0.7168	1.13 (0.59, 2.17)	1.14 (0.57, 2.27)	0.67 (-3.09, 4.47)	
Age											
<65 years	69	2	2.9	63	3	4.8					
>=65 years	237	14	5.9	242	15	6.2					
Sex											
Male	269	13	4.8	255	15	5.9					
Female	37	3	8.1	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	6	5.5	112	2	1.8					
>70%	197	10	5.1	193	16	8.3					
Type of AF therapy											
Nintedanib	173	10	5.8	178	14	7.9					
Pirfenidone	133	6	4.5	127	4	3.1					
Region											
Europe	136	6	4.4	136	11	8.1					
Asia	72	4	5.6	79	4	5.1					
Canada and USA	75	5	6.7	56	2	3.6					
Rest of the World	23	1	4.3	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	6	2.0	305	20	6.6	0.0049	3.34 (1.36, 8.21)	3.51 (1.39, 8.86)	4.60 (1.40, 8.11)	
Age											0.3930
<65 years	69	0	0.0	63	4	6.3	0.0540	9.84 (0.54, >99)	NC (NC, NC)	6.35 (-0.18, 15.22)	
>=65 years	237	6	2.5	242	16	6.6	0.0329	2.61 (1.04, 6.56)	2.73 (1.05, 7.09)	4.08 (0.26, 8.17)	
Sex											0.9189
Male	269	6	2.2	255	18	7.1	0.0082	3.16 (1.28, 7.85)	3.33 (1.30, 8.53)	4.83 (1.22, 8.84)	
Female	37	0	0.0	50	2	4.0	0.3538	3.73 (0.18, 75.37)	NC (NC, NC)	4.00 (-5.84, 13.46)	
Baseline FVC percent predicted											0.4717
<=70%	109	3	2.8	112	7	6.3	0.2110	2.27 (0.60, 8.56)	2.36 (0.59, 9.36)	3.50 (-2.46, 9.85)	
>70%	197	3	1.5	193	13	6.7	0.0095	4.42 (1.28, 15.28)	4.67 (1.31, 16.66)	5.21 (1.24, 9.77)	
Type of AF therapy											0.4242
Nintedanib	173	4	2.3	178	10	5.6	0.1136	2.43 (0.78, 7.60)	2.51 (0.77, 8.18)	3.31 (-1.00, 7.94)	
Pirfenidone	133	2	1.5	127	10	7.9	0.0144	5.24 (1.17, 23.43)	5.60 (1.20, 26.08)	6.37 (1.17, 12.48)	
Region											0.2307
Europe	136	1	0.7	136	9	6.6	0.0099	9.00 (1.16, 70.07)	9.57 (1.20, 76.59)	5.88 (1.35, 11.40)	
Asia	72	2	2.8	79	4	5.1	0.4727	1.82 (0.34, 9.65)	1.87 (0.33, 10.51)	2.29 (-5.17, 9.80)	
Canada and USA	75	1	1.3	56	5	8.9	0.0397	6.70 (0.80, 55.73)	7.25 (0.82, 63.95)	7.60 (-0.13, 17.98)	
Rest of the World	23	2	8.7	34	2	5.9	0.6833	0.68 (0.10, 4.47)	0.66 (0.09, 5.03)	-2.81 (-21.41, 11.81)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	135	44.1	305	114	37.4	0.0900	0.85 (0.70, 1.03)	0.76 (0.55, 1.04)	-6.74	(-14.41, 1.05)	
Age												
<65 years	69	30	43.5	63	20	31.7						
>=65 years	237	105	44.3	242	94	38.8						
Sex												
Male	269	124	46.1	255	94	36.9						
Female	37	11	29.7	50	20	40.0						
Baseline FVC percent predicted												
<=70%	109	58	53.2	112	45	40.2						
>70%	197	77	39.1	193	69	35.8						
Type of AF therapy												
Nintedanib	173	78	45.1	178	61	34.3						
Pirfenidone	133	57	42.9	127	53	41.7						
Region												
Europe	136	60	44.1	136	50	36.8						
Asia	72	21	29.2	79	25	31.6						
Canada and USA	75	41	54.7	56	26	46.4						
Rest of the World	23	13	56.5	34	13	38.2						

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	37	12.1	305	49	16.1	0.1579	1.33 (0.89, 1.97)	1.39 (0.88, 2.20)	3.97 (-1.57, 9.52)	
Age											
<65 years	69	5	7.2	63	5	7.9					
>=65 years	237	32	13.5	242	44	18.2					
Sex											
Male	269	35	13.0	255	38	14.9					
Female	37	2	5.4	50	11	22.0					
Baseline FVC percent predicted											
<=70%	109	11	10.1	112	10	8.9					
>70%	197	26	13.2	193	39	20.2					
Type of AF therapy											
Nintedanib	173	15	8.7	178	31	17.4					
Pirfenidone	133	22	16.5	127	18	14.2					
Region											
Europe	136	24	17.6	136	22	16.2					
Asia	72	5	6.9	79	12	15.2					
Canada and USA	75	4	5.3	56	6	10.7					
Rest of the World	23	4	17.4	34	9	26.5					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 1 Proportion of patients with frequent AEs by SOC (incidence in either arm >= 10% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	23	7.5	305	22	7.2	0.8859	0.96 (0.55, 1.68)	0.96 (0.52, 1.76)	-0.30 (-4.56, 3.94)	
Age											
<65 years	69	5	7.2	63	2	3.2					
>=65 years	237	18	7.6	242	20	8.3					
Sex											
Male	269	22	8.2	255	18	7.1					
Female	37	1	2.7	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	7	6.4	112	5	4.5					
>70%	197	16	8.1	193	17	8.8					
Type of AF therapy											
Nintedanib	173	13	7.5	178	15	8.4					
Pirfenidone	133	10	7.5	127	7	5.5					
Region											
Europe	136	9	6.6	136	14	10.3					
Asia	72	7	9.7	79	4	5.1					
Canada and USA	75	5	6.7	56	1	1.8					
Rest of the World	23	2	8.7	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	16	5.2	305	16	5.2	0.9924	1.00 (0.51, 1.97)	1.00 (0.49, 2.04)	0.02 (-3.66, 3.70)	
Age											
<65 years	69	6	8.7	63	3	4.8					
>=65 years	237	10	4.2	242	13	5.4					
Sex											
Male	269	16	5.9	255	14	5.5					
Female	37	0	0.0	50	2	4.0					
Baseline FVC percent predicted											
<=70%	109	8	7.3	112	8	7.1					
>70%	197	8	4.1	193	8	4.1					
Type of AF therapy											
Nintedanib	173	7	4.0	178	8	4.5					
Pirfenidone	133	9	6.8	127	8	6.3					
Region											
Europe	136	6	4.4	136	10	7.4					
Asia	72	2	2.8	79	2	2.5					
Canada and USA	75	5	6.7	56	3	5.4					
Rest of the World	23	3	13.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	7	2.3	305	11	3.6	0.3350	1.58 (0.62, 4.01)	1.60 (0.61, 4.18)	1.32 (-1.52, 4.30)	
Age											
<65 years	69	2	2.9	63	0	0.0					
>=65 years	237	5	2.1	242	11	4.5					
Sex											
Male	269	6	2.2	255	10	3.9					
Female	37	1	2.7	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	4	3.6					
>70%	197	5	2.5	193	7	3.6					
Type of AF therapy											
Nintedanib	173	4	2.3	178	8	4.5					
Pirfenidone	133	3	2.3	127	3	2.4					
Region											
Europe	136	2	1.5	136	3	2.2					
Asia	72	2	2.8	79	5	6.3					
Canada and USA	75	2	2.7	56	1	1.8					
Rest of the World	23	1	4.3	34	2	5.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	25	8.2	305	28	9.2	0.6573	1.12 (0.67, 1.88)	1.14 (0.65, 2.00)	1.01 (-3.53, 5.57)	
Age											
<65 years	69	6	8.7	63	2	3.2					
>=65 years	237	19	8.0	242	26	10.7					
Sex											
Male	269	25	9.3	255	24	9.4					
Female	37	0	0.0	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	11	10.1	112	18	16.1					
>70%	197	14	7.1	193	10	5.2					
Type of AF therapy											
Nintedanib	173	15	8.7	178	18	10.1					
Pirfenidone	133	10	7.5	127	10	7.9					
Region											
Europe	136	12	8.8	136	12	8.8					
Asia	72	9	12.5	79	6	7.6					
Canada and USA	75	4	5.3	56	4	7.1					
Rest of the World	23	0	0.0	34	6	17.6					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	25	8.2	305	36	11.8	0.1342	1.44 (0.89, 2.35)	1.50 (0.88, 2.57)	3.63 (-1.16, 8.48)	
Age											
<65 years	69	3	4.3	63	5	7.9					
>=65 years	237	22	9.3	242	31	12.8					
Sex											
Male	269	24	8.9	255	32	12.5					
Female	37	1	2.7	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	15	13.8	112	19	17.0					
>70%	197	10	5.1	193	17	8.8					
Type of AF therapy											
Nintedanib	173	13	7.5	178	20	11.2					
Pirfenidone	133	12	9.0	127	16	12.6					
Region											
Europe	136	8	5.9	136	12	8.8					
Asia	72	8	11.1	79	15	19.0					
Canada and USA	75	8	10.7	56	5	8.9					
Rest of the World	23	1	4.3	34	4	11.8					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	16	5.2	305	9	3.0	0.1553	0.56 (0.25, 1.26)	0.55 (0.24, 1.27)	-2.28 (-5.67, 0.96)	
Age											
<65 years	69	1	1.4	63	2	3.2					
>=65 years	237	15	6.3	242	7	2.9					
Sex											
Male	269	16	5.9	255	8	3.1					
Female	37	0	0.0	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	5	4.6	112	2	1.8					
>70%	197	11	5.6	193	7	3.6					
Type of AF therapy											
Nintedanib	173	8	4.6	178	4	2.2					
Pirfenidone	133	8	6.0	127	5	3.9					
Region											
Europe	136	3	2.2	136	4	2.9					
Asia	72	6	8.3	79	2	2.5					
Canada and USA	75	3	4.0	56	1	1.8					
Rest of the World	23	4	17.4	34	2	5.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 2 Proportion of patients with frequent serious AEs by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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 ratio p-value*	Risk ratio (95% CI)	Odds ratio	Odds ratio (95% CI)	Risk diff.	Risk diff. (95% CI)	Interaction p-value**
Overall	306	32	10.5	305	36	11.8	0.5969	1.13 (0.72, 1.77)	1.15 (0.69, 1.90)		1.35 (-3.70, 6.40)		
Age													
<65 years	69	8	11.6	63	5	7.9							
>=65 years	237	24	10.1	242	31	12.8							
Sex													
Male	269	30	11.2	255	30	11.8							
Female	37	2	5.4	50	6	12.0							
Baseline FVC percent predicted													
<=70%	109	15	13.8	112	19	17.0							
>70%	197	17	8.6	193	17	8.8							
Type of AF therapy													
Nintedanib	173	18	10.4	178	20	11.2							
Pirfenidone	133	14	10.5	127	16	12.6							
Region													
Europe	136	11	8.1	136	14	10.3							
Asia	72	8	11.1	79	10	12.7							
Canada and USA	75	11	14.7	56	6	10.7							
Rest of the World	23	2	8.7	34	6	17.6							

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.2.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	12	3.9	305	14	4.6	0.6823	1.17 (0.55, 2.49)	1.18 (0.54, 2.59)	0.67 (-2.69, 4.07)	
Age											
<65 years	69	6	8.7	63	4	6.3					
>=65 years	237	6	2.5	242	10	4.1					
Sex											
Male	269	12	4.5	255	13	5.1					
Female	37	0	0.0	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	6	5.5	112	8	7.1					
>70%	197	6	3.0	193	6	3.1					
Type of AF therapy											
Nintedanib	173	5	2.9	178	8	4.5					
Pirfenidone	133	7	5.3	127	6	4.7					
Region											
Europe	136	4	2.9	136	8	5.9					
Asia	72	1	1.4	79	2	2.5					
Canada and USA	75	4	5.3	56	3	5.4					
Rest of the World	23	3	13.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0. 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 H.2.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (AF background)
SOC: Gastrointestinal disorders

Subgroup	Placebo			Nera 18mg			Nera 18mg vs Placebo					Interaction
Category	N	n	%	N	n	%	p-value*	Risk ratio (95% CI)		Odds ratio (95% CI)		Risk diff. (95% CI)		p-value**
Overall	306	8	2.6	305	20	6.6	0.0198	2.51 (1.12,	5.61)	2.61 (1.13,	6.03)	3.94 (0.59,	7.53)	
Age														0.1244
<65 years	69	3	4.3	63	2	3.2	0.7243	0.73 (0.13,	4.23)	0.72 (0.12,	4.46)	-1.17 (-9.18,	7.02)	
>=65 years	237	5	2.1	242	18	7.4	0.0064	3.53 (1.33,	9.34)	3.73 (1.36,	10.21)	5.33 (1.50,	9.52)	
Sex														0.3551
Male	269	7	2.6	255	19	7.5	0.0106	2.86 (1.22,	6.70)	3.01 (1.24,	7.30)	4.85 (1.10,	8.96)	
Female	37	1	2.7	50	1	2.0	0.8288	0.74 (0.05,	11.45)	0.73 (0.04,	12.14)	-0.70 (-11.95,	8.08)	
Baseline FVC percent predicted														0.2681
<=70%	109	1	0.9	112	7	6.3	0.0338	6.81 (0.85,	54.46)	7.20 (0.87,	59.53)	5.33 (0.14,	11.47)	
>70%	197	7	3.6	193	13	6.7	0.1543	1.90 (0.77,	4.65)	1.96 (0.76,	5.02)	3.18 (-1.35,	7.99)	
Type of AF therapy														0.2255
Nintedanib	173	5	2.9	178	17	9.6	0.0101	3.30 (1.25,	8.76)	3.55 (1.28,	9.84)	6.66 (1.57,	12.13)	
Pirfenidone	133	3	2.3	127	3	2.4	0.9544	1.05 (0.22,	5.09)	1.05 (0.21,	5.29)	0.11 (-4.34,	4.71)	
Region														0.6140
Europe	136	3	2.2	136	11	8.1	0.0281	3.67 (1.05,	12.85)	3.90 (1.06,	14.31)	5.88 (0.50,	11.88)	
Asia	72	2	2.8	79	6	7.6	0.1869	2.73 (0.57,	13.12)	2.88 (0.56,	14.73)	4.82 (-3.10,	13.07)	
Canada and USA	75	2	2.7	56	1	1.8	0.7388	0.67 (0.06,	7.20)	0.66 (0.06,	7.51)	-0.88 (-7.59,	7.02)	
Rest of the World	23	1	4.3	34	2	5.9	0.7991	1.35 (0.13,	14.06)	1.38 (0.12,	16.11)	1.53 (-15.64,	15.22)	

Study: 1305-0014. MedDRA version: 27.0. 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 H.2.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	24	7.8	305	28	9.2	0.5537	1.17 (0.69, 1.97)	1.19 (0.67, 2.10)	1.34 (-3.16, 5.87)	
Age											
<65 years	69	6	8.7	63	2	3.2					
>=65 years	237	18	7.6	242	26	10.7					
Sex											
Male	269	24	8.9	255	24	9.4					
Female	37	0	0.0	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	11	10.1	112	17	15.2					
>70%	197	13	6.6	193	11	5.7					
Type of AF therapy											
Nintedanib	173	15	8.7	178	19	10.7					
Pirfenidone	133	9	6.8	127	9	7.1					
Region											
Europe	136	12	8.8	136	12	8.8					
Asia	72	8	11.1	79	6	7.6					
Canada and USA	75	4	5.3	56	4	7.1					
Rest of the World	23	0	0.0	34	6	17.6					

Study: 1305-0014. MedDRA version: 27.0. 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 H.2.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	25	8.2	305	31	10.2	0.3930	1.24 (0.75, 2.06)	1.27 (0.73, 2.21)	1.99 (-2.65, 6.67)	
Age											
<65 years	69	3	4.3	63	6	9.5					
>=65 years	237	22	9.3	242	25	10.3					
Sex											
Male	269	25	9.3	255	28	11.0					
Female	37	0	0.0	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	12	11.0	112	16	14.3					
>70%	197	13	6.6	193	15	7.8					
Type of AF therapy											
Nintedanib	173	12	6.9	178	19	10.7					
Pirfenidone	133	13	9.8	127	12	9.4					
Region											
Europe	136	7	5.1	136	12	8.8					
Asia	72	7	9.7	79	13	16.5					
Canada and USA	75	10	13.3	56	2	3.6					
Rest of the World	23	1	4.3	34	4	11.8					

Study: 1305-0014. MedDRA version: 27.0. 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 H.2.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	4	1.3	305	10	3.3	0.1034	2.51 (0.80, 7.91)	2.56 (0.79, 8.25)	1.97 (-0.53, 4.74)	
Age											
<65 years	69	2	2.9	63	1	1.6					
>=65 years	237	2	0.8	242	9	3.7					
Sex											
Male	269	3	1.1	255	7	2.7					
Female	37	1	2.7	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	5	4.5					
>70%	197	2	1.0	193	5	2.6					
Type of AF therapy											
Nintedanib	173	3	1.7	178	9	5.1					
Pirfenidone	133	1	0.8	127	1	0.8					
Region											
Europe	136	2	1.5	136	6	4.4					
Asia	72	0	0.0	79	3	3.8					
Canada and USA	75	1	1.3	56	1	1.8					
Rest of the World	23	1	4.3	34	0	0.0					

Study: 1305-0014. MedDRA version: 27.0. 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 H.2.1.2.1.4: 3 Proportion of patients with frequent AEs with CTCAE grade >=3 by SOC (incidence in either arm >= 5% or incidence >=1% and >=10 patients affected in either arm) over the whole trial (DBL1) - 18mg - TS (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	306	22	7.2	305	24	7.9	0.7503	1.09 (0.63, 1.91)	1.10 (0.60, 2.01)	0.68 (-3.60, 4.98)	
Age											
<65 years	69	6	8.7	63	3	4.8					
>=65 years	237	16	6.8	242	21	8.7					
Sex											
Male	269	21	7.8	255	20	7.8					
Female	37	1	2.7	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	14	12.8	112	13	11.6					
>70%	197	8	4.1	193	11	5.7					
Type of AF therapy											
Nintedanib	173	13	7.5	178	14	7.9					
Pirfenidone	133	9	6.8	127	10	7.9					
Region											
Europe	136	9	6.6	136	10	7.4					
Asia	72	3	4.2	79	5	6.3					
Canada and USA	75	8	10.7	56	4	7.1					
Rest of the World	23	2	8.7	34	5	14.7					

Study: 1305-0014. MedDRA version: 27.0. 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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H.2.1.2.1.5 Adverse events on PT level over the whole trial

Table H.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 (AF background)
SOC: Gastrointestinal disorders
PT: Abdominal pain

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	306	9	2.9	305	13	4.3	0.3808	1.45 (0.63, 3.34)	1.47 (0.62, 3.49)	1.32 (-1.78, 4.53)	
Age											
<65 years	69	4	5.8	63	5	7.9					
>=65 years	237	5	2.1	242	8	3.3					
Sex											
Male	269	7	2.6	255	8	3.1					
Female	37	2	5.4	50	5	10.0					
Baseline FVC percent predicted											
<=70%	109	5	4.6	112	5	4.5					
>70%	197	4	2.0	193	8	4.1					
Type of AF therapy											
Nintedanib	173	7	4.0	178	10	5.6					
Pirfenidone	133	2	1.5	127	3	2.4					
Region											
Europe	136	5	3.7	136	11	8.1					
Asia	72	0	0.0	79	0	0.0					
Canada and USA	75	4	5.3	56	1	1.8					
Rest of the World	23	0	0.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Gastrointestinal disorders
PT: Constipation

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	306	13	4.2	305	8	2.6	0.2702	0.62 (0.26, 1.47)	0.61 (0.25, 1.49)	-1.63 (-4.78, 1.40)	
Age											
<65 years	69	2	2.9	63	0	0.0					
>=65 years	237	11	4.6	242	8	3.3					
Sex											
Male	269	12	4.5	255	6	2.4					
Female	37	1	2.7	50	2	4.0					
Baseline FVC percent predicted											
<=70%	109	7	6.4	112	2	1.8					
>70%	197	6	3.0	193	6	3.1					
Type of AF therapy											
Nintedanib	173	1	0.6	178	4	2.2					
Pirfenidone	133	12	9.0	127	4	3.1					
Region											
Europe	136	3	2.2	136	4	2.9					
Asia	72	3	4.2	79	2	2.5					
Canada and USA	75	5	6.7	56	1	1.8					
Rest of the World	23	2	8.7	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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 ratio p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	59	19.3	305	140	45.9	<.0001	2.38 (1.84, 3.09)	3.55 (2.47, 5.10)	26.62 (19.32, 33.53)	
Age											0.5584
<65 years	69	12	17.4	63	22	34.9	0.0214	2.01 (1.09, 3.71)	2.55 (1.13, 5.73)	17.53 (2.55, 31.78)	
>=65 years	237	47	19.8	242	118	48.8	<.0001	2.46 (1.85, 3.28)	3.85 (2.56, 5.78)	28.93 (20.59, 36.69)	
Sex											0.3506
Male	269	53	19.7	255	113	44.3	<.0001	2.25 (1.70, 2.97)	3.24 (2.20, 4.79)	24.61 (16.72, 32.11)	
Female	37	6	16.2	50	27	54.0	0.0003	3.33 (1.53, 7.23)	6.07 (2.15, 17.09)	37.78 (17.59, 53.38)	
Baseline FVC percent predicted											0.0173
<=70%	109	25	22.9	112	40	35.7	0.0371	1.56 (1.02, 2.38)	1.87 (1.03, 3.37)	12.78 (0.75, 24.28)	
>70%	197	34	17.3	193	100	51.8	<.0001	3.00 (2.15, 4.20)	5.15 (3.24, 8.21)	34.55 (25.39, 42.91)	
Type of AF therapy											0.4859
Nintedanib	173	48	27.7	178	110	61.8	<.0001	2.23 (1.71, 2.91)	4.21 (2.69, 6.60)	34.05 (23.86, 43.22)	
Pirfenidone	133	11	8.3	127	30	23.6	0.0007	2.86 (1.50, 5.45)	3.43 (1.64, 7.19)	15.35 (6.52, 24.21)	
Region											0.2828
Europe	136	32	23.5	136	71	52.2	<.0001	2.22 (1.57, 3.13)	3.55 (2.11, 5.97)	28.68 (17.26, 39.06)	
Asia	72	5	6.9	79	29	36.7	<.0001	5.29 (2.16, 12.92)	7.77 (2.81, 21.50)	29.76 (16.93, 41.46)	
Canada and USA	75	17	22.7	56	25	44.6	0.0077	1.97 (1.18, 3.28)	2.75 (1.29, 5.85)	21.98 (5.73, 37.20)	
Rest of the World	23	5	21.7	34	15	44.1	0.0824	2.03 (0.86, 4.81)	2.84 (0.86, 9.44)	22.38 (-2.89, 42.77)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	24	7.8	305	26	8.5	0.7586	1.09 (0.64, 1.85)	1.09 (0.61, 1.95)	0.68 (-3.75, 5.13)	
Age											
<65 years	69	8	11.6	63	2	3.2					
>=65 years	237	16	6.8	242	24	9.9					
Sex											
Male	269	20	7.4	255	18	7.1					
Female	37	4	10.8	50	8	16.0					
Baseline FVC percent predicted											
<=70%	109	10	9.2	112	6	5.4					
>70%	197	14	7.1	193	20	10.4					
Type of AF therapy											
Nintedanib	173	14	8.1	178	17	9.6					
Pirfenidone	133	10	7.5	127	9	7.1					
Region											
Europe	136	8	5.9	136	16	11.8					
Asia	72	3	4.2	79	3	3.8					
Canada and USA	75	9	12.0	56	4	7.1					
Rest of the World	23	4	17.4	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF 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	306	17	5.6	305	18	5.9	0.8540	1.06 (0.56, 2.02)	1.07 (0.54, 2.11)	0.35 (-3.47, 4.18)	
Age											
<65 years	69	4	5.8	63	5	7.9					
>=65 years	237	13	5.5	242	13	5.4					
Sex											
Male	269	11	4.1	255	10	3.9					
Female	37	6	16.2	50	8	16.0					
Baseline FVC percent predicted											
<=70%	109	6	5.5	112	2	1.8					
>70%	197	11	5.6	193	16	8.3					
Type of AF therapy											
Nintedanib	173	13	7.5	178	16	9.0					
Pirfenidone	133	4	3.0	127	2	1.6					
Region											
Europe	136	10	7.4	136	13	9.6					
Asia	72	1	1.4	79	1	1.3					
Canada and USA	75	6	8.0	56	3	5.4					
Rest of the World	23	0	0.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: General disorders and administration site conditions
PT: Asthenia

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	306	5	1.6	305	16	5.2	0.0143	3.21 (1.19, 8.65)	3.33 (1.21, 9.22)	3.61 (0.69, 6.85)	
Age											0.4228
<65 years	69	1	1.4	63	1	1.6	0.9483	1.10 (0.07, 17.14)	1.10 (0.07, 17.91)	0.14 (-6.31, 7.11)	
>=65 years	237	4	1.7	242	15	6.2	0.0114	3.67 (1.24, 10.90)	3.85 (1.26, 11.77)	4.51 (0.99, 8.42)	
Sex											0.5168
Male	269	4	1.5	255	9	3.5	0.1330	2.37 (0.74, 7.61)	2.42 (0.74, 7.97)	2.04 (-0.77, 5.22)	
Female	37	1	2.7	50	7	14.0	0.0714	5.18 (0.67, 40.31)	5.86 (0.69, 49.89)	11.30 (-1.87, 23.68)	
Baseline FVC percent predicted											0.8825
<=70%	109	2	1.8	112	6	5.4	0.1611	2.92 (0.60, 14.15)	3.03 (0.60, 15.34)	3.52 (-1.91, 9.51)	
>70%	197	3	1.5	193	10	5.2	0.0442	3.40 (0.95, 12.17)	3.53 (0.96, 13.04)	3.66 (-0.04, 7.87)	
Type of AF therapy											0.1806
Nintedanib	173	2	1.2	178	12	6.7	0.0075	5.83 (1.32, 25.67)	6.18 (1.36, 28.04)	5.59 (1.48, 10.33)	
Pirfenidone	133	3	2.3	127	4	3.1	0.6562	1.40 (0.32, 6.12)	1.41 (0.31, 6.42)	0.89 (-3.69, 5.79)	
Region											0.8387
Europe	136	5	3.7	136	11	8.1	0.1221	2.20 (0.79, 6.16)	2.31 (0.78, 6.82)	4.41 (-1.41, 10.59)	
Asia	72	0	0.0	79	1	1.3	0.5174	2.74 (0.11, 66.15)	NC (NC, NC)	1.27 (-3.91, 6.83)	
Canada and USA	75	0	0.0	56	3	5.4	0.0670	9.33 (0.49, >99)	NC (NC, NC)	5.36 (-0.65, 14.61)	
Rest of the World	23	0	0.0	34	1	2.9	0.6461	2.06 (0.09, 48.40)	NC (NC, NC)	2.94 (-11.57, 14.92)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: General disorders and administration site conditions
PT: Chest pain

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	306	6	2.0	305	10	3.3	0.3077	1.67 (0.62, 4.54)	1.69 (0.61, 4.72)	1.32 (-1.38, 4.17)	
Age											
<65 years	69	3	4.3	63	1	1.6					
>=65 years	237	3	1.3	242	9	3.7					
Sex											
Male	269	6	2.2	255	9	3.5					
Female	37	0	0.0	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	2	1.8					
>70%	197	4	2.0	193	8	4.1					
Type of AF therapy											
Nintedanib	173	3	1.7	178	4	2.2					
Pirfenidone	133	3	2.3	127	6	4.7					
Region											
Europe	136	4	2.9	136	1	0.7					
Asia	72	1	1.4	79	3	3.8					
Canada and USA	75	1	1.3	56	5	8.9					
Rest of the World	23	0	0.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	31	10.1	305	36	11.8	0.5082	1.17 (0.74, 1.83)	1.19 (0.71, 1.97)	1.67 (-3.34, 6.70)	
Age											
<65 years	69	5	7.2	63	5	7.9					
>=65 years	237	26	11.0	242	31	12.8					
Sex											
Male	269	31	11.5	255	33	12.9					
Female	37	0	0.0	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	15	13.8	112	23	20.5					
>70%	197	16	8.1	193	13	6.7					
Type of AF therapy											
Nintedanib	173	18	10.4	178	21	11.8					
Pirfenidone	133	13	9.8	127	15	11.8					
Region											
Europe	136	13	9.6	136	19	14.0					
Asia	72	10	13.9	79	7	8.9					
Canada and USA	75	8	10.7	56	4	7.1					
Rest of the World	23	0	0.0	34	6	17.6					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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 ratio p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff.	(95% CI)	Interaction p-value**
Overall	306	20	6.5	305	21	6.9	0.8630	1.05 (0.58, 1.90)	1.06 (0.56, 1.99)	0.35	(-3.73, 4.44)	
Age												
<65 years	69	5	7.2	63	2	3.2						
>=65 years	237	15	6.3	242	19	7.9						
Sex												
Male	269	18	6.7	255	18	7.1						
Female	37	2	5.4	50	3	6.0						
Baseline FVC percent predicted												
<=70%	109	7	6.4	112	5	4.5						
>70%	197	13	6.6	193	16	8.3						
Type of AF therapy												
Nintedanib	173	11	6.4	178	11	6.2						
Pirfenidone	133	9	6.8	127	10	7.9						
Region												
Europe	136	9	6.6	136	9	6.6						
Asia	72	3	4.2	79	1	1.3						
Canada and USA	75	8	10.7	56	8	14.3						
Rest of the World	23	0	0.0	34	3	8.8						

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	26	8.5	305	29	9.5	0.6623	1.12 (0.68, 1.85)	1.13 (0.65, 1.97)	1.01 (-3.60, 5.65)	
Age											
<65 years	69	8	11.6	63	4	6.3					
>=65 years	237	18	7.6	242	25	10.3					
Sex											
Male	269	24	8.9	255	27	10.6					
Female	37	2	5.4	50	2	4.0					
Baseline FVC percent predicted											
<=70%	109	11	10.1	112	14	12.5					
>70%	197	15	7.6	193	15	7.8					
Type of AF therapy											
Nintedanib	173	12	6.9	178	17	9.6					
Pirfenidone	133	14	10.5	127	12	9.4					
Region											
Europe	136	16	11.8	136	21	15.4					
Asia	72	6	8.3	79	2	2.5					
Canada and USA	75	3	4.0	56	5	8.9					
Rest of the World	23	1	4.3	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	45	14.7	305	41	13.4	0.6535	0.91 (0.62, 1.35)	0.90 (0.57, 1.42)	-1.26 (-6.81, 4.29)	
Age											
<65 years	69	12	17.4	63	6	9.5					
>=65 years	237	33	13.9	242	35	14.5					
Sex											
Male	269	42	15.6	255	32	12.5					
Female	37	3	8.1	50	9	18.0					
Baseline FVC percent predicted											
<=70%	109	16	14.7	112	14	12.5					
>70%	197	29	14.7	193	27	14.0					
Type of AF therapy											
Nintedanib	173	23	13.3	178	21	11.8					
Pirfenidone	133	22	16.5	127	20	15.7					
Region											
Europe	136	14	10.3	136	17	12.5					
Asia	72	9	12.5	79	11	13.9					
Canada and USA	75	16	21.3	56	10	17.9					
Rest of the World	23	6	26.1	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	11	3.6	305	12	3.9	0.8254	1.09 (0.49, 2.44)	1.10 (0.48, 2.53)	0.34 (-2.86, 3.57)	
Age											
<65 years	69	5	7.2	63	5	7.9					
>=65 years	237	6	2.5	242	7	2.9					
Sex											
Male	269	10	3.7	255	11	4.3					
Female	37	1	2.7	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	5	4.6	112	4	3.6					
>70%	197	6	3.0	193	8	4.1					
Type of AF therapy											
Nintedanib	173	7	4.0	178	6	3.4					
Pirfenidone	133	4	3.0	127	6	4.7					
Region											
Europe	136	8	5.9	136	5	3.7					
Asia	72	1	1.4	79	3	3.8					
Canada and USA	75	1	1.3	56	1	1.8					
Rest of the World	23	1	4.3	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Infections and infestations
PT: Nasopharyngitis

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	306	36	11.8	305	32	10.5	0.6169	0.89 (0.57, 1.40)	0.88 (0.53, 1.46)	-1.27	(-6.32, 3.77)	
Age												
<65 years	69	11	15.9	63	10	15.9						
>=65 years	237	25	10.5	242	22	9.1						
Sex												
Male	269	31	11.5	255	28	11.0						
Female	37	5	13.5	50	4	8.0						
Baseline FVC percent predicted												
<=70%	109	14	12.8	112	9	8.0						
>70%	197	22	11.2	193	23	11.9						
Type of AF therapy												
Nintedanib	173	21	12.1	178	19	10.7						
Pirfenidone	133	15	11.3	127	13	10.2						
Region												
Europe	136	24	17.6	136	19	14.0						
Asia	72	5	6.9	79	11	13.9						
Canada and USA	75	7	9.3	56	2	3.6						
Rest of the World	23	0	0.0	34	0	0.0						

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	22	7.2	305	25	8.2	0.6404	1.14 (0.66,	1.98)	1.15 (0.63,	2.09)	1.01 (-3.31, 5.35)	
Age													
<65 years	69	3	4.3	63	5	7.9							
>=65 years	237	19	8.0	242	20	8.3							
Sex													
Male	269	19	7.1	255	23	9.0							
Female	37	3	8.1	50	2	4.0							
Baseline FVC percent predicted													
<=70%	109	12	11.0	112	12	10.7							
>70%	197	10	5.1	193	13	6.7							
Type of AF therapy													
Nintedanib	173	8	4.6	178	11	6.2							
Pirfenidone	133	14	10.5	127	14	11.0							
Region													
Europe	136	7	5.1	136	8	5.9							
Asia	72	8	11.1	79	11	13.9							
Canada and USA	75	7	9.3	56	5	8.9							
Rest of the World	23	0	0.0	34	1	2.9							

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	8	2.6	305	17	5.6	0.0648	2.13 (0.93, 4.87)	2.20 (0.93, 5.17)	2.96 (-0.25, 6.38)	
Age											
<65 years	69	3	4.3	63	7	11.1					
>=65 years	237	5	2.1	242	10	4.1					
Sex											
Male	269	8	3.0	255	13	5.1					
Female	37	0	0.0	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	4	3.7	112	4	3.6					
>70%	197	4	2.0	193	13	6.7					
Type of AF therapy											
Nintedanib	173	1	0.6	178	9	5.1					
Pirfenidone	133	7	5.3	127	8	6.3					
Region											
Europe	136	6	4.4	136	14	10.3					
Asia	72	1	1.4	79	0	0.0					
Canada and USA	75	0	0.0	56	0	0.0					
Rest of the World	23	1	4.3	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Infections and infestations
PT: Rhinitis

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	306	12	3.9	305	7	2.3	0.2468	0.59 (0.23, 1.47)	0.58 (0.22, 1.48)	-1.63 (-4.67, 1.27)	
Age											
<65 years	69	3	4.3	63	1	1.6					
>=65 years	237	9	3.8	242	6	2.5					
Sex											
Male	269	11	4.1	255	5	2.0					
Female	37	1	2.7	50	2	4.0					
Baseline FVC percent predicted											
<=70%	109	7	6.4	112	3	2.7					
>70%	197	5	2.5	193	4	2.1					
Type of AF therapy											
Nintedanib	173	6	3.5	178	1	0.6					
Pirfenidone	133	6	4.5	127	6	4.7					
Region											
Europe	136	6	4.4	136	3	2.2					
Asia	72	3	4.2	79	4	5.1					
Canada and USA	75	3	4.0	56	0	0.0					
Rest of the World	23	0	0.0	34	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Infections and infestations
PT: Upper 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	306	35	11.4	305	39	12.8	0.6093	1.12 (0.73,	1.71)	1.14 (0.70,	1.85)	1.35 (-3.87, 6.58)	
Age													
<65 years	69	6	8.7	63	6	9.5							
>=65 years	237	29	12.2	242	33	13.6							
Sex													
Male	269	27	10.0	255	31	12.2							
Female	37	8	21.6	50	8	16.0							
Baseline FVC percent predicted													
<=70%	109	13	11.9	112	8	7.1							
>70%	197	22	11.2	193	31	16.1							
Type of AF therapy													
Nintedanib	173	14	8.1	178	24	13.5							
Pirfenidone	133	21	15.8	127	15	11.8							
Region													
Europe	136	6	4.4	136	9	6.6							
Asia	72	16	22.2	79	13	16.5							
Canada and USA	75	11	14.7	56	9	16.1							
Rest of the World	23	2	8.7	34	8	23.5							

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Infections and infestations
PT: Urinary 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	306	11	3.6	305	10	3.3	0.8302	0.91 (0.39, 2.12)	0.91 (0.38, 2.17)	-0.32 (-3.42, 2.77)	
Age											
<65 years	69	1	1.4	63	1	1.6					
>=65 years	237	10	4.2	242	9	3.7					
Sex											
Male	269	7	2.6	255	7	2.7					
Female	37	4	10.8	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	3	2.8	112	2	1.8					
>70%	197	8	4.1	193	8	4.1					
Type of AF therapy											
Nintedanib	173	8	4.6	178	5	2.8					
Pirfenidone	133	3	2.3	127	5	3.9					
Region											
Europe	136	6	4.4	136	6	4.4					
Asia	72	1	1.4	79	1	1.3					
Canada and USA	75	3	4.0	56	2	3.6					
Rest of the World	23	1	4.3	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	28	9.2	305	38	12.5	0.1877	1.36 (0.86, 2.16)	1.41 (0.84, 2.37)	3.31 (-1.66, 8.31)	
Age											
<65 years	69	5	7.2	63	5	7.9					
>=65 years	237	23	9.7	242	33	13.6					
Sex											
Male	269	25	9.3	255	33	12.9					
Female	37	3	8.1	50	5	10.0					
Baseline FVC percent predicted											
<=70%	109	13	11.9	112	15	13.4					
>70%	197	15	7.6	193	23	11.9					
Type of AF therapy											
Nintedanib	173	21	12.1	178	29	16.3					
Pirfenidone	133	7	5.3	127	9	7.1					
Region											
Europe	136	6	4.4	136	18	13.2					
Asia	72	8	11.1	79	11	13.9					
Canada and USA	75	12	16.0	56	5	8.9					
Rest of the World	23	2	8.7	34	4	11.8					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	20	6.5	305	30	9.8	0.1368	1.50 (0.87, | 2.59)	1.56 (0.87, 2.81)	3.30	(-1.10, 7.77)	
Age													
<65 years	69	2	2.9	63	5	7.9							
>=65 years	237	18	7.6	242	25	10.3							
Sex													
Male	269	18	6.7	255	25	9.8							
Female	37	2	5.4	50	5	10.0							
Baseline FVC percent predicted													
<=70%	109	10	9.2	112	15	13.4							
>70%	197	10	5.1	193	15	7.8							
Type of AF therapy													
Nintedanib	173	7	4.0	178	13	7.3							
Pirfenidone	133	13	9.8	127	17	13.4							
Region													
Europe	136	4	2.9	136	10	7.4							
Asia	72	9	12.5	79	13	16.5							
Canada and USA	75	6	8.0	56	5	8.9							
Rest of the World	23	1	4.3	34	2	5.9							

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	16	5.2	305	13	4.3	0.5743	0.82 (0.40, 1.67)	0.81 (0.38, 1.71)	-0.97 (-4.52, 2.54)	
Age											
<65 years	69	6	8.7	63	1	1.6					
>=65 years	237	10	4.2	242	12	5.0					
Sex											
Male	269	14	5.2	255	9	3.5					
Female	37	2	5.4	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	8	7.3	112	4	3.6					
>70%	197	8	4.1	193	9	4.7					
Type of AF therapy											
Nintedanib	173	11	6.4	178	6	3.4					
Pirfenidone	133	5	3.8	127	7	5.5					
Region											
Europe	136	4	2.9	136	6	4.4					
Asia	72	5	6.9	79	0	0.0					
Canada and USA	75	4	5.3	56	6	10.7					
Rest of the World	23	3	13.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	12	3.9	305	19	6.2	0.1937	1.59 (0.78, 3.22)	1.63 (0.78, 3.41)	2.31 (-1.26, 6.00)	
Age											
<65 years	69	2	2.9	63	4	6.3					
>=65 years	237	10	4.2	242	15	6.2					
Sex											
Male	269	10	3.7	255	12	4.7					
Female	37	2	5.4	50	7	14.0					
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	4	3.6					
>70%	197	10	5.1	193	15	7.8					
Type of AF therapy											
Nintedanib	173	7	4.0	178	11	6.2					
Pirfenidone	133	5	3.8	127	8	6.3					
Region											
Europe	136	2	1.5	136	6	4.4					
Asia	72	4	5.6	79	5	6.3					
Canada and USA	75	3	4.0	56	5	8.9					
Rest of the World	23	3	13.0	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Musculoskeletal and connective tissue disorders
PT: Pain in extremity

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	306	4	1.3	305	10	3.3	0.1034	2.51 (0.80, 7.91)	2.56 (0.79, 8.25)	1.97 (-0.53, 4.74)	
Age											
<65 years	69	1	1.4	63	1	1.6					
>=65 years	237	3	1.3	242	9	3.7					
Sex											
Male	269	4	1.5	255	7	2.7					
Female	37	0	0.0	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	1	0.9	112	4	3.6					
>70%	197	3	1.5	193	6	3.1					
Type of AF therapy											
Nintedanib	173	2	1.2	178	7	3.9					
Pirfenidone	133	2	1.5	127	3	2.4					
Region											
Europe	136	4	2.9	136	6	4.4					
Asia	72	0	0.0	79	0	0.0					
Canada and USA	75	0	0.0	56	4	7.1					
Rest of the World	23	0	0.0	34	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Nervous system disorders
PT: Dizziness

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	306	15	4.9	305	18	5.9	0.5847	1.20 (0.62, 2.34)	1.22 (0.60, 2.46)	1.00 (-2.71, 4.75)	
Age											
<65 years	69	3	4.3	63	1	1.6					
>=65 years	237	12	5.1	242	17	7.0					
Sex											
Male	269	15	5.6	255	16	6.3					
Female	37	0	0.0	50	2	4.0					
Baseline FVC percent predicted											
<=70%	109	3	2.8	112	5	4.5					
>70%	197	12	6.1	193	13	6.7					
Type of AF therapy											
Nintedanib	173	11	6.4	178	14	7.9					
Pirfenidone	133	4	3.0	127	4	3.1					
Region											
Europe	136	7	5.1	136	7	5.1					
Asia	72	1	1.4	79	6	7.6					
Canada and USA	75	6	8.0	56	5	8.9					
Rest of the World	23	1	4.3	34	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF 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	306	15	4.9	305	24	7.9	0.1336	1.61 (0.86, 3.00)	1.66 (0.85, 3.22)	2.97 (-0.97, 7.02)	
Age											
<65 years	69	6	8.7	63	3	4.8					
>=65 years	237	9	3.8	242	21	8.7					
Sex											
Male	269	13	4.8	255	18	7.1					
Female	37	2	5.4	50	6	12.0					
Baseline FVC percent predicted											
<=70%	109	5	4.6	112	11	9.8					
>70%	197	10	5.1	193	13	6.7					
Type of AF therapy											
Nintedanib	173	9	5.2	178	12	6.7					
Pirfenidone	133	6	4.5	127	12	9.4					
Region											
Europe	136	9	6.6	136	11	8.1					
Asia	72	2	2.8	79	3	3.8					
Canada and USA	75	3	4.0	56	6	10.7					
Rest of the World	23	1	4.3	34	4	11.8					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	29	9.5	305	27	8.9	0.7890	0.93 (0.57, 1.54)	0.93 (0.54, 1.61)	-0.62 (-5.29, 4.03)	
Age											
<65 years	69	4	5.8	63	5	7.9					
>=65 years	237	25	10.5	242	22	9.1					
Sex											
Male	269	23	8.6	255	17	6.7					
Female	37	6	16.2	50	10	20.0					
Baseline FVC percent predicted											
<=70%	109	14	12.8	112	9	8.0					
>70%	197	15	7.6	193	18	9.3					
Type of AF therapy											
Nintedanib	173	15	8.7	178	13	7.3					
Pirfenidone	133	14	10.5	127	14	11.0					
Region											
Europe	136	16	11.8	136	11	8.1					
Asia	72	5	6.9	79	6	7.6					
Canada and USA	75	5	6.7	56	7	12.5					
Rest of the World	23	3	13.0	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	30	9.8	305	28	9.2	0.7926	0.94 (0.57, 1.53)	0.93 (0.54, 1.60)	-0.62 (-5.35, 4.10)	
Age											
<65 years	69	8	11.6	63	5	7.9					
>=65 years	237	22	9.3	242	23	9.5					
Sex											
Male	269	23	8.6	255	23	9.0					
Female	37	7	18.9	50	5	10.0					
Baseline FVC percent predicted											
<=70%	109	13	11.9	112	13	11.6					
>70%	197	17	8.6	193	15	7.8					
Type of AF therapy											
Nintedanib	173	11	6.4	178	15	8.4					
Pirfenidone	133	19	14.3	127	13	10.2					
Region											
Europe	136	11	8.1	136	15	11.0					
Asia	72	10	13.9	79	6	7.6					
Canada and USA	75	8	10.7	56	4	7.1					
Rest of the World	23	1	4.3	34	3	8.8					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Cough

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	306	65	21.2	305	53	17.4	0.2263	0.82 (0.59, 1.13)	0.78 (0.52, 1.17)	-3.86	(-10.11, 2.41)	
Age												
<65 years	69	14	20.3	63	11	17.5						
>=65 years	237	51	21.5	242	42	17.4						
Sex												
Male	269	62	23.0	255	43	16.9						
Female	37	3	8.1	50	10	20.0						
Baseline FVC percent predicted												
<=70%	109	29	26.6	112	19	17.0						
>70%	197	36	18.3	193	34	17.6						
Type of AF therapy												
Nintedanib	173	32	18.5	178	28	15.7						
Pirfenidone	133	33	24.8	127	25	19.7						
Region												
Europe	136	29	21.3	136	31	22.8						
Asia	72	9	12.5	79	9	11.4						
Canada and USA	75	20	26.7	56	10	17.9						
Rest of the World	23	7	30.4	34	3	8.8						

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF 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	306	39	12.7	305	31	10.2	0.3165	0.80 (0.51, 1.24)	0.77 (0.47, 1.28)	-2.58 (-7.69, 2.52)	
Age											
<65 years	69	6	8.7	63	2	3.2					
>=65 years	237	33	13.9	242	29	12.0					
Sex											
Male	269	36	13.4	255	27	10.6					
Female	37	3	8.1	50	4	8.0					
Baseline FVC percent predicted											
<=70%	109	22	20.2	112	11	9.8					
>70%	197	17	8.6	193	20	10.4					
Type of AF therapy											
Nintedanib	173	24	13.9	178	16	9.0					
Pirfenidone	133	15	11.3	127	15	11.8					
Region											
Europe	136	21	15.4	136	15	11.0					
Asia	72	1	1.4	79	5	6.3					
Canada and USA	75	13	17.3	56	10	17.9					
Rest of the World	23	4	17.4	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Productive 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	306	7	2.3	305	10	3.3	0.4564	1.43 (0.55, 3.72)	1.45 (0.54, 3.85)	0.99 (-1.80, 3.89)	
Age											
<65 years	69	0	0.0	63	3	4.8					
>=65 years	237	7	3.0	242	7	2.9					
Sex											
Male	269	6	2.2	255	9	3.5					
Female	37	1	2.7	50	1	2.0					
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	1	0.9					
>70%	197	5	2.5	193	9	4.7					
Type of AF therapy											
Nintedanib	173	6	3.5	178	7	3.9					
Pirfenidone	133	1	0.8	127	3	2.4					
Region											
Europe	136	2	1.5	136	5	3.7					
Asia	72	1	1.4	79	1	1.3					
Canada and USA	75	4	5.3	56	3	5.4					
Rest of the World	23	0	0.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pulmonary hypertension

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	306	7	2.3	305	12	3.9	0.2410	1.72 (0.69, 4.31)	1.75 (0.68, 4.51)	1.65 (-1.24, 4.70)	
Age											
<65 years	69	1	1.4	63	1	1.6					
>=65 years	237	6	2.5	242	11	4.5					
Sex											
Male	269	5	1.9	255	12	4.7					
Female	37	2	5.4	50	0	0.0					
Baseline FVC percent predicted											
<=70%	109	3	2.8	112	6	5.4					
>70%	197	4	2.0	193	6	3.1					
Type of AF therapy											
Nintedanib	173	4	2.3	178	6	3.4					
Pirfenidone	133	3	2.3	127	6	4.7					
Region											
Europe	136	1	0.7	136	6	4.4					
Asia	72	4	5.6	79	3	3.8					
Canada and USA	75	2	2.7	56	2	3.6					
Rest of the World	23	0	0.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Rhinorrhoea

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	306	7	2.3	305	13	4.3	0.1702	1.86 (0.75, 4.61)	1.90 (0.75, 4.83)	1.97 (-0.96, 5.10)	
Age											
<65 years	69	2	2.9	63	2	3.2					
>=65 years	237	5	2.1	242	11	4.5					
Sex											
Male	269	6	2.2	255	10	3.9					
Female	37	1	2.7	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	2	1.8	112	6	5.4					
>70%	197	5	2.5	193	7	3.6					
Type of AF therapy											
Nintedanib	173	2	1.2	178	6	3.4					
Pirfenidone	133	5	3.8	127	7	5.5					
Region											
Europe	136	4	2.9	136	8	5.9					
Asia	72	1	1.4	79	2	2.5					
Canada and USA	75	2	2.7	56	2	3.6					
Rest of the World	23	0	0.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	306	9	2.9	305	10	3.3	0.8101	1.11 (0.46, 2.71)	1.12 (0.45, 2.79)	0.34 (-2.62, 3.33)	
Age											
<65 years	69	4	5.8	63	1	1.6					
>=65 years	237	5	2.1	242	9	3.7					
Sex											
Male	269	8	3.0	255	7	2.7					
Female	37	1	2.7	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	3	2.8	112	3	2.7					
>70%	197	6	3.0	193	7	3.6					
Type of AF therapy											
Nintedanib	173	7	4.0	178	6	3.4					
Pirfenidone	133	2	1.5	127	4	3.1					
Region											
Europe	136	2	1.5	136	7	5.1					
Asia	72	5	6.9	79	1	1.3					
Canada and USA	75	0	0.0	56	0	0.0					
Rest of the World	23	2	8.7	34	2	5.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	21	6.9	305	25	8.2	0.5321	1.19 (0.68, 2.09)	1.21 (0.66, 2.21)	1.33 (-2.94, 5.64)	
Age											
<65 years	69	5	7.2	63	2	3.2					
>=65 years	237	16	6.8	242	23	9.5					
Sex											
Male	269	21	7.8	255	22	8.6					
Female	37	0	0.0	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	9	8.3	112	16	14.3					
>70%	197	12	6.1	193	9	4.7					
Type of AF therapy											
Nintedanib	173	13	7.5	178	16	9.0					
Pirfenidone	133	8	6.0	127	9	7.1					
Region											
Europe	136	9	6.6	136	11	8.1					
Asia	72	9	12.5	79	6	7.6					
Canada and USA	75	3	4.0	56	2	3.6					
Rest of the World	23	0	0.0	34	6	17.6					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	13	4.2	305	14	4.6	0.8371	1.08 (0.52, 2.26)	1.08 (0.50, 2.35)	0.34 (-3.08, 3.79)	
Age											
<65 years	69	1	1.4	63	1	1.6					
>=65 years	237	12	5.1	242	13	5.4					
Sex											
Male	269	12	4.5	255	14	5.5					
Female	37	1	2.7	50	0	0.0					
Baseline FVC percent predicted											
<=70%	109	8	7.3	112	7	6.3					
>70%	197	5	2.5	193	7	3.6					
Type of AF therapy											
Nintedanib	173	4	2.3	178	7	3.9					
Pirfenidone	133	9	6.8	127	7	5.5					
Region											
Europe	136	4	2.9	136	3	2.2					
Asia	72	4	5.6	79	9	11.4					
Canada and USA	75	5	6.7	56	2	3.6					
Rest of the World	23	0	0.0	34	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (AF background)
SOC: Respiratory, thoracic and mediastinal disorders
PT: Pulmonary hypertension

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	306	7	2.3	305	12	3.9	0.2410	1.72 (0.69, 4.31)	1.75 (0.68, 4.51)	1.65 (-1.24, 4.70)	
Age											
<65 years	69	1	1.4	63	1	1.6					
>=65 years	237	6	2.5	242	11	4.5					
Sex											
Male	269	5	1.9	255	12	4.7					
Female	37	2	5.4	50	0	0.0					
Baseline FVC percent predicted											
<=70%	109	3	2.8	112	6	5.4					
>70%	197	4	2.0	193	6	3.1					
Type of AF therapy											
Nintedanib	173	4	2.3	178	6	3.4					
Pirfenidone	133	3	2.3	127	6	4.7					
Region											
Europe	136	1	0.7	136	6	4.4					
Asia	72	4	5.6	79	3	3.8					
Canada and USA	75	2	2.7	56	2	3.6					
Rest of the World	23	0	0.0	34	1	2.9					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 (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	306	1	0.3	305	11	3.6	0.0035	>10 (1.43, 84.96)	>10 (1.46, 88.94)	3.28 (1.10, 6.03)	
Age											
<65 years	69	1	1.4	63	2	3.2					
>=65 years	237	0	0.0	242	9	3.7					
Sex											0.2212
Male	269	1	0.4	255	11	4.3	0.0026	>10 (1.51, 89.24)	>10 (1.55, 94.27)	3.94 (1.40, 7.20)	
Female	37	0	0.0	50	0	0.0	0.8820	0.75 (0.02, 36.71)	NC (NC, NC)	0.00 (NC, NC)	
Baseline FVC percent predicted											0.7336
<=70%	109	0	0.0	112	2	1.8	0.2546	4.87 (0.24, >99)	NC (NC, NC)	1.79 (-1.86, 6.28)	
>70%	197	1	0.5	193	9	4.7	0.0094	9.19 (1.18, 71.82)	9.59 (1.20, 76.41)	4.16 (0.97, 8.14)	
Type of AF therapy											0.3018
Nintedanib	173	1	0.6	178	11	6.2	0.0039	>10 (1.40, 81.92)	>10 (1.45, 88.73)	5.60 (1.84, 10.17)	
Pirfenidone	133	0	0.0	127	0	0.0	0.9817	1.05 (0.02, 52.37)	NC (NC, NC)	0.00 (NC, NC)	
Region											0.6369
Europe	136	1	0.7	136	9	6.6	0.0099	9.00 (1.16, 70.07)	9.57 (1.20, 76.59)	5.88 (1.35, 11.40)	
Asia	72	0	0.0	79	2	2.5	0.2769	4.56 (0.22, 93.47)	NC (NC, NC)	2.53 (-2.86, 8.77)	
Canada and USA	75	0	0.0	56	0	0.0	0.8848	1.33 (0.03, 66.19)	NC (NC, NC)	0.00 (NC, NC)	
Rest of the World	23	0	0.0	34	0	0.0	0.8482	0.69 (0.01, 33.38)	NC (NC, NC)	0.00 (NC, NC)	

Study: 1305-0014. MedDRA version: 27.0. 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 H.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 (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	306	20	6.5	305	24	7.9	0.5240	1.20 (0.68, 2.13)	1.22 (0.66, 2.26)	1.33 (-2.86, 5.56)	
Age											
<65 years	69	5	7.2	63	2	3.2					
>=65 years	237	15	6.3	242	22	9.1					
Sex											
Male	269	20	7.4	255	21	8.2					
Female	37	0	0.0	50	3	6.0					
Baseline FVC percent predicted											
<=70%	109	9	8.3	112	15	13.4					
>70%	197	11	5.6	193	9	4.7					
Type of AF therapy											
Nintedanib	173	13	7.5	178	16	9.0					
Pirfenidone	133	7	5.3	127	8	6.3					
Region											
Europe	136	9	6.6	136	10	7.4					
Asia	72	8	11.1	79	6	7.6					
Canada and USA	75	3	4.0	56	2	3.6					
Rest of the World	23	0	0.0	34	6	17.6					

Study: 1305-0014. MedDRA version: 27.0. 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 H.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 (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	306	11	3.6	305	12	3.9	0.8254	1.09 (0.49, 2.44)	1.10 (0.48, 2.53)	0.34 (-2.86, 3.57)	
Age											
<65 years	69	0	0.0	63	2	3.2					
>=65 years	237	11	4.6	242	10	4.1					
Sex											
Male	269	11	4.1	255	12	4.7					
Female	37	0	0.0	50	0	0.0					
Baseline FVC percent predicted											
<=70%	109	6	5.5	112	7	6.3					
>70%	197	5	2.5	193	5	2.6					
Type of AF therapy											
Nintedanib	173	3	1.7	178	7	3.9					
Pirfenidone	133	8	6.0	127	5	3.9					
Region											
Europe	136	3	2.2	136	3	2.2					
Asia	72	4	5.6	79	8	10.1					
Canada and USA	75	4	5.3	56	1	1.8					
Rest of the World	23	0	0.0	34	0	0.0					

Study: 1305-0014. MedDRA version: 27.0. 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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H.2.1.3 Further analysis

H.2.1.3.1 Time to event analyses: treatment policy approach to lung transplant

Table H.2.1.3.1: 1 Cox model for time to first confirmed acute IPF exacerbation or death - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (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	306	31 (19/ 12)	10.1	9.48	305	37 (22/ 15)	12.1	11.41	1.25	(0.78, 2.02)	0.3563	
Age												0.8906
<65 years	69	5 (4/ 1)	7.2	6.49	63	5 (3/ 2)	7.9	7.32	1.16	(0.33, 4.00)	0.8196	
>=65 years	237	26 (15/ 11)	11.0	10.40	242	32 (19/ 13)	13.2	12.50	1.27	(0.75, 2.14)	0.3680	
Sex												0.9802
Male	269	31 (19/ 12)	11.5	10.83	255	32 (19/ 13)	12.5	11.80	1.18	(0.72, 1.93)	0.5234	
Female	37	0 (0/ 0)	0.0	0.00	50	5 (3/ 2)	10.0	9.43	>10	(NC, NC)	0.9799	
Baseline FVC percent predicted												0.4937
<=70%	109	16 (10/ 6)	14.7	14.08	112	22 (12/ 10)	19.6	19.69	1.42	(0.74, 2.72)	0.2884	
>70%	197	15 (9/ 6)	7.6	7.03	193	15 (10/ 5)	7.8	7.06	1.01	(0.49, 2.08)	0.9682	
Type of AF therapy												0.2805
Nintedanib	173	17 (11/ 6)	9.8	9.12	178	17 (11/ 6)	9.6	9.05	0.98	(0.50, 1.92)	0.9481	
Pirfenidone	133	14 (8/ 6)	10.5	9.94	127	20 (11/ 9)	15.7	14.66	1.66	(0.83, 3.31)	0.1490	
Region												0.3305
Europe	136	11 (7/ 4)	8.1	7.73	136	19 (11/ 8)	14.0	13.35	1.63	(0.77, 3.43)	0.1992	
Asia	72	10 (8/ 2)	13.9	13.08	79	7 (5/ 2)	8.9	8.09	0.71	(0.27, 1.88)	0.4900	
Canada and USA	75	9 (4/ 5)	12.0	10.96	56	6 (3/ 3)	10.7	9.75	0.91	(0.32, 2.55)	0.8546	
Rest of the World	23	1 (0/ 1)	4.3	3.81	34	5 (3/ 2)	14.7	14.76	4.42	(0.51, 38.05)	0.1761	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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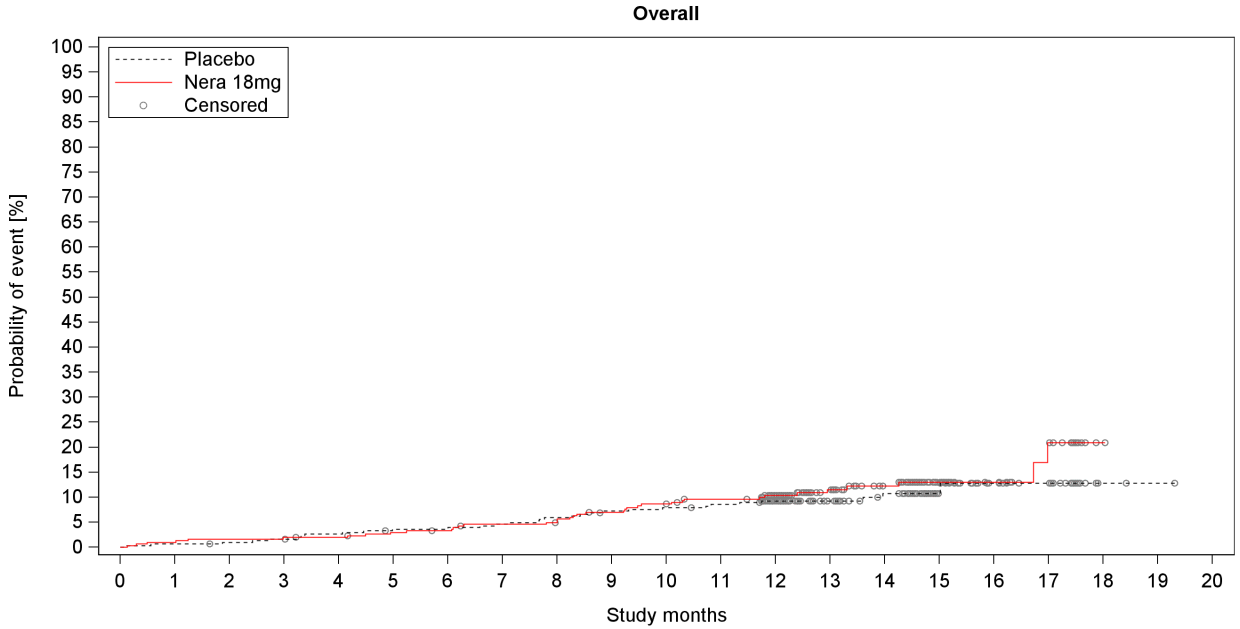

Number at risk (percentage relative to baseline)

Placebo	306	304	302	300	296	292	292	289	285	280	278	275	203	138	121	42	25	21	2	1	0
%	100.0	99.3	98.7	98.0	96.7	95.4	95.4	94.4	93.1	91.5	90.8	89.9	66.3	45.1	39.5	13.7	8.2	6.9	0.7	0.3	0.0
Nera 18mg	305	302	300	299	298	294	292	287	285	278	273	267	200	141	119	43	27	20	1	0	0
%	100.0	99.0	98.4	98.0	97.7	96.4	95.7	94.1	93.4	91.1	89.5	87.5	65.6	46.2	39.0	14.1	8.9	6.6	0.3	0.0	0.0

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

Placebo	0	0	1	1	2	3	3	3	3	4	4	5	75	140	155	234	250	254	273	274	275
%	0.0	0.0	0.3	0.3	0.7	1.0	1.0	1.0	1.0	1.3	1.3	1.6	24.5	45.8	50.7	76.5	81.7	83.0	89.2	89.5	89.9
Nera 18mg	0	0	0	0	1	2	3	4	5	6	6	9	74	131	152	227	243	248	267	268	268
%	0.0	0.0	0.0	0.0	0.3	0.7	1.0	1.3	1.6	2.0	2.0	3.0	24.3	43.0	49.8	74.4	79.7	81.3	87.5	87.9	87.9

Study: 1305-0014

Figure H.2.1.3.1: 1 Time to first confirmed acute IPF exacerbation or death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (AF background)

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Table H.2.1.3.1: 2 Cox model for time to first confirmed or suspected acute IPF exacerbation or death - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (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	306	33 (22/ 11)	10.8	10.12	305	40 (29/ 11)	13.1	12.40	1.29	(0.81, 2.04)	0.2880	
Age												0.8380
<65 years	69	5 (4/ 1)	7.2	6.49	63	5 (3/ 2)	7.9	7.32	1.14	(0.33, 3.94)	0.8359	
>=65 years	237	28 (18/ 10)	11.8	11.24	242	35 (26/ 9)	14.5	13.77	1.31	(0.80, 2.16)	0.2885	
Sex												0.9796
Male	269	33 (22/ 11)	12.3	11.57	255	35 (26/ 9)	13.7	12.98	1.22	(0.76, 1.97)	0.4126	
Female	37	0 (0/ 0)	0.0	0.00	50	5 (3/ 2)	10.0	9.45	>10	(NC, NC)	0.9793	
Baseline FVC percent predicted												0.1900
<=70%	109	16 (10/ 6)	14.7	14.08	112	25 (18/ 7)	22.3	22.68	1.67	(0.89, 3.14)	0.1131	
>70%	197	17 (12/ 5)	8.6	8.00	193	15 (11/ 4)	7.8	7.06	0.89	(0.44, 1.79)	0.7455	
Type of AF therapy												0.3277
Nintedanib	173	18 (13/ 5)	10.4	9.71	178	19 (15/ 4)	10.7	10.15	1.04	(0.54, 1.98)	0.9078	
Pirfenidone	133	15 (9/ 6)	11.3	10.67	127	21 (14/ 7)	16.5	15.51	1.65	(0.85, 3.22)	0.1416	
Region												0.2940
Europe	136	12 (8/ 4)	8.8	8.44	136	20 (14/ 6)	14.7	14.15	1.59	(0.77, 3.25)	0.2084	
Asia	72	10 (8/ 2)	13.9	13.08	79	8 (6/ 2)	10.1	9.26	0.84	(0.33, 2.15)	0.7127	
Canada and USA	75	10 (6/ 4)	13.3	12.30	56	6 (3/ 3)	10.7	9.75	0.80	(0.29, 2.21)	0.6738	
Rest of the World	23	1 (0/ 1)	4.3	3.81	34	6 (6/ 0)	17.6	18.01	5.57	(0.67, 46.59)	0.1133	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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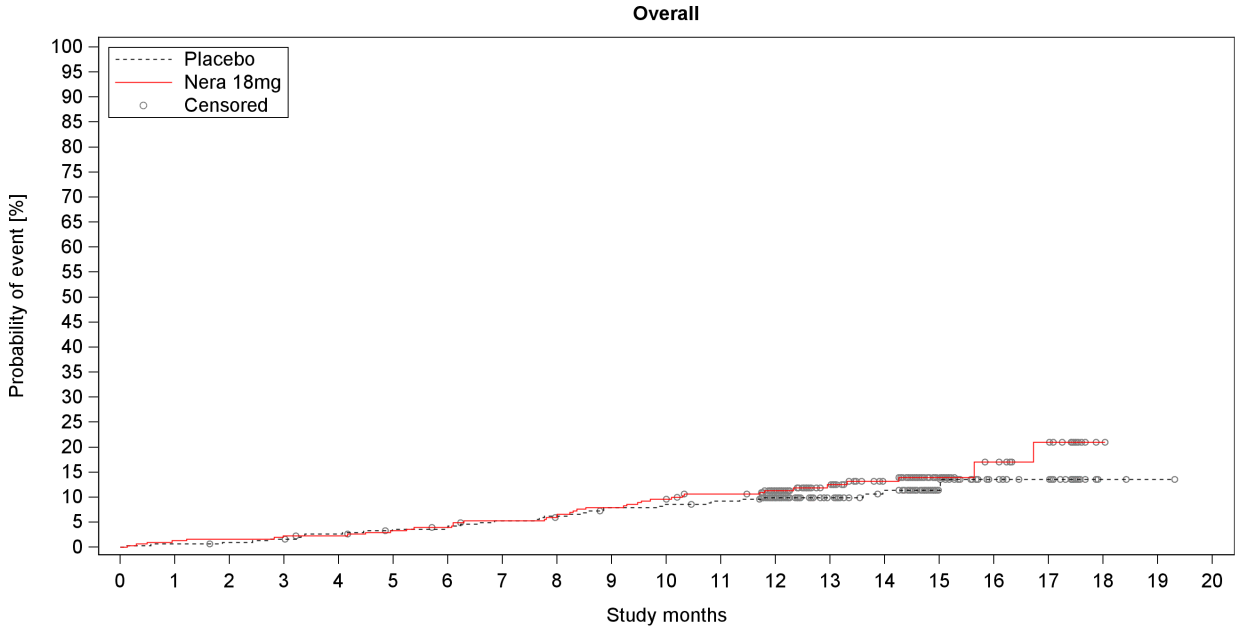

Number at risk (percentage relative to baseline)

Placebo	306	304	302	300	296	292	291	287	284	278	276	273	202	137	120	41	25	21	2	1	0
%	100.0	99.3	98.7	98.0	96.7	95.4	95.1	93.8	92.8	90.8	90.2	89.2	66.0	44.8	39.2	13.4	8.2	6.9	0.7	0.3	0.0
Nera 18mg	305	301	300	298	297	293	290	285	282	276	271	265	198	140	118	43	26	20	1	0	0
%	100.0	98.7	98.4	97.7	97.4	96.1	95.1	93.4	92.5	90.5	88.9	86.9	64.9	45.9	38.7	14.1	8.5	6.6	0.3	0.0	0.0

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

Placebo	0	0	1	1	2	3	3	3	3	4	4	5	74	139	154	233	248	252	271	272	273
%	0.0	0.0	0.3	0.3	0.7	1.0	1.0	1.0	1.0	1.3	1.3	1.6	24.2	45.4	50.3	76.1	81.0	82.4	88.6	88.9	89.2
Nera 18mg	0	0	0	0	1	2	3	4	5	5	5	8	73	129	150	224	240	245	264	265	265
%	0.0	0.0	0.0	0.0	0.3	0.7	1.0	1.3	1.6	1.6	1.6	2.6	23.9	42.3	49.2	73.4	78.7	80.3	86.6	86.9	86.9

Study: 1305-0014

Figure H.2.1.3.1: 2 Time to first confirmed or suspected acute IPF exacerbation or death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (AF background)

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Figure H.2.1.3.1: 2

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Table H.2.1.3.1: 3 Cox model for time to death - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (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	306	19	6.2	5.64	305	20	6.6	5.95	1.13	(0.60, 2.13)	0.7022	
Age												0.9478
<65 years	69	2	2.9	2.56	63	2	3.2	2.85	1.21	(0.17, 8.59)	0.8515	
>=65 years	237	17	7.2	6.57	242	18	7.4	6.77	1.13	(0.58, 2.19)	0.7285	
Sex												0.9843
Male	269	19	7.1	6.42	255	15	5.9	5.31	0.92	(0.47, 1.82)	0.8127	
Female	37	0	0.0	0.00	50	5	10.0	9.28	>10	(NC, NC)	0.9844	
Baseline FVC percent predicted												0.3922
<=70%	109	10	9.2	8.39	112	13	11.6	10.98	1.47	(0.64, 3.38)	0.3690	
>70%	197	9	4.6	4.13	193	7	3.6	3.22	0.84	(0.31, 2.25)	0.7228	
Type of AF therapy												0.1568
Nintedanib	173	12	6.9	6.29	178	9	5.1	4.63	0.75	(0.31, 1.77)	0.5059	
Pirfenidone	133	7	5.3	4.80	127	11	8.7	7.76	1.89	(0.73, 4.93)	0.1924	
Region												0.4578
Europe	136	8	5.9	5.55	136	11	8.1	7.42	1.25	(0.50, 3.12)	0.6352	
Asia	72	4	5.6	4.89	79	2	2.5	2.22	0.54	(0.10, 2.97)	0.4781	
Canada and USA	75	6	8.0	7.08	56	3	5.4	4.74	0.71	(0.18, 2.83)	0.6244	
Rest of the World	23	1	4.3	3.81	34	4	11.8	11.55	4.33	(0.48, 39.28)	0.1931	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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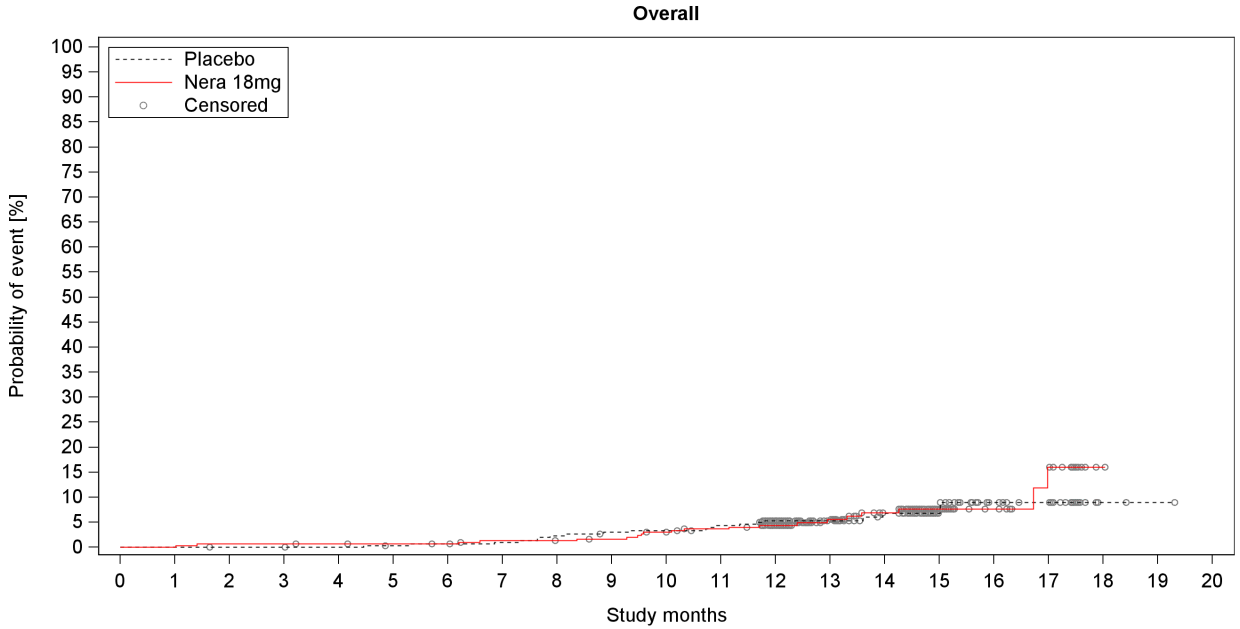

Number at risk (percentage relative to baseline)

Placebo	306	306	305	305	304	302	301	299	295	292	291	287	212	144	126	44	25	21	2	1	0
%	100.0	100.0	99.7	99.7	99.3	98.7	98.4	97.7	96.4	95.4	95.1	93.8	69.3	47.1	41.2	14.4	8.2	6.9	0.7	0.3	0.0
Nera 18mg	305	305	303	303	302	301	300	297	296	294	289	284	215	154	128	45	27	20	1	0	0
%	100.0	100.0	99.3	99.3	99.0	98.7	98.4	97.4	97.0	96.4	94.8	93.1	70.5	50.5	42.0	14.8	8.9	6.6	0.3	0.0	0.0

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

Placebo	0	0	1	1	2	3	3	4	4	5	5	6	78	146	162	244	262	266	285	286	287
%	0.0	0.0	0.3	0.3	0.7	1.0	1.0	1.3	1.3	1.6	1.6	2.0	25.5	47.7	52.9	79.7	85.6	86.9	93.1	93.5	93.8
Nera 18mg	0	0	0	0	1	2	3	4	5	6	7	10	77	136	160	242	260	265	284	285	285
%	0.0	0.0	0.0	0.0	0.3	0.7	1.0	1.3	1.6	2.0	2.3	3.3	25.2	44.6	52.5	79.3	85.2	86.9	93.1	93.4	93.4

Study: 1305-0014

Figure H.2.1.3.1: 3 Time to death - treatment policy approach to lung transplant - over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (AF background)

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Figure H.2.1.3.1: 3

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Table H.2.1.3.1: 4 Cox model for time to first confirmed acute IPF exacerbation - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (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	306	19	6.2	5.81	305	22	7.2	6.78	1.19	(0.64, 2.21)	0.5727	
Age												0.5671
<65 years	69	4	5.8	5.19	63	3	4.8	4.39	0.80	(0.18, 3.59)	0.7724	
>=65 years	237	15	6.3	6.00	242	19	7.9	7.42	1.30	(0.66, 2.55)	0.4552	
Sex												0.9846
Male	269	19	7.1	6.64	255	19	7.5	7.00	1.12	(0.59, 2.12)	0.7306	
Female	37	0	0.0	0.00	50	3	6.0	5.66	>10	(NC, NC)	0.9845	
Baseline FVC percent predicted												0.9180
<=70%	109	10	9.2	8.80	112	12	10.7	10.74	1.19	(0.51, 2.78)	0.6791	
>70%	197	9	4.6	4.22	193	10	5.2	4.70	1.12	(0.45, 2.76)	0.8056	
Type of AF therapy												0.4555
Nintedanib	173	11	6.4	5.90	178	11	6.2	5.85	0.97	(0.42, 2.23)	0.9385	
Pirfenidone	133	8	6.0	5.69	127	11	8.7	8.06	1.55	(0.62, 3.88)	0.3473	
Region												0.7099
Europe	136	7	5.1	4.92	136	11	8.1	7.73	1.49	(0.58, 3.85)	0.4114	
Asia	72	8	11.1	10.46	79	5	6.3	5.78	0.61	(0.20, 1.90)	0.3981	
Canada and USA	75	4	5.3	4.88	56	3	5.4	4.87	1.03	(0.23, 4.59)	0.9735	
Rest of the World	23	0	0.0	0.00	34	3	8.8	8.86	>10	(NC, NC)	0.9871	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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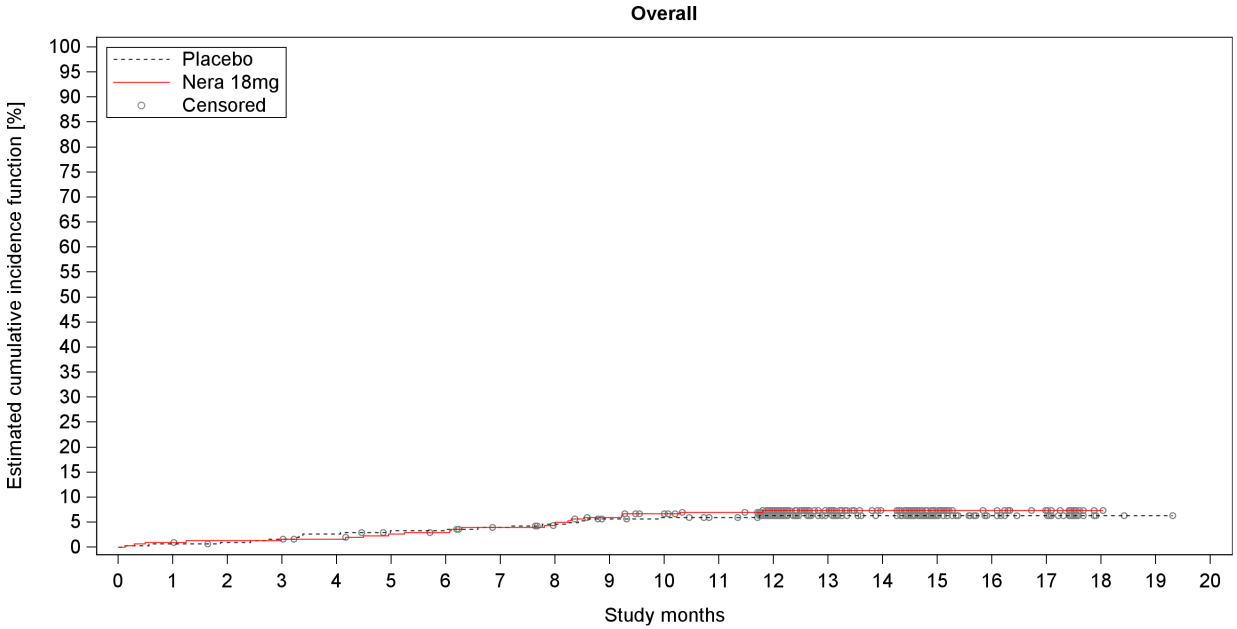

Number at risk (percentage relative to baseline)

Placebo	306	304	302	300	296	292	292	289	285	280	278	275	203	137	121	42	25	21	2	1	0
%	100.0	99.3	98.7	98.0	96.7	95.4	95.4	94.4	93.1	91.5	90.8	89.9	66.3	44.8	39.5	13.7	8.2	6.9	0.7	0.3	0.0
Nera 18mg	305	302	300	299	298	294	292	287	285	278	273	267	200	141	119	43	27	20	1	0	0
%	100.0	99.0	98.4	98.0	97.7	96.4	95.7	94.1	93.4	91.1	89.5	87.5	65.6	46.2	39.0	14.1	8.9	6.6	0.3	0.0	0.0

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

Placebo	0	0	1	1	2	4	4	5	7	9	10	13	84	150	166	245	262	266	285	286	287
%	0.0	0.0	0.3	0.3	0.7	1.3	1.3	1.6	2.3	2.9	3.3	4.2	27.5	49.0	54.2	80.1	85.6	86.9	93.1	93.5	93.8
Nera 18mg	0	0	1	1	2	3	4	6	7	9	12	17	83	142	164	240	256	263	282	283	283
%	0.0	0.0	0.3	0.3	0.7	1.0	1.3	2.0	2.3	3.0	3.9	5.6	27.2	46.6	53.8	78.7	83.9	86.2	92.5	92.8	92.8

Study: 1305-0014

Figure H.2.1.3.1: 4 Time to first confirmed acute IPF exacerbation - treatment policy approach to lung transplant - over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (AF background)

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Table H.2.1.3.1: 5 Cox model for time to first confirmed or suspected acute IPF exacerbation - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (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	306	22	7.2	6.75	305	29	9.5	8.99	1.37	(0.79, 2.39)	0.2671	
Age												0.4525
<65 years	69	4	5.8	5.19	63	3	4.8	4.39	0.81	(0.18, 3.61)	0.7786	
>=65 years	237	18	7.6	7.23	242	26	10.7	10.23	1.50	(0.82, 2.74)	0.1900	
Sex												0.9833
Male	269	22	8.2	7.72	255	26	10.2	9.64	1.34	(0.76, 2.36)	0.3202	
Female	37	0	0.0	0.00	50	3	6.0	5.67	>10	(NC, NC)	0.9830	
Baseline FVC percent predicted												0.2200
<=70%	109	10	9.2	8.80	112	18	16.1	16.33	1.85	(0.85, 4.03)	0.1195	
>70%	197	12	6.1	5.65	193	11	5.7	5.18	0.92	(0.40, 2.08)	0.8341	
Type of AF therapy												0.4159
Nintedanib	173	13	7.5	7.01	178	15	8.4	8.02	1.12	(0.53, 2.36)	0.7649	
Pirfenidone	133	9	6.8	6.41	127	14	11.0	10.34	1.79	(0.77, 4.15)	0.1777	
Region												0.6323
Europe	136	8	5.9	5.63	136	14	10.3	9.91	1.65	(0.69, 3.94)	0.2603	
Asia	72	8	11.1	10.46	79	6	7.6	6.95	0.77	(0.26, 2.24)	0.6295	
Canada and USA	75	6	8.0	7.39	56	3	5.4	4.87	0.68	(0.17, 2.72)	0.5850	
Rest of the World	23	0	0.0	0.00	34	6	17.6	18.01	>10	(NC, NC)	0.9854	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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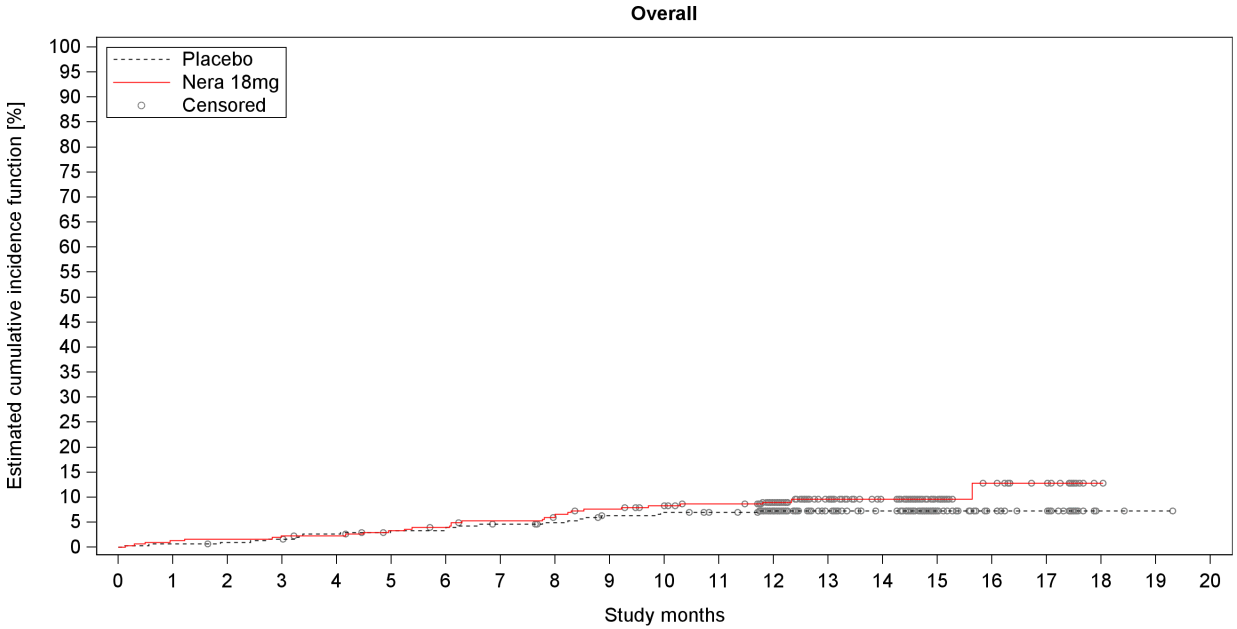

Number at risk (percentage relative to baseline)

Placebo	306	304	302	300	296	292	291	287	284	278	276	273	202	136	120	41	25	21	2	1	0
%	100.0	99.3	98.7	98.0	96.7	95.4	95.1	93.8	92.8	90.8	90.2	89.2	66.0	44.4	39.2	13.4	8.2	6.9	0.7	0.3	0.0
Nera 18mg	305	301	300	298	297	293	290	285	282	276	271	265	198	140	118	43	26	20	1	0	0
%	100.0	98.7	98.4	97.7	97.4	96.1	95.1	93.4	92.5	90.5	88.9	86.9	64.9	45.9	38.7	14.1	8.5	6.6	0.3	0.0	0.0

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

Placebo	0	0	1	1	2	4	4	5	7	9	9	12	82	148	164	243	259	263	282	283	284
%	0.0	0.0	0.3	0.3	0.7	1.3	1.3	1.6	2.3	2.9	2.9	3.9	26.8	48.4	53.6	79.4	84.6	85.9	92.2	92.5	92.8
Nera 18mg	0	0	0	0	1	2	3	4	5	6	9	14	80	137	159	234	250	256	275	276	276
%	0.0	0.0	0.0	0.0	0.3	0.7	1.0	1.3	1.6	2.0	3.0	4.6	26.2	44.9	52.1	76.7	82.0	83.9	90.2	90.5	90.5

Study: 1305-0014

Figure H.2.1.3.1: 5 Time to first confirmed or suspected acute IPF exacerbation - treatment policy approach to lung transplant - over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (AF background)

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Figure H.2.1.3.1: 5

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H.2.2 Population with non-AF background

H.2.2.1 Efficacy Analysis

H.2.2.1.1 Time to event analyses

H.2.2.1.1.1 Analyses of composite endpoints

H.2.2.1.1.1.1 Time to first confirmed acute IPF exacerbation or death

Table H.2.2.1.1.1.1: 1 Cox model for time to first confirmed acute IPF 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	87	13 (5/ 8)	14.9	14.46	87	8 (7/ 1)	9.2	8.69	0.72 (0.29, 1.79)	0.4794	
Age											0.5880
<65 years	17	3 (1/ 2)	17.6	17.96	20	2 (2/ 0)	10.0	9.01	0.46 (0.07, 2.88)	0.4076	
>=65 years	70	10 (4/ 6)	14.3	13.66	67	6 (5/ 1)	9.0	8.59	0.82 (0.29, 2.31)	0.7051	
Sex											0.1604
Male	68	12 (4/ 8)	17.6	17.27	68	5 (4/ 1)	7.4	6.95	0.51 (0.17, 1.48)	0.2159	
Female	19	1 (1/ 0)	5.3	4.89	19	3 (3/ 0)	15.8	14.93	3.04 (0.31, 29.46)	0.3382	
Baseline FVC percent predicted											0.5783
<=70%	24	6 (3/ 3)	25.0	26.67	19	3 (2/ 1)	15.8	15.87	0.44 (0.10, 2.01)	0.2888	
>70%	63	7 (2/ 5)	11.1	10.38	68	5 (5/ 0)	7.4	6.83	0.75 (0.24, 2.38)	0.6238	
Region											0.8830
Europe	14	1 (0/ 1)	7.1	6.19	12	1 (1/ 0)	8.3	8.23	2.71 (0.16, 45.34)	0.4870	
Asia	41	5 (3/ 2)	12.2	11.67	49	5 (4/ 1)	10.2	9.02	0.85 (0.24, 2.98)	0.7992	
Canada and USA	13	5 (1/ 4)	38.5	39.61	14	2 (2/ 0)	14.3	16.99	0.73 (0.14, 3.89)	0.7085	
Rest of the World	19	2 (1/ 1)	10.5	10.91	12	0 (0/ 0)	0.0	0.00	0.00 (NC, NC)	0.9907	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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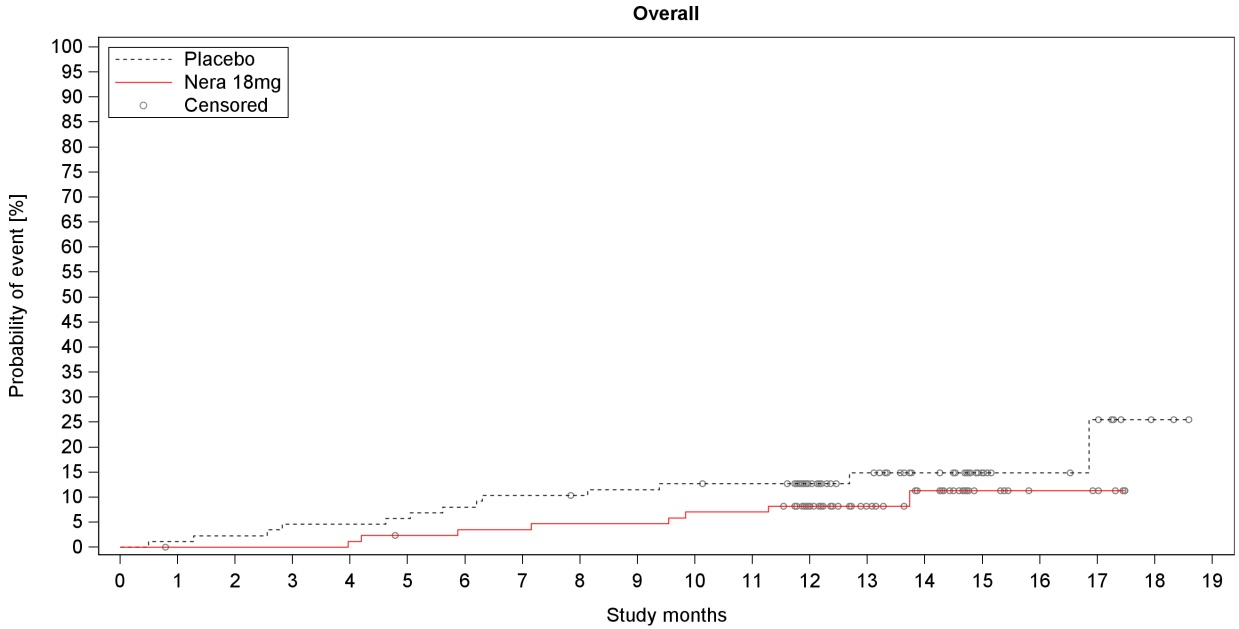

Number at risk (percentage relative to baseline)

Placebo	87	86	85	83	83	82	80	78	77	76	75	74	50	38	30	13	9	7	2	0
%	100.0	98.9	97.7	95.4	95.4	94.3	92.0	89.7	88.5	87.4	86.2	85.1	57.5	43.7	34.5	14.9	10.3	8.0	2.3	0.0
Nera 18mg	87	86	86	86	85	83	82	82	81	81	79	79	54	34	27	12	7	6	0	0
%	100.0	98.9	98.9	98.9	97.7	95.4	94.3	94.3	93.1	93.1	90.8	90.8	62.1	39.1	31.0	13.8	8.0	6.9	0.0	0.0

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

Placebo	0	0	0	0	0	0	0	0	1	1	1	2	26	37	45	62	66	67	72	74
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	2.3	29.9	42.5	51.7	71.3	75.9	77.0	82.8	85.1
Nera 18mg	0	1	1	1	1	2	2	2	2	2	2	2	26	46	52	67	72	73	79	79
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	2.3	2.3	29.9	52.9	59.8	77.0	82.8	83.9	90.8	90.8

Study: 1305-0014

Figure H.2.2.1.1.1.1: 1 Time to first confirmed acute IPF exacerbation or death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (non-AF background)

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Figure H.2.2.1.1.1.1: 1

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H.2.2.1.1.1.2 Time to first confirmed or suspected acute IPF exacerbation or death

Table H.2.2.1.1.1.2: 1 Cox model for time to first confirmed or suspected acute IPF exacerbation or death over the whole trial (DBL1) - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	Placebo n	Placebo e/	Placebo d)	Placebo %	Placebo Rate°	Nera 18mg N	Nera 18mg n	Nera 18mg e/	Nera 18mg d)	Nera 18mg %	Nera 18mg Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)		p-value	Interaction p-value
Overall	87	16	8/	8)	18.4	18.17	87	10	9/	1)	11.5	11.02	0.70	(0.31,	1.59)	0.3959	
Age																	0.5972
<65 years	17	3	1/	2)	17.6	17.96	20	2	2/	0)	10.0	9.01	0.45	(0.07,	2.80)	0.3928	
>=65 years	70	13	7/	6)	18.6	18.22	67	8	7/	1)	11.9	11.68	0.78	(0.32,	1.91)	0.5836	
Sex																	0.4245
Male	68	13	5/	8)	19.1	18.92	68	6	5/	1)	8.8	8.42	0.57	(0.21,	1.52)	0.2602	
Female	19	3	3/	0)	15.8	15.52	19	4	4/	0)	21.1	20.59	1.18	(0.26,	5.36)	0.8340	
Baseline FVC percent predicted																	0.3218
<=70%	24	9	6/	3)	37.5	43.66	19	4	3/	1)	21.1	21.97	0.39	(0.11,	1.40)	0.1500	
>70%	63	7	2/	5)	11.1	10.38	68	6	6/	0)	8.8	8.28	0.91	(0.30,	2.71)	0.8600	
Region																	0.8178
Europe	14	2	1/	1)	14.3	12.98	12	1	1/	0)	8.3	8.23	1.39	(0.12,	16.05)	0.7911	
Asia	41	6	4/	2)	14.6	14.19	49	6	5/	1)	12.2	10.93	0.77	(0.24,	2.42)	0.6482	
Canada and USA	13	6	2/	4)	46.2	49.92	14	3	3/	0)	21.4	27.48	1.90	(0.44,	8.13)	0.3887	
Rest of the World	19	2	1/	1)	10.5	10.91	12	0	0/	0)	0.0	0.00	0.00	(NC,	NC)	0.9893	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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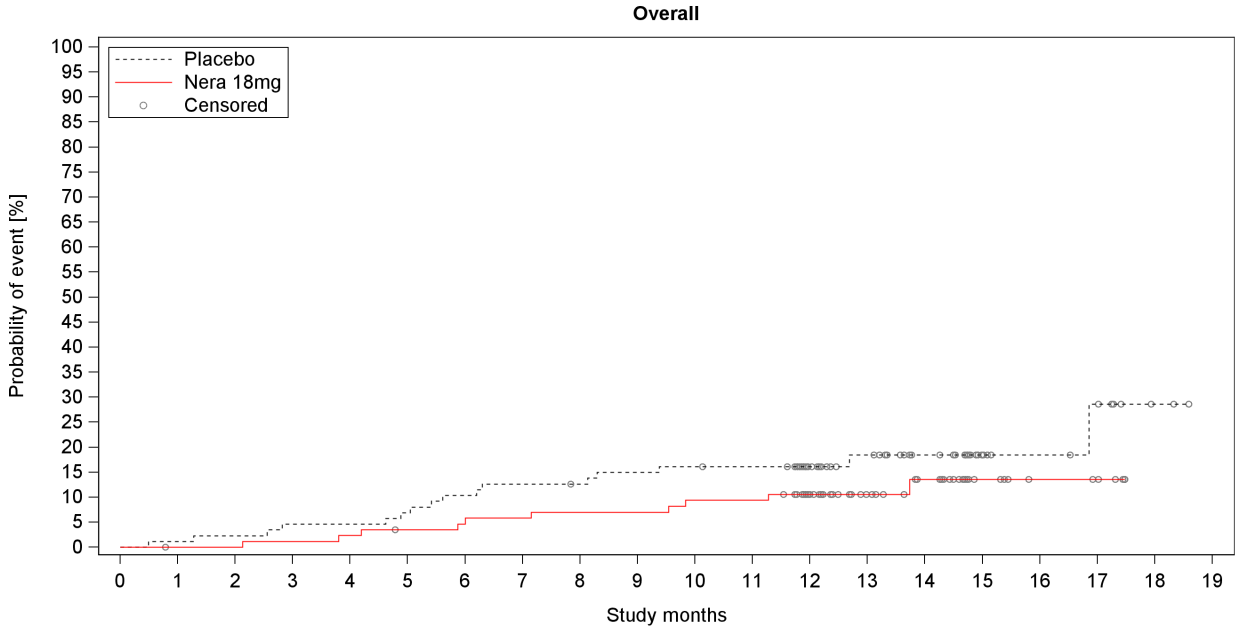

Number at risk (percentage relative to baseline)																				
Placebo	87	86	85	83	83	81	78	76	75	73	72	71	47	36	28	13	9	7	2	0
%	100.0	98.9	97.7	95.4	95.4	93.1	89.7	87.4	86.2	83.9	82.8	81.6	54.0	41.4	32.2	14.9	10.3	8.0	2.3	0.0
Nera 18mg	87	86	86	85	84	82	81	80	79	79	77	77	52	34	27	12	7	6	0	0
%	100.0	98.9	98.9	97.7	96.6	94.3	93.1	92.0	90.8	90.8	88.5	88.5	59.8	39.1	31.0	13.8	8.0	6.9	0.0	0.0
Number censored (percentage relative to number at risk at baseline)																				
Placebo	0	0	0	0	0	0	0	0	1	1	1	2	26	36	44	59	63	64	69	71
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	2.3	29.9	41.4	50.6	67.8	72.4	73.6	79.3	81.6
Nera 18mg	0	1	1	1	1	2	2	2	2	2	2	2	26	44	50	65	70	71	77	77
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	2.3	2.3	29.9	50.6	57.5	74.7	80.5	81.6	88.5	88.5

Study: 1305-0014

Figure H.2.2.1.1.2: 1 Time to first confirmed or suspected acute IPF exacerbation or death over the whole trial, Kaplan-Meier estimate (DBL1) - 18mg - FAS (non-AF background)

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Figure H.2.2.1.1.2: 1

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H.2.2.1.1.2 Analyses of single endpoints

H.2.2.1.1.2.1 Time to death

Table H.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	87	9	10.3	9.73	87	1	1.1	1.04	0.14	(0.02, 1.16)	0.0680	
Age												
<65 years	17	2	11.8		20	0	0.0					
>=65 years	70	7	10.0		67	1	1.5					
Sex												
Male	68	8	11.8		68	1	1.5					
Female	19	1	5.3		19	0	0.0					
Baseline FVC percent predicted												
<=70%	24	4	16.7		19	1	5.3					
>70%	63	5	7.9		68	0	0.0					
Region												
Europe	14	1	7.1		12	0	0.0					
Asia	41	3	7.3		49	1	2.0					
Canada and USA	13	4	30.8		14	0	0.0					
Rest of the World	19	1	5.3		12	0	0.0					

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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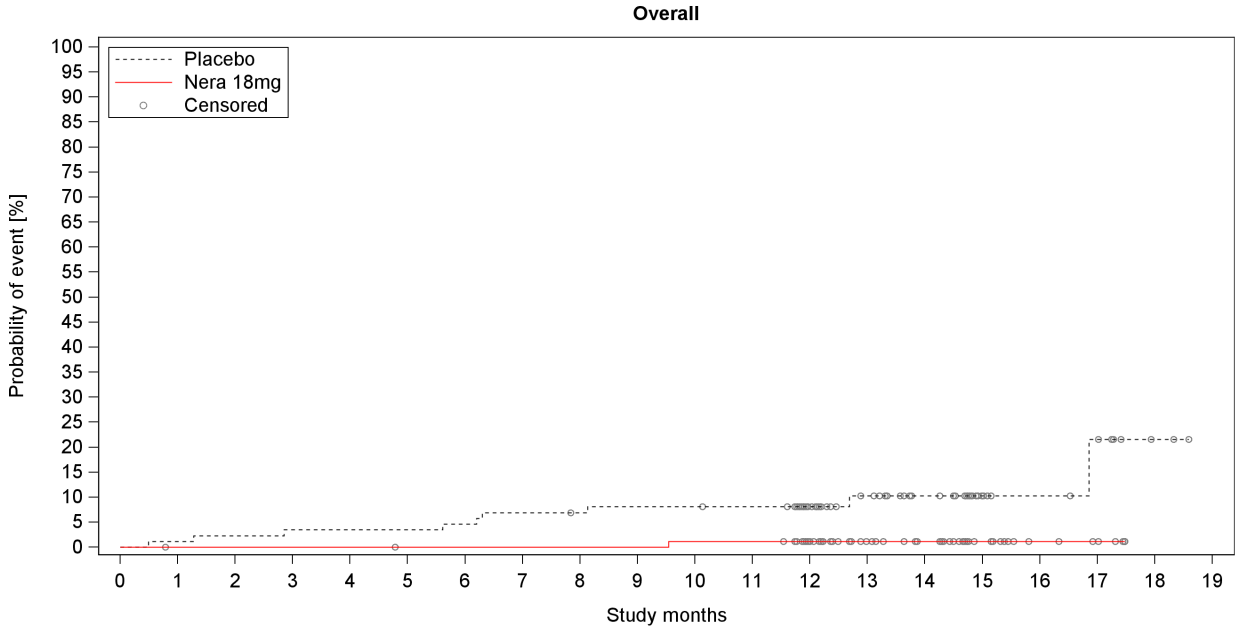

Number at risk (percentage relative to baseline)

Placebo	87	86	85	84	84	84	83	81	80	79	79	78	53	39	31	13	9	7	2	0
%	100.0	98.9	97.7	96.6	96.6	96.6	95.4	93.1	92.0	90.8	90.8	89.7	60.9	44.8	35.6	14.9	10.3	8.0	2.3	0.0
Nera 18mg	87	86	86	86	86	85	85	85	85	85	84	84	60	40	34	17	9	7	0	0
%	100.0	98.9	98.9	98.9	98.9	97.7	97.7	97.7	97.7	97.7	96.6	96.6	69.0	46.0	39.1	19.5	10.3	8.0	0.0	0.0

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

Placebo	0	0	0	0	0	0	0	0	1	1	1	2	27	40	48	66	70	71	76	78
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	2.3	31.0	46.0	55.2	75.9	80.5	81.6	87.4	89.7
Nera 18mg	0	1	1	1	1	2	2	2	2	2	2	2	26	46	52	69	77	79	86	86
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	2.3	2.3	29.9	52.9	59.8	79.3	88.5	90.8	98.9	98.9

Study: 1305-0014

Figure H.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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H.2.2.1.1.2.2 Time to first confirmed acute IPF exacerbation

Table H.2.2.1.1.2.2: 1 Cox model for time to first confirmed acute IPF 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	87	5	5.7	5.57	87	7	8.0	7.60	1.46	(0.45, 4.72)	0.5284	
Age												
<65 years	17	1	5.9		20	2	10.0					
>=65 years	70	4	5.7		67	5	7.5					
Sex												
Male	68	4	5.9		68	4	5.9					
Female	19	1	5.3		19	3	15.8					
Baseline FVC percent predicted												
<=70%	24	3	12.5		19	2	10.5					
>70%	63	2	3.2		68	5	7.4					
Region												
Europe	14	0	0.0		12	1	8.3					
Asia	41	3	7.3		49	4	8.2					
Canada and USA	13	1	7.7		14	2	14.3					
Rest of the World	19	1	5.3		12	0	0.0					

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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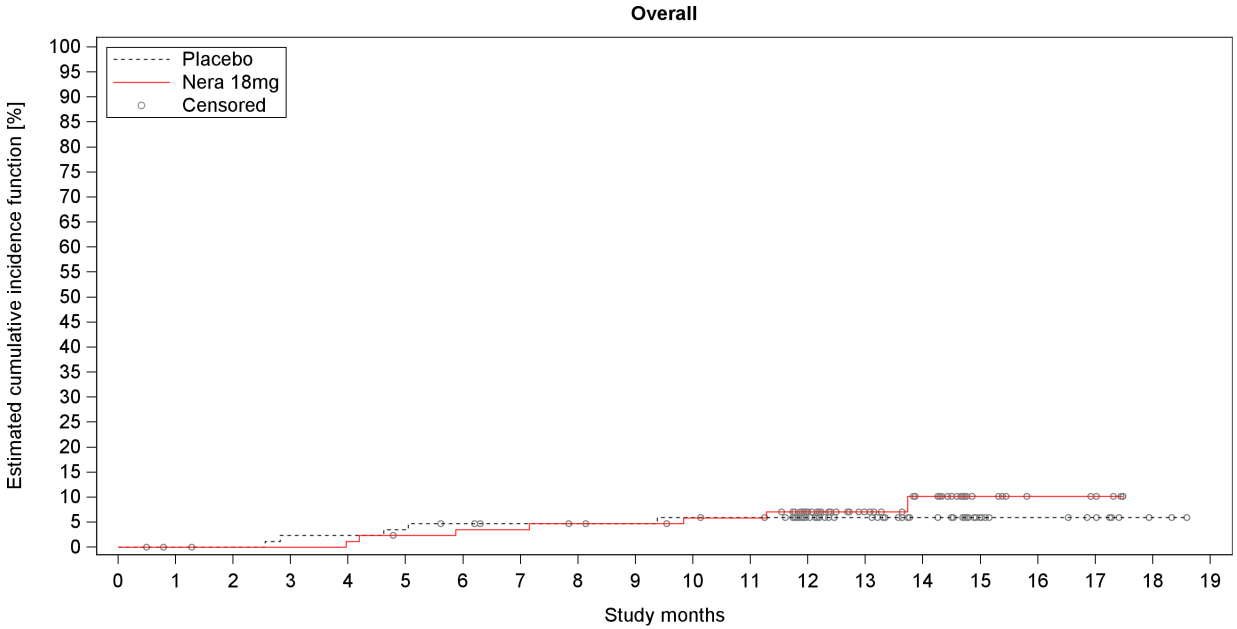

Number at risk (percentage relative to baseline)

Placebo	87	86	85	83	83	82	80	78	77	76	75	74	49	38	30	13	9	7	2	0
%	100.0	98.9	97.7	95.4	95.4	94.3	92.0	89.7	88.5	87.4	86.2	85.1	56.3	43.7	34.5	14.9	10.3	8.0	2.3	0.0
Nera 18mg	87	86	86	86	85	83	82	82	81	81	79	79	54	34	27	12	7	6	0	0
%	100.0	98.9	98.9	98.9	97.7	95.4	94.3	94.3	93.1	93.1	90.8	90.8	62.1	39.1	31.0	13.8	8.0	6.9	0.0	0.0

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

Placebo	0	1	2	2	2	2	3	5	6	7	7	8	33	44	52	69	73	75	80	82
%	0.0	1.1	2.3	2.3	2.3	2.3	3.4	5.7	6.9	8.0	8.0	9.2	37.9	50.6	59.8	79.3	83.9	86.2	92.0	94.3
Nera 18mg	0	1	1	1	1	2	2	2	2	2	3	3	27	47	53	68	73	74	80	80
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	3.4	3.4	31.0	54.0	60.9	78.2	83.9	85.1	92.0	92.0

Study: 1305-0014

Figure H.2.2.1.1.2.2: 1 Time to first confirmed acute IPF exacerbation over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (non-AF background)

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Figure H.2.2.1.1.2.2: 1

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H.2.2.1.1.2.3 Time to first confirmed or suspected acute IPF exacerbation

Table H.2.2.1.1.2.3: 1 Cox model for time to first confirmed or suspected acute IPF 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	87	8	9.2	9.10	87	9	10.3	9.92	1.13	(0.43, 3.02)	0.8010	
Age												0.9018
<65 years	17	1	5.9	5.99	20	2	10.0	9.01	1.33	(0.12, 15.27)	0.8203	
>=65 years	70	7	10.0	9.83	67	7	10.4	10.22	1.12	(0.39, 3.25)	0.8310	
Sex												0.9762
Male	68	5	7.4	7.29	68	5	7.4	7.01	1.11	(0.32, 3.91)	0.8692	
Female	19	3	15.8	15.52	19	4	21.1	20.59	1.08	(0.24, 4.92)	0.9218	
Baseline FVC percent predicted												
<=70%	24	6	25.0		19	3	15.8					
>70%	63	2	3.2		68	6	8.8					
Region												
Europe	14	1	7.1		12	1	8.3					
Asia	41	4	9.8		49	5	10.2					
Canada and USA	13	2	15.4		14	3	21.4					
Rest of the World	19	1	5.3		12	0	0.0					

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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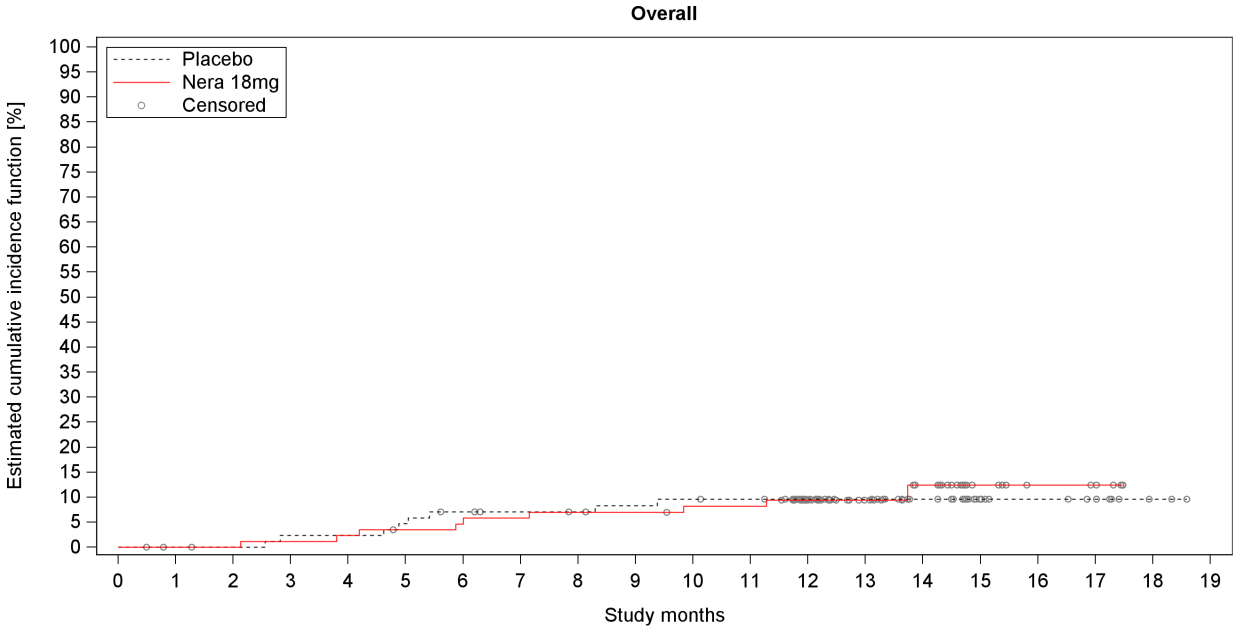

Number at risk (percentage relative to baseline)

Placebo	87	86	85	83	83	81	78	76	75	73	72	71	46	36	28	13	9	7	2	0
%	100.0	98.9	97.7	95.4	95.4	93.1	89.7	87.4	86.2	83.9	82.8	81.6	52.9	41.4	32.2	14.9	10.3	8.0	2.3	0.0
Nera 18mg	87	86	86	85	84	82	81	80	79	79	77	77	52	34	27	12	7	6	0	0
%	100.0	98.9	98.9	97.7	96.6	94.3	93.1	92.0	90.8	90.8	88.5	88.5	59.8	39.1	31.0	13.8	8.0	6.9	0.0	0.0

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

Placebo	0	1	2	2	2	2	3	5	6	7	7	8	33	43	51	66	70	72	77	79
%	0.0	1.1	2.3	2.3	2.3	2.3	3.4	5.7	6.9	8.0	8.0	9.2	37.9	49.4	58.6	75.9	80.5	82.8	88.5	90.8
Nera 18mg	0	1	1	1	1	2	2	2	2	2	3	3	27	45	51	66	71	72	78	78
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	3.4	3.4	31.0	51.7	58.6	75.9	81.6	82.8	89.7	89.7

Study: 1305-0014

Figure H.2.2.1.1.2.3: 1 Time to first confirmed or suspected acute IPF exacerbation over the whole trial, estimated cumulative incidence function (DBL1) - 18mg - FAS (non-AF background)

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Figure H.2.2.1.1.2.3: 1

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H.2.2.2 Safety analysis

H.2.2.2.1 Safety analysis over the whole trial

H.2.2.2.1.1 Adverse events overall over the whole trial

Table H.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: p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	85	97.7	87	79	90.8	0.0507	0.93 (0.86, 1.00)	0.23 (0.05, 1.13)	-6.90 (-14.98, 0.34)	
Age											0.7397
<65 years	17	16	94.1	20	18	90.0	0.6475	0.96 (0.79, 1.15)	0.56 (0.05, 6.81)	-4.12 (-24.79, 18.18)	
>=65 years	70	69	98.6	67	61	91.0	0.0455	0.92 (0.85, 1.00)	0.15 (0.02, 1.26)	-7.53 (-16.84, 0.33)	
Sex											0.8441
Male	68	67	98.5	68	62	91.2	0.0523	0.93 (0.85, 1.00)	0.15 (0.02, 1.32)	-7.35 (-16.55, 0.60)	
Female	19	18	94.7	19	17	89.5	0.5475	0.94 (0.78, 1.14)	0.47 (0.04, 5.70)	-5.26 (-26.58, 15.55)	
Baseline FVC percent predicted											0.7555
<=70%	24	24	100.0	19	18	94.7	0.2555	0.95 (0.85, 1.05)	0.00 (NC, NC)	-5.26 (-24.64, 9.20)	
>70%	63	61	96.8	68	61	89.7	0.1075	0.93 (0.84, 1.02)	0.29 (0.06, 1.43)	-7.12 (-16.86, 2.17)	
Region											0.1620
Europe	14	14	100.0	12	11	91.7	0.2707	0.92 (0.77, 1.09)	0.00 (NC, NC)	-8.33 (-35.39, 14.26)	
Asia	41	40	97.6	49	48	98.0	0.8984	1.00 (0.94, 1.07)	1.20 (0.07, 19.80)	0.40 (-8.48, 10.69)	
Canada and USA	13	13	100.0	14	11	78.6	0.0767	0.79 (0.60, 1.03)	0.00 (NC, NC)	-21.43 (-47.59, 5.26)	
Rest of the World	19	18	94.7	12	9	75.0	0.1103	0.79 (0.56, 1.12)	0.17 (0.02, 1.84)	-19.74 (-48.30, 5.46)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	84	96.6	87	79	90.8	0.1193	0.94 (0.87, 1.02)	0.35 (0.09, 1.38)	-5.75 (-13.98, 1.90)	
Age											0.8489
<65 years	17	16	94.1	20	18	90.0	0.6475	0.96 (0.79, 1.15)	0.56 (0.05, 6.81)	-4.12 (-24.79, 18.18)	
>=65 years	70	68	97.1	67	61	91.0	0.1281	0.94 (0.86, 1.02)	0.30 (0.06, 1.54)	-6.10 (-15.56, 2.36)	
Sex											0.5126
Male	68	67	98.5	68	62	91.2	0.0523	0.93 (0.85, 1.00)	0.15 (0.02, 1.32)	-7.35 (-16.55, 0.60)	
Female	19	17	89.5	19	17	89.5	1.0000	1.00 (0.80, 1.24)	1.00 (0.13, 7.94)	0.00 (-22.21, 22.21)	
Baseline FVC percent predicted											0.4363
<=70%	24	23	95.8	19	18	94.7	0.8654	0.99 (0.86, 1.13)	0.78 (0.05, 13.39)	-1.10 (-20.77, 15.55)	
>70%	63	61	96.8	68	61	89.7	0.1075	0.93 (0.84, 1.02)	0.29 (0.06, 1.43)	-7.12 (-16.86, 2.17)	
Region											0.1097
Europe	14	14	100.0	12	11	91.7	0.2707	0.92 (0.77, 1.09)	0.00 (NC, NC)	-8.33 (-35.39, 14.26)	
Asia	41	39	95.1	49	48	98.0	0.4552	1.03 (0.95, 1.12)	2.46 (0.22, 28.17)	2.84 (-6.51, 14.22)	
Canada and USA	13	13	100.0	14	11	78.6	0.0767	0.79 (0.60, 1.03)	0.00 (NC, NC)	-21.43 (-47.59, 5.26)	
Rest of the World	19	18	94.7	12	9	75.0	0.1103	0.79 (0.56, 1.12)	0.17 (0.02, 1.84)	-19.74 (-48.30, 5.46)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	32	36.8	87	24	27.6	0.1942	0.75 (0.48, 1.16)	0.65 (0.34, 1.24)	-9.20 (-22.57, 4.65)	
Age											0.5013
<65 years	17	5	29.4	20	3	15.0	0.2886	0.51 (0.14, 1.83)	0.42 (0.08, 2.12)	-14.41 (-40.06, 12.10)	
>=65 years	70	27	38.6	67	21	31.3	0.3754	0.81 (0.51, 1.29)	0.73 (0.36, 1.47)	-7.23 (-22.52, 8.63)	
Sex											0.3666
Male	68	29	42.6	68	20	29.4	0.1079	0.69 (0.44, 1.09)	0.56 (0.28, 1.14)	-13.24 (-28.41, 2.85)	
Female	19	3	15.8	19	4	21.1	0.6756	1.33 (0.34, 5.17)	1.42 (0.27, 7.44)	5.26 (-19.87, 29.80)	
Baseline FVC percent predicted											0.7700
<=70%	24	11	45.8	19	6	31.6	0.3424	0.69 (0.31, 1.52)	0.55 (0.16, 1.92)	-14.25 (-39.30, 14.45)	
>70%	63	21	33.3	68	18	26.5	0.3907	0.79 (0.47, 1.35)	0.72 (0.34, 1.53)	-6.86 (-22.12, 8.66)	
Region											0.6246
Europe	14	5	35.7	12	2	16.7	0.2750	0.47 (0.11, 1.98)	0.36 (0.06, 2.34)	-19.05 (-47.24, 15.11)	
Asia	41	15	36.6	49	16	32.7	0.6958	0.89 (0.51, 1.58)	0.84 (0.35, 2.01)	-3.93 (-23.03, 15.15)	
Canada and USA	13	8	61.5	14	4	28.6	0.0850	0.46 (0.18, 1.18)	0.25 (0.05, 1.25)	-32.97 (-59.70, 3.87)	
Rest of the World	19	4	21.1	12	2	16.7	0.7634	0.79 (0.17, 3.68)	0.75 (0.11, 4.90)	-4.39 (-29.68, 26.42)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	31	35.6	87	22	25.3	0.1382	0.71 (0.45, 1.12)	0.61 (0.32, 1.17)	-10.34 (-23.50, 3.32)	
Age											0.5629
<65 years	17	5	29.4	20	3	15.0	0.2886	0.51 (0.14, 1.83)	0.42 (0.08, 2.12)	-14.41 (-40.06, 12.10)	
>=65 years	70	26	37.1	67	19	28.4	0.2738	0.76 (0.47, 1.24)	0.67 (0.33, 1.38)	-8.78 (-23.79, 6.88)	
Sex											0.6225
Male	68	28	41.2	68	19	27.9	0.1046	0.68 (0.42, 1.09)	0.55 (0.27, 1.13)	-13.24 (-28.29, 2.71)	
Female	19	3	15.8	19	3	15.8	1.0000	1.00 (0.23, 4.34)	1.00 (0.17, 5.72)	0.00 (-24.08, 24.08)	
Baseline FVC percent predicted											0.8874
<=70%	24	10	41.7	19	6	31.6	0.4967	0.76 (0.34, 1.71)	0.65 (0.18, 2.28)	-10.09 (-35.45, 18.16)	
>70%	63	21	33.3	68	16	23.5	0.2130	0.71 (0.41, 1.23)	0.62 (0.29, 1.33)	-9.80 (-24.75, 5.56)	
Region											0.3921
Europe	14	4	28.6	12	1	8.3	0.1918	0.29 (0.04, 2.27)	0.23 (0.02, 2.39)	-20.24 (-47.20, 11.63)	
Asia	41	15	36.6	49	16	32.7	0.6958	0.89 (0.51, 1.58)	0.84 (0.35, 2.01)	-3.93 (-23.03, 15.15)	
Canada and USA	13	8	61.5	14	3	21.4	0.0341	0.35 (0.12, 1.04)	0.17 (0.03, 0.93)	-40.11 (-65.06, -3.22)	
Rest of the World	19	4	21.1	12	2	16.7	0.7634	0.79 (0.17, 3.68)	0.75 (0.11, 4.90)	-4.39 (-29.68, 26.42)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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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H.2.2.2.1.2 Adverse events by intensity over the whole trial

Table H.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: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	28	32.2	87	17	19.5	0.0569	0.61 (0.36, 1.03)	0.51 (0.26, 1.03)	-12.64 (-25.15, 0.39)	
Age											0.7573
<65 years	17	5	29.4	20	3	15.0	0.2886	0.51 (0.14, 1.83)	0.42 (0.08, 2.12)	-14.41 (-40.06, 12.10)	
>=65 years	70	23	32.9	67	14	20.9	0.1150	0.64 (0.36, 1.13)	0.54 (0.25, 1.17)	-11.96 (-26.10, 2.94)	
Sex											0.1049
Male	68	26	38.2	68	13	19.1	0.0137	0.50 (0.28, 0.89)	0.38 (0.18, 0.83)	-19.12 (-33.22, -3.90)	
Female	19	2	10.5	19	4	21.1	0.3736	2.00 (0.41, 9.65)	2.27 (0.36, 14.19)	10.53 (-13.82, 34.07)	
Baseline FVC percent predicted											0.9682
<=70%	24	10	41.7	19	5	26.3	0.2942	0.63 (0.26, 1.54)	0.50 (0.14, 1.84)	-15.35 (-39.66, 12.95)	
>70%	63	18	28.6	68	12	17.6	0.1371	0.62 (0.32, 1.18)	0.54 (0.23, 1.23)	-10.92 (-25.06, 3.51)	
Region											0.2644
Europe	14	4	28.6	12	1	8.3	0.1918	0.29 (0.04, 2.27)	0.23 (0.02, 2.39)	-20.24 (-47.20, 11.63)	
Asia	41	12	29.3	49	13	26.5	0.7727	0.91 (0.47, 1.76)	0.87 (0.35, 2.20)	-2.74 (-21.12, 15.28)	
Canada and USA	13	8	61.5	14	2	14.3	0.0111	0.23 (0.06, 0.90)	0.10 (0.02, 0.67)	-47.25 (-70.41, -10.71)	
Rest of the World	19	4	21.1	12	1	8.3	0.3483	0.40 (0.05, 3.13)	0.34 (0.03, 3.49)	-12.72 (-36.03, 17.10)	

Study: 1305-0014. MedDRA version: 27.0. 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 H.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: Risk ratio p-value*	Risk ratio (95% CI)	Odds ratio p-value*	Odds ratio (95% CI)	Risk diff. p-value*	Risk diff. (95% CI)	Interaction p-value**
Overall	87	27	31.0	87	13	14.9	0.0117	0.48 (0.27, 0.87)	0.0117	0.39 (0.19, 0.82)	0.0117	-16.09 (-28.05, -3.57)	
Age													0.3973
<65 years	17	4	23.5	20	1	5.0	0.1004	0.21 (0.03, 1.72)	0.1004	0.17 (0.02, 1.71)	0.1004	-18.53 (-42.62, 4.75)	
>=65 years	70	23	32.9	67	12	17.9	0.0449	0.55 (0.30, 1.01)	0.0449	0.45 (0.20, 0.99)	0.0449	-14.95 (-28.72, -0.30)	
Sex													0.1489
Male	68	25	36.8	68	10	14.7	0.0033	0.40 (0.21, 0.77)	0.0033	0.30 (0.13, 0.68)	0.0033	-22.06 (-35.61, -7.38)	
Female	19	2	10.5	19	3	15.8	0.6313	1.50 (0.28, 7.99)	0.6313	1.59 (0.23, 10.82)	0.6313	5.26 (-17.99, 28.32)	
Baseline FVC percent predicted													0.9623
<=70%	24	10	41.7	19	4	21.1	0.1520	0.51 (0.19, 1.36)	0.1520	0.37 (0.09, 1.47)	0.1520	-20.61 (-43.80, 7.53)	
>70%	63	17	27.0	68	9	13.2	0.0487	0.49 (0.24, 1.02)	0.0487	0.41 (0.17, 1.01)	0.0487	-13.75 (-27.26, 0.01)	
Region													0.1826
Europe	14	4	28.6	12	0	0.0	0.0715	0.13 (0.01, 2.16)	0.0715	0.00 (NC, NC)	0.0715	-28.57 (-54.65, 0.96)	
Asia	41	11	26.8	49	11	22.4	0.6301	0.84 (0.41, 1.73)	0.6301	0.79 (0.30, 2.07)	0.6301	-4.38 (-22.18, 13.06)	
Canada and USA	13	8	61.5	14	1	7.1	0.0027	0.12 (0.02, 0.81)	0.0027	0.05 (0.00, 0.49)	0.0027	-54.40 (-75.96, -18.78)	
Rest of the World	19	4	21.1	12	1	8.3	0.3483	0.40 (0.05, 3.13)	0.3483	0.34 (0.03, 3.49)	0.3483	-12.72 (-36.03, 17.10)	

Study: 1305-0014. MedDRA version: 27.0. 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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H.2.2.2.1.3 Adverse events leading to treatment discontinuation over the whole trial

Table H.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: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	7	8.0	87	6	6.9	0.7731	0.86 (0.30, 2.45)	0.85 (0.27, 2.63)	-1.15 (-9.64, 7.26)	
Age											0.4980
<65 years	17	2	11.8	20	1	5.0	0.4525	0.43 (0.04, 4.29)	0.39 (0.03, 4.78)	-6.76 (-29.71, 13.69)	
>=65 years	70	5	7.1	67	5	7.5	0.9427	1.04 (0.32, 3.45)	1.05 (0.29, 3.80)	0.32 (-9.19, 10.05)	
Sex											0.3978
Male	68	7	10.3	68	5	7.4	0.5454	0.71 (0.24, 2.14)	0.69 (0.21, 2.30)	-2.94 (-13.28, 7.23)	
Female	19	0	0.0	19	1	5.3	0.4682	3.00 (0.13, 69.31)	NC (NC, NC)	5.26 (-12.10, 24.64)	
Baseline FVC percent predicted											
<=70%	24	2	8.3	19	3	15.8					
>70%	63	5	7.9	68	3	4.4					
Region											
Europe	14	0	0.0	12	0	0.0					
Asia	41	4	9.8	49	4	8.2					
Canada and USA	13	2	15.4	14	1	7.1					
Rest of the World	19	1	5.3	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	7	8.0	87	6	6.9	0.7731	0.86 (0.30, 2.45)	0.85 (0.27, 2.63)	-1.15 (-9.64, 7.26)	
Age											0.4980
<65 years	17	2	11.8	20	1	5.0	0.4525	0.43 (0.04, 4.29)	0.39 (0.03, 4.78)	-6.76 (-29.71, 13.69)	
>=65 years	70	5	7.1	67	5	7.5	0.9427	1.04 (0.32, 3.45)	1.05 (0.29, 3.80)	0.32 (-9.19, 10.05)	
Sex											0.3978
Male	68	7	10.3	68	5	7.4	0.5454	0.71 (0.24, 2.14)	0.69 (0.21, 2.30)	-2.94 (-13.28, 7.23)	
Female	19	0	0.0	19	1	5.3	0.4682	3.00 (0.13, 69.31)	NC (NC, NC)	5.26 (-12.10, 24.64)	
Baseline FVC percent predicted											
<=70%	24	2	8.3	19	3	15.8					
>70%	63	5	7.9	68	3	4.4					
Region											
Europe	14	0	0.0	12	0	0.0					
Asia	41	4	9.8	49	4	8.2					
Canada and USA	13	2	15.4	14	1	7.1					
Rest of the World	19	1	5.3	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	 %
Overall	87	7	8.0	87	6	6.9
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		3	3.4		1	1.1
Ductal adenocarcinoma of pancreas		1	1.1		0	0.0
Metastases to liver		1	1.1		0	0.0
Metastases to lung		1	1.1		0	0.0
Prostate cancer		0	0.0		1	1.1
Rectal cancer		1	1.1		0	0.0
Transitional cell carcinoma		1	1.1		0	0.0
Gastrointestinal disorders		1	1.1		1	1.1
Abdominal pain		1	1.1		0	0.0
Diarrhoea		0	0.0		1	1.1
Vomiting		0	0.0		1	1.1
Metabolism and nutrition disorders		0	0.0		2	2.3
Decreased appetite		0	0.0		2	2.3
General disorders and administration site conditions		0	0.0		1	1.1
Asthenia		0	0.0		1	1.1
Fatigue		0	0.0		1	1.1
Infections and infestations		1	1.1		0	0.0
Pneumonia		1	1.1		0	0.0
Injury, poisoning and procedural complications		1	1.1		0	0.0
Fall		1	1.1		0	0.0
Investigations		0	0.0		1	1.1
Red blood cell sedimentation rate increased		0	0.0		1	1.1
Respiratory, thoracic and mediastinal disorders		1	1.1		0	0.0
Respiratory failure		1	1.1		0	0.0
Vascular disorders		0	0.0		1	1.1
Vasculitis		0	0.0		1	1.1

Study: 1305-0014. MedDRA version: 27.0
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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H.2.2.2.1.4 Adverse events on SOC level over the whole trial

Table H.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 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	87	27	31.0	87	37	42.5	0.1159	1.37 (0.92, 2.04)	1.64 (0.88, 3.06)	11.49 (-2.80, 25.15)	
Age											
<65 years	17	6	35.3	20	10	50.0					
>=65 years	70	21	30.0	67	27	40.3					
Sex											
Male	68	17	25.0	68	31	45.6					
Female	19	10	52.6	19	6	31.6					
Baseline FVC percent predicted											
<=70%	24	10	41.7	19	6	31.6					
>70%	63	17	27.0	68	31	45.6					
Region											
Europe	14	6	42.9	12	7	58.3					
Asia	41	13	31.7	49	22	44.9					
Canada and USA	13	5	38.5	14	6	42.9					
Rest of the World	19	3	15.8	12	2	16.7					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 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	87	22	25.3	87	24	27.6	0.7310	1.09 (0.66, 1.79)	1.13 (0.57, 2.21)	2.30 (-10.73, 15.22)	
Age											
<65 years	17	5	29.4	20	7	35.0					
>=65 years	70	17	24.3	67	17	25.4					
Sex											
Male	68	16	23.5	68	15	22.1					
Female	19	6	31.6	19	9	47.4					
Baseline FVC percent predicted											
<=70%	24	11	45.8	19	8	42.1					
>70%	63	11	17.5	68	16	23.5					
Region											
Europe	14	5	35.7	12	4	33.3					
Asia	41	9	22.0	49	13	26.5					
Canada and USA	13	4	30.8	14	5	35.7					
Rest of the World	19	4	21.1	12	2	16.7					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	43	49.4	87	53	60.9	0.1274	1.23 (0.94, 1.62)	1.60 (0.87, 2.91)	11.49 (-3.22, 25.53)	
Age											
<65 years	17	8	47.1	20	8	40.0					
>=65 years	70	35	50.0	67	45	67.2					
Sex											
Male	68	30	44.1	68	42	61.8					
Female	19	13	68.4	19	11	57.9					
Baseline FVC percent predicted											
<=70%	24	13	54.2	19	11	57.9					
>70%	63	30	47.6	68	42	61.8					
Region											
Europe	14	9	64.3	12	8	66.7					
Asia	41	17	41.5	49	30	61.2					
Canada and USA	13	7	53.8	14	9	64.3					
Rest of the World	19	10	52.6	12	6	50.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	8	9.2	87	11	12.6	0.4659	1.38 (0.58, 3.25)	1.43 (0.55, 3.75)	3.45 (-6.15, 13.13)	
Age											
<65 years	17	0	0.0	20	1	5.0					
>=65 years	70	8	11.4	67	10	14.9					
Sex											
Male	68	5	7.4	68	7	10.3					
Female	19	3	15.8	19	4	21.1					
Baseline FVC percent predicted											
<=70%	24	4	16.7	19	0	0.0					
>70%	63	4	6.3	68	11	16.2					
Region											
Europe	14	2	14.3	12	0	0.0					
Asia	41	3	7.3	49	8	16.3					
Canada and USA	13	1	7.7	14	3	21.4					
Rest of the World	19	2	10.5	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	13	14.9	87	18	20.7	0.3219	1.38 (0.72, 2.65)	1.48 (0.68, 3.26)	5.75 (-5.74, 17.12)	
Age											
<65 years	17	3	17.6	20	4	20.0					
>=65 years	70	10	14.3	67	14	20.9					
Sex											
Male	68	12	17.6	68	14	20.6					
Female	19	1	5.3	19	4	21.1					
Baseline FVC percent predicted											
<=70%	24	5	20.8	19	5	26.3					
>70%	63	8	12.7	68	13	19.1					
Region											
Europe	14	4	28.6	12	4	33.3					
Asia	41	6	14.6	49	12	24.5					
Canada and USA	13	1	7.7	14	1	7.1					
Rest of the World	19	2	10.5	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	5	5.7	87	16	18.4	0.0105	3.20 (1.23, 8.35)	3.70 (1.29, 10.60)	12.64 (2.92, 22.61)	
Age											0.2281
<65 years	17	2	11.8	20	3	15.0	0.7742	1.28 (0.24, 6.76)	1.32 (0.19, 9.02)	3.24 (-21.36, 25.92)	
>=65 years	70	3	4.3	67	13	19.4	0.0059	4.53 (1.35, 15.18)	5.38 (1.46, 19.84)	15.12 (4.32, 26.49)	
Sex											0.6142
Male	68	4	5.9	68	11	16.2	0.0553	2.75 (0.92, 8.21)	3.09 (0.93, 10.24)	10.29 (-0.49, 21.40)	
Female	19	1	5.3	19	5	26.3	0.0752	5.00 (0.64, 38.87)	6.43 (0.67, 61.47)	21.05 (-3.15, 43.94)	
Baseline FVC percent predicted											0.7074
<=70%	24	2	8.3	19	4	21.1	0.2319	2.53 (0.52, 12.35)	2.93 (0.48, 18.10)	12.72 (-8.83, 35.80)	
>70%	63	3	4.8	68	12	17.6	0.0207	3.71 (1.10, 12.53)	4.29 (1.15, 15.99)	12.89 (1.84, 24.05)	
Region											0.5355
Europe	14	1	7.1	12	1	8.3	0.9096	1.17 (0.08, 16.72)	1.18 (0.07, 21.17)	1.19 (-24.08, 28.87)	
Asia	41	2	4.9	49	12	24.5	0.0106	5.02 (1.19, 21.15)	6.32 (1.32, 30.19)	19.61 (4.63, 33.66)	
Canada and USA	13	1	7.7	14	3	21.4	0.3154	2.79 (0.33, 23.52)	3.27 (0.29, 36.31)	13.74 (-15.39, 40.65)	
Rest of the World	19	1	5.3	12	0	0.0	0.6673	0.51 (0.02, 11.65)	0.00 (NC, NC)	-5.26 (-24.64, 19.37)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	19	21.8	87	16	18.4	0.5705	0.84 (0.46, 1.53)	0.81 (0.38, 1.70)	-3.45 (-15.32, 8.52)	
Age											
<65 years	17	3	17.6	20	4	20.0					
>=65 years	70	16	22.9	67	12	17.9					
Sex											
Male	68	17	25.0	68	12	17.6					
Female	19	2	10.5	19	4	21.1					
Baseline FVC percent predicted											
<=70%	24	6	25.0	19	3	15.8					
>70%	63	13	20.6	68	13	19.1					
Region											
Europe	14	5	35.7	12	3	25.0					
Asia	41	8	19.5	49	9	18.4					
Canada and USA	13	2	15.4	14	4	28.6					
Rest of the World	19	4	21.1	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	17	19.5	87	14	16.1	0.5523	0.82 (0.43, 1.56)	0.79 (0.36, 1.72)	-3.45 (-14.86, 8.03)	
Age											
<65 years	17	6	35.3	20	2	10.0					
>=65 years	70	11	15.7	67	12	17.9					
Sex											
Male	68	13	19.1	68	10	14.7					
Female	19	4	21.1	19	4	21.1					
Baseline FVC percent predicted											
<=70%	24	6	25.0	19	3	15.8					
>70%	63	11	17.5	68	11	16.2					
Region											
Europe	14	5	35.7	12	2	16.7					
Asia	41	5	12.2	49	7	14.3					
Canada and USA	13	4	30.8	14	4	28.6					
Rest of the World	19	3	15.8	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	14	16.1	87	20	23.0	0.2513	1.43 (0.77, 2.64)	1.56 (0.73, 3.33)	6.90 (-4.97, 18.58)	
Age											
<65 years	17	4	23.5	20	5	25.0					
>=65 years	70	10	14.3	67	15	22.4					
Sex											
Male	68	12	17.6	68	14	20.6					
Female	19	2	10.5	19	6	31.6					
Baseline FVC percent predicted											
<=70%	24	2	8.3	19	4	21.1					
>70%	63	12	19.0	68	16	23.5					
Region											
Europe	14	1	7.1	12	5	41.7					
Asia	41	8	19.5	49	10	20.4					
Canada and USA	13	2	15.4	14	3	21.4					
Rest of the World	19	3	15.8	12	2	16.7					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	3	3.4	87	12	13.8	0.0151	4.00 (1.17, 13.68)	4.48 (1.22, 16.49)	10.34 (1.90, 19.42)	
Age											0.8995
<65 years	17	0	0.0	20	2	10.0	0.2863	4.29 (0.22, 83.57)	NC (NC, NC)	10.00 (-9.79, 30.10)	
>=65 years	70	3	4.3	67	10	14.9	0.0337	3.48 (1.00, 12.11)	3.92 (1.03, 14.93)	10.64 (0.59, 21.43)	
Sex											0.1829
Male	68	1	1.5	68	9	13.2	0.0086	9.00 (1.17, 69.11)	>10 (1.26, 83.08)	11.76 (2.91, 21.88)	
Female	19	2	10.5	19	3	15.8	0.6313	1.50 (0.28, 7.99)	1.59 (0.23, 10.82)	5.26 (-17.99, 28.32)	
Baseline FVC percent predicted											0.3434
<=70%	24	0	0.0	19	4	21.1	0.0297	>10 (0.64, >99)	NC (NC, NC)	21.05 (2.40, 43.33)	
>70%	63	3	4.8	68	8	11.8	0.1488	2.47 (0.69, 8.90)	2.67 (0.67, 10.54)	7.00 (-3.08, 17.26)	
Region											
Europe	14	0	0.0	12	3	25.0					
Asia	41	0	0.0	49	6	12.2					
Canada and USA	13	1	7.7	14	2	14.3					
Rest of the World	19	2	10.5	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 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	87	27	31.0	87	28	32.2	0.8705	1.04 (0.67, 1.61)	1.05 (0.56, 2.00)	1.15 (-12.49, 14.73)	
Age											
<65 years	17	6	35.3	20	7	35.0					
>=65 years	70	21	30.0	67	21	31.3					
Sex											
Male	68	23	33.8	68	23	33.8					
Female	19	4	21.1	19	5	26.3					
Baseline FVC percent predicted											
<=70%	24	12	50.0	19	8	42.1					
>70%	63	15	23.8	68	20	29.4					
Region											
Europe	14	5	35.7	12	6	50.0					
Asia	41	12	29.3	49	13	26.5					
Canada and USA	13	7	53.8	14	8	57.1					
Rest of the World	19	3	15.8	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	12	13.8	87	11	12.6	0.8229	0.92 (0.43, 1.96)	0.90 (0.38, 2.18)	-1.15 (-11.48, 9.18)	
Age											
<65 years	17	3	17.6	20	2	10.0					
>=65 years	70	9	12.9	67	9	13.4					
Sex											
Male	68	9	13.2	68	9	13.2					
Female	19	3	15.8	19	2	10.5					
Baseline FVC percent predicted											
<=70%	24	2	8.3	19	0	0.0					
>70%	63	10	15.9	68	11	16.2					
Region											
Europe	14	4	28.6	12	4	33.3					
Asia	41	3	7.3	49	5	10.2					
Canada and USA	13	2	15.4	14	2	14.3					
Rest of the World	19	3	15.8	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	6	6.9	87	5	5.7	0.7554	0.83 (0.26, 2.63)	0.82 (0.24, 2.80)	-1.15 (-9.19, 6.78)	
Age											
<65 years	17	1	5.9	20	2	10.0					
>=65 years	70	5	7.1	67	3	4.5					
Sex											
Male	68	5	7.4	68	4	5.9					
Female	19	1	5.3	19	1	5.3					
Baseline FVC percent predicted											
<=70%	24	3	12.5	19	1	5.3					
>70%	63	3	4.8	68	4	5.9					
Region											
Europe	14	3	21.4	12	1	8.3					
Asia	41	2	4.9	49	2	4.1					
Canada and USA	13	1	7.7	14	2	14.3					
Rest of the World	19	0	0.0	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	10	11.5	87	5	5.7	0.1768	0.50 (0.18, 1.40)	0.47 (0.15, 1.44)	-5.75 (-14.75, 2.94)	
Age											
<65 years	17	2	11.8	20	2	10.0					
>=65 years	70	8	11.4	67	3	4.5					
Sex											
Male	68	9	13.2	68	4	5.9					
Female	19	1	5.3	19	1	5.3					
Baseline FVC percent predicted											
<=70%	24	3	12.5	19	2	10.5					
>70%	63	7	11.1	68	3	4.4					
Region											
Europe	14	1	7.1	12	0	0.0					
Asia	41	7	17.1	49	4	8.2					
Canada and USA	13	0	0.0	14	1	7.1					
Rest of the World	19	2	10.5	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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: 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	87	6	6.9	87	2	2.3	0.1476	0.33 (0.07, 1.61)	0.32 (0.06, 1.62)	-4.60 (-12.13, 2.20)	
Age											
<65 years	17	0	0.0	20	0	0.0					
>=65 years	70	6	8.6	67	2	3.0					
Sex											
Male	68	6	8.8	68	2	2.9					
Female	19	0	0.0	19	0	0.0					
Baseline FVC percent predicted											
<=70%	24	1	4.2	19	0	0.0					
>70%	63	5	7.9	68	2	2.9					
Region											
Europe	14	0	0.0	12	0	0.0					
Asia	41	3	7.3	49	0	0.0					
Canada and USA	13	3	23.1	14	1	7.1					
Rest of the World	19	0	0.0	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 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	87	11	12.6	87	7	8.0	0.3194	0.64 (0.26, 1.56)	0.60 (0.22, 1.64)	-4.60	(-14.12, 4.78)	
Age												
<65 years	17	2	11.8	20	2	10.0						
>=65 years	70	9	12.9	67	5	7.5						
Sex												
Male	68	9	13.2	68	6	8.8						
Female	19	2	10.5	19	1	5.3						
Baseline FVC percent predicted												
<=70%	24	6	25.0	19	3	15.8						
>70%	63	5	7.9	68	4	5.9						
Region												
Europe	14	1	7.1	12	0	0.0						
Asia	41	4	9.8	49	5	10.2						
Canada and USA	13	4	30.8	14	1	7.1						
Rest of the World	19	2	10.5	12	1	8.3						

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	8	9.2	87	6	6.9	0.5772	0.75 (0.27,	2.07)	0.73 (0.24,	2.20)	-2.30 (-11.03,	6.29)	
Age														
<65 years	17	1	5.9	20	2	10.0								
>=65 years	70	7	10.0	67	4	6.0								
Sex														
Male	68	7	10.3	68	4	5.9								
Female	19	1	5.3	19	2	10.5								
Baseline FVC percent predicted														
<=70%	24	4	16.7	19	1	5.3								
>70%	63	4	6.3	68	5	7.4								
Region														
Europe	14	3	21.4	12	1	8.3								
Asia	41	3	7.3	49	3	6.1								
Canada and USA	13	1	7.7	14	2	14.3								
Rest of the World	19	1	5.3	12	0	0.0								

Study: 1305-0014. MedDRA version: 27.0. 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 H.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 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	87	8	9.2	87	3	3.4	0.1193	0.38 (0.10, 1.37)	0.35 (0.09, 1.38)	-5.75 (-13.98, 1.90)	
Age											
<65 years	17	2	11.8	20	0	0.0					
>=65 years	70	6	8.6	67	3	4.5					
Sex											
Male	68	7	10.3	68	3	4.4					
Female	19	1	5.3	19	0	0.0					
Baseline FVC percent predicted											
<=70%	24	2	8.3	19	1	5.3					
>70%	63	6	9.5	68	2	2.9					
Region											
Europe	14	1	7.1	12	0	0.0					
Asia	41	6	14.6	49	2	4.1					
Canada and USA	13	0	0.0	14	1	7.1					
Rest of the World	19	1	5.3	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0. 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 H.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: 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	87	5	5.7	87	0	0.0	0.0378	0.09 (0.01, 1.62)	0.00 (NC, NC)	-5.75 (-12.76, -0.40)	
Age											
<65 years	17	0	0.0	20	0	0.0					
>=65 years	70	5	7.1	67	0	0.0					
Sex											
Male	68	5	7.4	68	0	0.0					
Female	19	0	0.0	19	0	0.0					
Baseline FVC percent predicted											
<=70%	24	1	4.2	19	0	0.0					
>70%	63	4	6.3	68	0	0.0					
Region											
Europe	14	0	0.0	12	0	0.0					
Asia	41	3	7.3	49	0	0.0					
Canada and USA	13	2	15.4	14	0	0.0					
Rest of the World	19	0	0.0	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0. 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 H.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 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	87	9	10.3	87	5	5.7	0.2649	0.56 (0.19, 1.59)	0.53 (0.17, 1.65)	-4.60	(-13.39, 3.90)	
Age												
<65 years	17	0	0.0	20	0	0.0						
>=65 years	70	9	12.9	67	5	7.5						
Sex												
Male	68	7	10.3	68	4	5.9						
Female	19	2	10.5	19	1	5.3						
Baseline FVC percent predicted												
<=70%	24	7	29.2	19	2	10.5						
>70%	63	2	3.2	68	3	4.4						
Region												
Europe	14	1	7.1	12	0	0.0						
Asia	41	2	4.9	49	3	6.1						
Canada and USA	13	4	30.8	14	1	7.1						
Rest of the World	19	2	10.5	12	1	8.3						

Study: 1305-0014. MedDRA version: 27.0. 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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H.2.2.2.1.5 Adverse events on PT level over the whole trial

Table H.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 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	87	7	8.0	87	23	26.4	0.0013	3.29 (1.49, 7.26)	4.11 (1.66, 10.18)	18.39 (7.24, 29.31)	
Age											0.4946
<65 years	17	1	5.9	20	7	35.0	0.0320	5.95 (0.81, 43.66)	8.62 (0.94, 79.28)	29.12 (2.10, 51.36)	
>=65 years	70	6	8.6	67	16	23.9	0.0147	2.79 (1.16, 6.69)	3.35 (1.22, 9.17)	15.31 (2.93, 27.64)	
Sex											0.8397
Male	68	6	8.8	68	19	27.9	0.0040	3.17 (1.35, 7.44)	4.01 (1.49, 10.80)	19.12 (6.12, 31.66)	
Female	19	1	5.3	19	4	21.1	0.1500	4.00 (0.49, 32.57)	4.80 (0.48, 47.68)	15.79 (-7.29, 38.49)	
Baseline FVC percent predicted											0.7232
<=70%	24	2	8.3	19	4	21.1	0.2319	2.53 (0.52, 12.35)	2.93 (0.48, 18.10)	12.72 (-8.83, 35.80)	
>70%	63	5	7.9	68	19	27.9	0.0031	3.52 (1.40, 8.87)	4.50 (1.56, 12.93)	20.00 (6.85, 32.47)	
Region											0.8834
Europe	14	1	7.1	12	4	33.3	0.0912	4.67 (0.60, 36.29)	6.50 (0.61, 68.96)	26.19 (-5.00, 54.41)	
Asia	41	3	7.3	49	13	26.5	0.0176	3.63 (1.11, 11.86)	4.57 (1.20, 17.39)	19.21 (3.30, 33.76)	
Canada and USA	13	2	15.4	14	4	28.6	0.4102	1.86 (0.41, 8.49)	2.20 (0.33, 14.73)	13.19 (-18.51, 41.51)	
Rest of the World	19	1	5.3	12	2	16.7	0.2955	3.17 (0.32, 31.24)	3.60 (0.29, 44.83)	11.40 (-11.37, 39.87)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	11	12.6	87	9	10.3	0.6345	0.82 (0.36, 1.88)	0.80 (0.31, 2.03)	-2.30 (-12.15, 7.51)	
Age											
<65 years	17	2	11.8	20	2	10.0					
>=65 years	70	9	12.9	67	7	10.4					
Sex											
Male	68	7	10.3	68	5	7.4					
Female	19	4	21.1	19	4	21.1					
Baseline FVC percent predicted											
<=70%	24	7	29.2	19	3	15.8					
>70%	63	4	6.3	68	6	8.8					
Region											
Europe	14	3	21.4	12	1	8.3					
Asia	41	5	12.2	49	5	10.2					
Canada and USA	13	2	15.4	14	3	21.4					
Rest of the World	19	1	5.3	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 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	87	5	5.7	87	15	17.2	0.0175	3.00 (1.14, 7.89)	3.42 (1.18, 9.87)	11.49 (1.93, 21.33)	
Age											0.5945
<65 years	17	1	5.9	20	2	10.0	0.6475	1.70 (0.17, 17.16)	1.78 (0.15, 21.51)	4.12 (-18.18, 24.79)	
>=65 years	70	4	5.7	67	13	19.4	0.0151	3.40 (1.17, 9.89)	3.97 (1.22, 12.89)	13.69 (2.53, 25.24)	
Sex											0.0932
Male	68	3	4.4	68	14	20.6	0.0043	4.67 (1.40, 15.51)	5.62 (1.53, 20.57)	16.18 (5.09, 27.60)	
Female	19	2	10.5	19	1	5.3	0.5475	0.50 (0.05, 5.06)	0.47 (0.04, 5.70)	-5.26 (-26.58, 15.55)	
Baseline FVC percent predicted											0.7725
<=70%	24	2	8.3	19	4	21.1	0.2319	2.53 (0.52, 12.35)	2.93 (0.48, 18.10)	12.72 (-8.83, 35.80)	
>70%	63	3	4.8	68	11	16.2	0.0346	3.40 (0.99, 11.62)	3.86 (1.02, 14.55)	11.41 (0.60, 22.38)	
Region											
Europe	14	0	0.0	12	3	25.0					
Asia	41	1	2.4	49	8	16.3					
Canada and USA	13	1	7.7	14	4	28.6					
Rest of the World	19	3	15.8	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	12	13.8	87	9	10.3	0.4851	0.75 (0.33, 1.69)	0.72 (0.29, 1.81)	-3.45 (-13.46, 6.52)	
Age											
<65 years	17	3	17.6	20	1	5.0					
>=65 years	70	9	12.9	67	8	11.9					
Sex											
Male	68	9	13.2	68	7	10.3					
Female	19	3	15.8	19	2	10.5					
Baseline FVC percent predicted											
<=70%	24	2	8.3	19	2	10.5					
>70%	63	10	15.9	68	7	10.3					
Region											
Europe	14	2	14.3	12	1	8.3					
Asia	41	6	14.6	49	6	12.2					
Canada and USA	13	1	7.7	14	1	7.1					
Rest of the World	19	3	15.8	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	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	87	8	9.2	87	13	14.9	0.2446	1.63 (0.71, 3.72)	1.73 (0.68, 4.42)	5.75 (-4.18, 15.76)	
Age											
<65 years	17	2	11.8	20	2	10.0					
>=65 years	70	6	8.6	67	11	16.4					
Sex											
Male	68	7	10.3	68	11	16.2					
Female	19	1	5.3	19	2	10.5					
Baseline FVC percent predicted											
<=70%	24	2	8.3	19	3	15.8					
>70%	63	6	9.5	68	10	14.7					
Region											
Europe	14	0	0.0	12	0	0.0					
Asia	41	5	12.2	49	10	20.4					
Canada and USA	13	1	7.7	14	2	14.3					
Rest of the World	19	2	10.5	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	5	5.7	87	9	10.3	0.2649	1.80 (0.63, 5.15)	1.89 (0.61, 5.90)	4.60 (-3.90, 13.39)	
Age											
<65 years	17	1	5.9	20	3	15.0					
>=65 years	70	4	5.7	67	6	9.0					
Sex											
Male	68	5	7.4	68	5	7.4					
Female	19	0	0.0	19	4	21.1					
Baseline FVC percent predicted											
<=70%	24	1	4.2	19	2	10.5					
>70%	63	4	6.3	68	7	10.3					
Region											
Europe	14	0	0.0	12	4	33.3					
Asia	41	3	7.3	49	4	8.2					
Canada and USA	13	0	0.0	14	0	0.0					
Rest of the World	19	2	10.5	12	1	8.3					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	4	4.6	87	10	11.5	0.0945	2.50 (0.82, 7.67)	2.69 (0.81, 8.95)	6.90 (-1.49, 15.74)	
Age											
<65 years	17	1	5.9	20	1	5.0					
>=65 years	70	3	4.3	67	9	13.4					
Sex											
Male	68	3	4.4	68	8	11.8					
Female	19	1	5.3	19	2	10.5					
Baseline FVC percent predicted											
<=70%	24	0	0.0	19	2	10.5					
>70%	63	4	6.3	68	8	11.8					
Region											
Europe	14	2	14.3	12	4	33.3					
Asia	41	1	2.4	49	3	6.1					
Canada and USA	13	1	7.7	14	3	21.4					
Rest of the World	19	0	0.0	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	12	13.8	87	6	6.9	0.1353	0.50 (0.20, 1.27)	0.46 (0.17, 1.30)	-6.90 (-16.43, 2.41)	
Age											
<65 years	17	2	11.8	20	1	5.0					
>=65 years	70	10	14.3	67	5	7.5					
Sex											
Male	68	12	17.6	68	5	7.4					
Female	19	0	0.0	19	1	5.3					
Baseline FVC percent predicted											
<=70%	24	6	25.0	19	0	0.0					
>70%	63	6	9.5	68	6	8.8					
Region											
Europe	14	4	28.6	12	2	16.7					
Asia	41	2	4.9	49	2	4.1					
Canada and USA	13	4	30.8	14	2	14.3					
Rest of the World	19	2	10.5	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	5	5.7	87	4	4.6	0.7321	0.80 (0.22, 2.88)	0.79 (0.20, 3.05)	-1.15 (-8.70, 6.25)	
Age											
<65 years	17	1	5.9	20	2	10.0					
>=65 years	70	4	5.7	67	2	3.0					
Sex											
Male	68	4	5.9	68	3	4.4					
Female	19	1	5.3	19	1	5.3					
Baseline FVC percent predicted											
<=70%	24	3	12.5	19	1	5.3					
>70%	63	2	3.2	68	3	4.4					
Region											
Europe	14	2	14.3	12	1	8.3					
Asia	41	2	4.9	49	2	4.1					
Canada and USA	13	1	7.7	14	1	7.1					
Rest of the World	19	0	0.0	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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: Risk p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	6	6.9	87	3	3.4	0.3045	0.50 (0.13, 1.94)	0.48 (0.12, 1.99)	-3.45 (-11.13, 3.78)	
Age											
<65 years	17	1	5.9	20	1	5.0					
>=65 years	70	5	7.1	67	2	3.0					
Sex											
Male	68	5	7.4	68	2	2.9					
Female	19	1	5.3	19	1	5.3					
Baseline FVC percent predicted											
<=70%	24	2	8.3	19	2	10.5					
>70%	63	4	6.3	68	1	1.5					
Region											
Europe	14	0	0.0	12	0	0.0					
Asia	41	5	12.2	49	3	6.1					
Canada and USA	13	0	0.0	14	0	0.0					
Rest of the World	19	1	5.3	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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 p-value*	Risk ratio (95% CI)	Odds ratio (95% CI)	Risk diff. (95% CI)	Interaction p-value**
Overall	87	6	6.9	87	5	5.7	0.7554	0.83 (0.26, 2.63)	0.82 (0.24, 2.80)	-1.15 (-9.19, 6.78)	
Age											
<65 years	17	1	5.9	20	2	10.0					
>=65 years	70	5	7.1	67	3	4.5					
Sex											
Male	68	5	7.4	68	3	4.4					
Female	19	1	5.3	19	2	10.5					
Baseline FVC percent predicted											
<=70%	24	3	12.5	19	1	5.3					
>70%	63	3	4.8	68	4	5.9					
Region											
Europe	14	2	14.3	12	1	8.3					
Asia	41	3	7.3	49	3	6.1					
Canada and USA	13	1	7.7	14	1	7.1					
Rest of the World	19	0	0.0	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0. 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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H.2.2.3 Further analysis

H.2.2.3.1 Further safety analysis

Table H.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	87	2	2.3	87	2	2.3	1.0000	1.00 (0.14, 6.94)	1.00 (0.14, 7.26)	0.00 (-5.94, 5.94)	
Age											
<65 years	17	0	0.0	20	0	0.0					
>=65 years	70	2	2.9	67	2	3.0					
Sex											
Male	68	1	1.5	68	2	2.9					
Female	19	1	5.3	19	0	0.0					
Baseline FVC percent predicted											
<=70%	24	0	0.0	19	0	0.0					
>70%	63	2	3.2	68	2	2.9					
Region											
Europe	14	1	7.1	12	2	16.7					
Asia	41	1	2.4	49	0	0.0					
Canada and USA	13	0	0.0	14	0	0.0					
Rest of the World	19	0	0.0	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	7	8.0	87	23	26.4	0.0013	3.29 (1.49, 7.26)	4.11 (1.66, 10.18)	18.39 (7.24, 29.31)	
Age											0.4946
<65 years	17	1	5.9	20	7	35.0	0.0320	5.95 (0.81, 43.66)	8.62 (0.94, 79.28)	29.12 (2.10, 51.36)	
>=65 years	70	6	8.6	67	16	23.9	0.0147	2.79 (1.16, 6.69)	3.35 (1.22, 9.17)	15.31 (2.93, 27.64)	
Sex											0.8397
Male	68	6	8.8	68	19	27.9	0.0040	3.17 (1.35, 7.44)	4.01 (1.49, 10.80)	19.12 (6.12, 31.66)	
Female	19	1	5.3	19	4	21.1	0.1500	4.00 (0.49, 32.57)	4.80 (0.48, 47.68)	15.79 (-7.29, 38.49)	
Baseline FVC percent predicted											0.7232
<=70%	24	2	8.3	19	4	21.1	0.2319	2.53 (0.52, 12.35)	2.93 (0.48, 18.10)	12.72 (-8.83, 35.80)	
>70%	63	5	7.9	68	19	27.9	0.0031	3.52 (1.40, 8.87)	4.50 (1.56, 12.93)	20.00 (6.85, 32.47)	
Region											0.8834
Europe	14	1	7.1	12	4	33.3	0.0912	4.67 (0.60, 36.29)	6.50 (0.61, 68.96)	26.19 (-5.00, 54.41)	
Asia	41	3	7.3	49	13	26.5	0.0176	3.63 (1.11, 11.86)	4.57 (1.20, 17.39)	19.21 (3.30, 33.76)	
Canada and USA	13	2	15.4	14	4	28.6	0.4102	1.86 (0.41, 8.49)	2.20 (0.33, 14.73)	13.19 (-18.51, 41.51)	
Rest of the World	19	1	5.3	12	2	16.7	0.2955	3.17 (0.32, 31.24)	3.60 (0.29, 44.83)	11.40 (-11.37, 39.87)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	3	3.4	87	4	4.6	0.6996	1.33 (0.31, 5.78)	1.35 (0.29, 6.22)	1.15 (-5.66, 8.16)	
Age											
<65 years	17	0	0.0	20	0	0.0					
>=65 years	70	3	4.3	67	4	6.0					
Sex											
Male	68	2	2.9	68	3	4.4					
Female	19	1	5.3	19	1	5.3					
Baseline FVC percent predicted											
<=70%	24	2	8.3	19	1	5.3					
>70%	63	1	1.6	68	3	4.4					
Region											
Europe	14	1	7.1	12	1	8.3					
Asia	41	0	0.0	49	1	2.0					
Canada and USA	13	2	15.4	14	2	14.3					
Rest of the World	19	0	0.0	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	2	2.3	87	4	4.6	0.4060	2.00 (0.38, 10.64)	2.05 (0.37, 11.49)	2.30 (-4.05, 9.14)	
Age											
<65 years	17	1	5.9	20	0	0.0					
>=65 years	70	1	1.4	67	4	6.0					
Sex											
Male	68	1	1.5	68	3	4.4					
Female	19	1	5.3	19	1	5.3					
Baseline FVC percent predicted											
<=70%	24	0	0.0	19	1	5.3					
>70%	63	2	3.2	68	3	4.4					
Region											
Europe	14	0	0.0	12	0	0.0					
Asia	41	1	2.4	49	1	2.0					
Canada and USA	13	1	7.7	14	3	21.4					
Rest of the World	19	0	0.0	12	0	0.0					

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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 H.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	87	27	31.0	87	37	42.5	0.1159	1.37 (0.92, 2.04)	1.64 (0.88, 3.06)	11.49 (-2.80, 25.15)	
Age											0.9083
<65 years	17	6	35.3	20	10	50.0	0.3682	1.42 (0.65, 3.09)	1.83 (0.49, 6.90)	14.71 (-16.13, 41.65)	
>=65 years	70	21	30.0	67	27	40.3	0.2066	1.34 (0.85, 2.13)	1.58 (0.78, 3.19)	10.30 (-5.58, 25.55)	
Sex											0.0186
Male	68	17	25.0	68	31	45.6	0.0120	1.82 (1.12, 2.97)	2.51 (1.21, 5.20)	20.59 (4.52, 35.25)	
Female	19	10	52.6	19	6	31.6	0.1888	0.60 (0.27, 1.32)	0.42 (0.11, 1.56)	-21.05 (-46.83, 9.61)	
Baseline FVC percent predicted											0.0967
<=70%	24	10	41.7	19	6	31.6	0.4967	0.76 (0.34, 1.71)	0.65 (0.18, 2.28)	-10.09 (-35.45, 18.16)	
>70%	63	17	27.0	68	31	45.6	0.0272	1.69 (1.04, 2.74)	2.27 (1.09, 4.72)	18.60 (2.10, 33.66)	
Region											0.9651
Europe	14	6	42.9	12	7	58.3	0.4314	1.36 (0.63, 2.94)	1.87 (0.39, 8.89)	15.48 (-20.56, 46.47)	
Asia	41	13	31.7	49	22	44.9	0.2011	1.42 (0.82, 2.44)	1.75 (0.74, 4.17)	13.19 (-6.90, 31.56)	
Canada and USA	13	5	38.5	14	6	42.9	0.8163	1.11 (0.45, 2.78)	1.20 (0.26, 5.59)	4.40 (-29.34, 36.54)	
Rest of the World	19	3	15.8	12	2	16.7	0.9484	1.06 (0.21, 5.42)	1.07 (0.15, 7.54)	0.88 (-23.97, 30.83)	

Study: 1305-0014. MedDRA version: 27.0
N = number of patients, n = number of patients with at least one event, NC = not calculable.
Confidence intervals (CIs): Wald asymptotic CI for risk ratios and odds ratios, Newcombe Hybrid Score CI for risk differences.
Subgroups are only analysed if at least 10 events occurred 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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H.2.2.3.2 Time to event analyses: treatment policy approach to lung transplant

Table H.2.2.3.2: 1 Cox model for time to first confirmed acute IPF exacerbation or death - treatment policy approach to lung transplant - 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	87	13 (5/ 8)	14.9	14.46	87	8 (7/ 1)	9.2	8.69	0.72 (0.29, 1.79)	0.4794	
Age											0.5880
<65 years	17	3 (1/ 2)	17.6	17.96	20	2 (2/ 0)	10.0	9.01	0.46 (0.07, 2.88)	0.4076	
>=65 years	70	10 (4/ 6)	14.3	13.66	67	6 (5/ 1)	9.0	8.59	0.82 (0.29, 2.31)	0.7051	
Sex											0.1604
Male	68	12 (4/ 8)	17.6	17.27	68	5 (4/ 1)	7.4	6.95	0.51 (0.17, 1.48)	0.2159	
Female	19	1 (1/ 0)	5.3	4.89	19	3 (3/ 0)	15.8	14.93	3.04 (0.31, 29.46)	0.3382	
Baseline FVC percent predicted											0.5783
<=70%	24	6 (3/ 3)	25.0	26.67	19	3 (2/ 1)	15.8	15.87	0.44 (0.10, 2.01)	0.2888	
>70%	63	7 (2/ 5)	11.1	10.38	68	5 (5/ 0)	7.4	6.83	0.75 (0.24, 2.38)	0.6238	
Region											0.8830
Europe	14	1 (0/ 1)	7.1	6.19	12	1 (1/ 0)	8.3	8.23	2.71 (0.16, 45.34)	0.4870	
Asia	41	5 (3/ 2)	12.2	11.67	49	5 (4/ 1)	10.2	9.02	0.85 (0.24, 2.98)	0.7992	
Canada and USA	13	5 (1/ 4)	38.5	39.61	14	2 (2/ 0)	14.3	16.99	0.73 (0.14, 3.89)	0.7085	
Rest of the World	19	2 (1/ 1)	10.5	10.91	12	0 (0/ 0)	0.0	0.00	0.00 (NC, NC)	0.9907	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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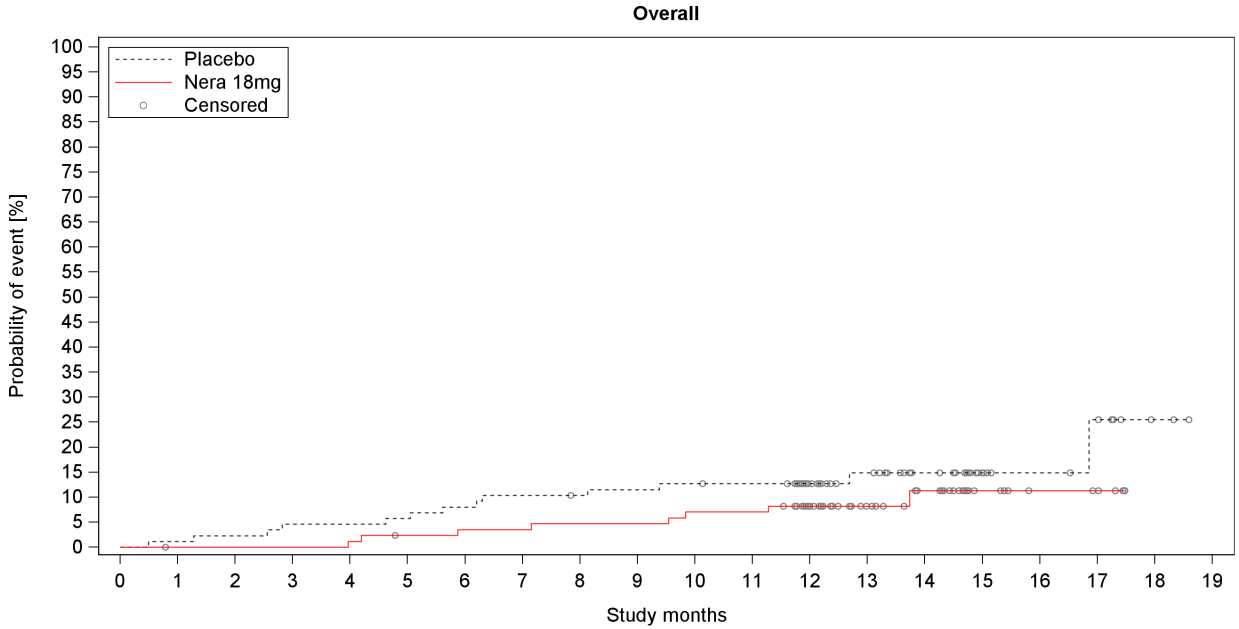

Number at risk (percentage relative to baseline)

Placebo	87	86	85	83	83	82	80	78	77	76	75	74	50	38	30	13	9	7	2	0
%	100.0	98.9	97.7	95.4	95.4	94.3	92.0	89.7	88.5	87.4	86.2	85.1	57.5	43.7	34.5	14.9	10.3	8.0	2.3	0.0
Nera 18mg	87	86	86	86	85	83	82	82	81	81	79	79	54	34	27	12	7	6	0	0
%	100.0	98.9	98.9	98.9	97.7	95.4	94.3	94.3	93.1	93.1	90.8	90.8	62.1	39.1	31.0	13.8	8.0	6.9	0.0	0.0

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

Placebo	0	0	0	0	0	0	0	0	1	1	1	2	26	37	45	62	66	67	72	74
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	2.3	29.9	42.5	51.7	71.3	75.9	77.0	82.8	85.1
Nera 18mg	0	1	1	1	1	2	2	2	2	2	2	2	26	46	52	67	72	73	79	79
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	2.3	2.3	29.9	52.9	59.8	77.0	82.8	83.9	90.8	90.8

Study: 1305-0014

Figure H.2.2.3.2: 1 Time to first confirmed acute IPF 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 H.2.2.3.2: 1

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Table H.2.2.3.2: 2 Cox model for time to first confirmed or suspected acute IPF exacerbation or death - treatment policy approach to lung transplant - over the whole trial (DBL1) - 18mg - FAS (non-AF background)

Subgroup Category	Placebo N	n	e/ d)	%	Rate°	Nera 18mg N	n	e/ d)	%	Rate°	Nera 18mg vs Placebo Hazard ratio	(95% CI)	p-value	Interaction p-value
Overall	87	16	8/ 8)	18.4	18.17	87	10	9/ 1)	11.5	11.02	0.70	(0.31, 1.59)	0.3959	
Age														0.5972
<65 years	17	3	1/ 2)	17.6	17.96	20	2	2/ 0)	10.0	9.01	0.45	(0.07, 2.80)	0.3928	
>=65 years	70	13	7/ 6)	18.6	18.22	67	8	7/ 1)	11.9	11.68	0.78	(0.32, 1.91)	0.5836	
Sex														0.4245
Male	68	13	5/ 8)	19.1	18.92	68	6	5/ 1)	8.8	8.42	0.57	(0.21, 1.52)	0.2602	
Female	19	3	3/ 0)	15.8	15.52	19	4	4/ 0)	21.1	20.59	1.18	(0.26, 5.36)	0.8340	
Baseline FVC percent predicted														0.3218
<=70%	24	9	6/ 3)	37.5	43.66	19	4	3/ 1)	21.1	21.97	0.39	(0.11, 1.40)	0.1500	
>70%	63	7	2/ 5)	11.1	10.38	68	6	6/ 0)	8.8	8.28	0.91	(0.30, 2.71)	0.8600	
Region														0.8178
Europe	14	2	1/ 1)	14.3	12.98	12	1	1/ 0)	8.3	8.23	1.39	(0.12, 16.05)	0.7911	
Asia	41	6	4/ 2)	14.6	14.19	49	6	5/ 1)	12.2	10.93	0.77	(0.24, 2.42)	0.6482	
Canada and USA	13	6	2/ 4)	46.2	49.92	14	3	3/ 0)	21.4	27.48	1.90	(0.44, 8.13)	0.3887	
Rest of the World	19	2	1/ 1)	10.5	10.91	12	0	0/ 0)	0.0	0.00	0.00	(NC, NC)	0.9893	

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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 IPF 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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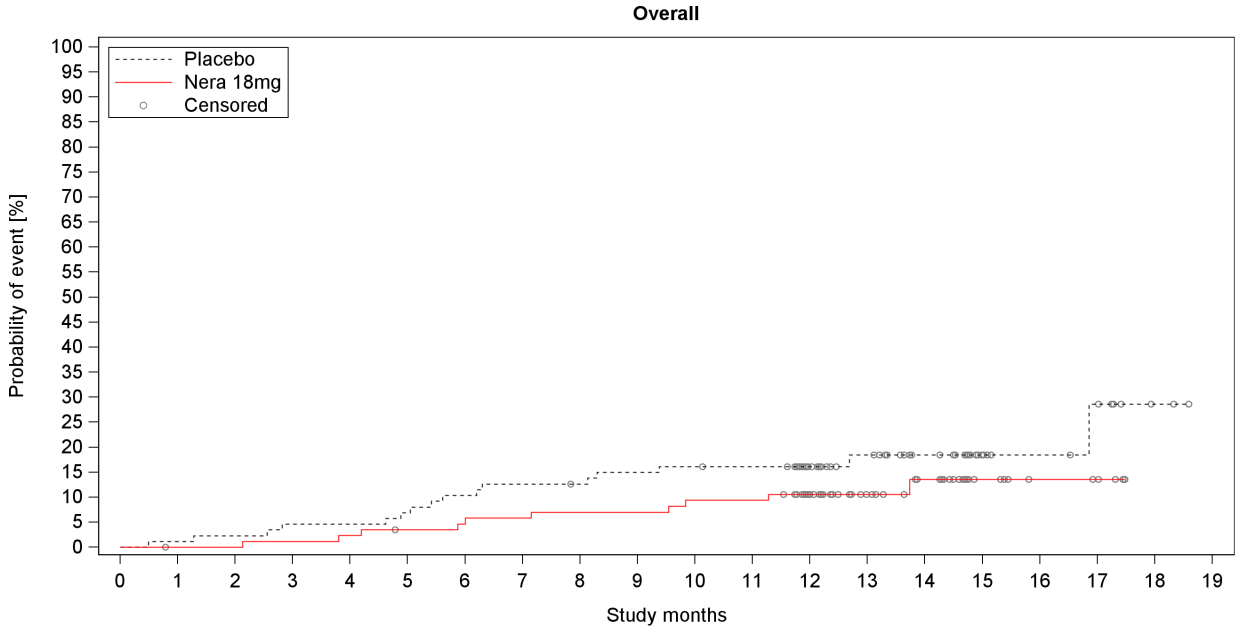

Number at risk (percentage relative to baseline)

Placebo	87	86	85	83	83	81	78	76	75	73	72	71	47	36	28	13	9	7	2	0
%	100.0	98.9	97.7	95.4	95.4	93.1	89.7	87.4	86.2	83.9	82.8	81.6	54.0	41.4	32.2	14.9	10.3	8.0	2.3	0.0
Nera 18mg	87	86	86	85	84	82	81	80	79	79	77	77	52	34	27	12	7	6	0	0
%	100.0	98.9	98.9	97.7	96.6	94.3	93.1	92.0	90.8	90.8	88.5	88.5	59.8	39.1	31.0	13.8	8.0	6.9	0.0	0.0

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

Placebo	0	0	0	0	0	0	0	0	1	1	1	2	26	36	44	59	63	64	69	71
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	2.3	29.9	41.4	50.6	67.8	72.4	73.6	79.3	81.6
Nera 18mg	0	1	1	1	1	2	2	2	2	2	2	2	26	44	50	65	70	71	77	77
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	2.3	2.3	29.9	50.6	57.5	74.7	80.5	81.6	88.5	88.5

Study: 1305-0014

Figure H.2.2.3.2: 2 Time to first confirmed or suspected acute IPF 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 H.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	87	9	10.3	9.73	87	1	1.1	1.04	0.14	(0.02, 1.16)	0.0680	
Age												
<65 years	17	2	11.8		20	0	0.0					
>=65 years	70	7	10.0		67	1	1.5					
Sex												
Male	68	8	11.8		68	1	1.5					
Female	19	1	5.3		19	0	0.0					
Baseline FVC percent predicted												
<=70%	24	4	16.7		19	1	5.3					
>70%	63	5	7.9		68	0	0.0					
Region												
Europe	14	1	7.1		12	0	0.0					
Asia	41	3	7.3		49	1	2.0					
Canada and USA	13	4	30.8		14	0	0.0					
Rest of the World	19	1	5.3		12	0	0.0					

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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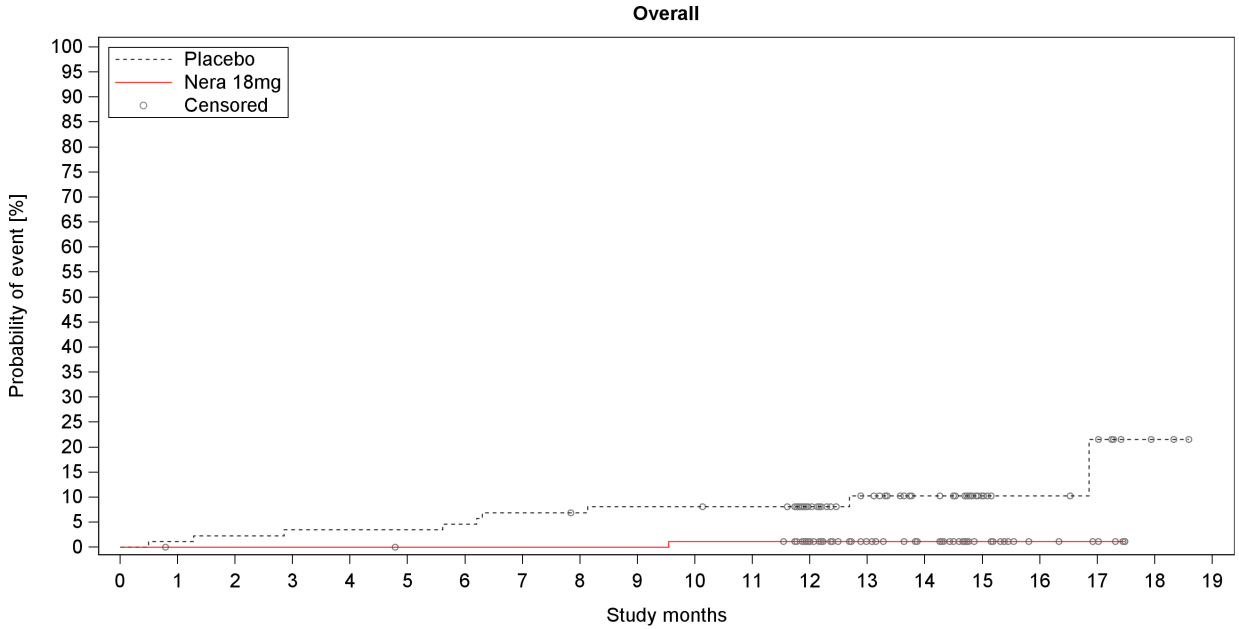

Number at risk (percentage relative to baseline)

Placebo	87	86	85	84	84	84	83	81	80	79	79	78	53	39	31	13	9	7	2	0
%	100.0	98.9	97.7	96.6	96.6	96.6	95.4	93.1	92.0	90.8	90.8	89.7	60.9	44.8	35.6	14.9	10.3	8.0	2.3	0.0
Nera 18mg	87	86	86	86	86	85	85	85	85	85	84	84	60	40	34	17	9	7	0	0
%	100.0	98.9	98.9	98.9	98.9	97.7	97.7	97.7	97.7	97.7	96.6	96.6	69.0	46.0	39.1	19.5	10.3	8.0	0.0	0.0

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

Placebo	0	0	0	0	0	0	0	0	1	1	1	2	27	40	48	66	70	71	76	78
%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	2.3	31.0	46.0	55.2	75.9	80.5	81.6	87.4	89.7
Nera 18mg	0	1	1	1	1	2	2	2	2	2	2	2	26	46	52	69	77	79	86	86
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	2.3	2.3	29.9	52.9	59.8	79.3	88.5	90.8	98.9	98.9

Study: 1305-0014

Figure H.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 H.2.2.3.2: 4 Cox model for time to first confirmed acute IPF 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	87	5	5.7	5.57	87	7	8.0	7.60	1.46	(0.45, 4.72)	0.5284	
Age												
<65 years	17	1	5.9		20	2	10.0					
>=65 years	70	4	5.7		67	5	7.5					
Sex												
Male	68	4	5.9		68	4	5.9					
Female	19	1	5.3		19	3	15.8					
Baseline FVC percent predicted												
<=70%	24	3	12.5		19	2	10.5					
>70%	63	2	3.2		68	5	7.4					
Region												
Europe	14	0	0.0		12	1	8.3					
Asia	41	3	7.3		49	4	8.2					
Canada and USA	13	1	7.7		14	2	14.3					
Rest of the World	19	1	5.3		12	0	0.0					

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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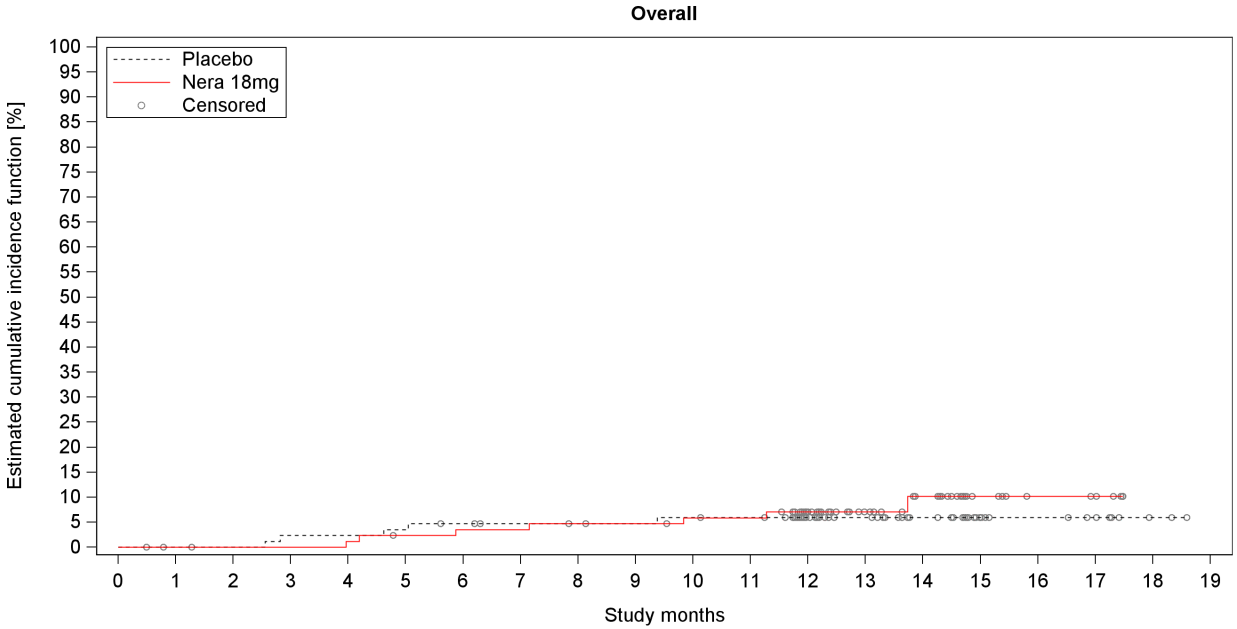

Number at risk (percentage relative to baseline)

Placebo	87	86	85	83	83	82	80	78	77	76	75	74	49	38	30	13	9	7	2	0
%	100.0	98.9	97.7	95.4	95.4	94.3	92.0	89.7	88.5	87.4	86.2	85.1	56.3	43.7	34.5	14.9	10.3	8.0	2.3	0.0
Nera 18mg	87	86	86	86	85	83	82	82	81	81	79	79	54	34	27	12	7	6	0	0
%	100.0	98.9	98.9	98.9	97.7	95.4	94.3	94.3	93.1	93.1	90.8	90.8	62.1	39.1	31.0	13.8	8.0	6.9	0.0	0.0

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

Placebo	0	1	2	2	2	2	3	5	6	7	7	8	33	44	52	69	73	75	80	82
%	0.0	1.1	2.3	2.3	2.3	2.3	3.4	5.7	6.9	8.0	8.0	9.2	37.9	50.6	59.8	79.3	83.9	86.2	92.0	94.3
Nera 18mg	0	1	1	1	1	2	2	2	2	2	3	3	27	47	53	68	73	74	80	80
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	3.4	3.4	31.0	54.0	60.9	78.2	83.9	85.1	92.0	92.0

Study: 1305-0014

Figure H.2.2.3.2: 4 Time to first confirmed acute IPF 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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Figure H.2.2.3.2: 4

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Table H.2.2.3.2: 5 Cox model for time to first confirmed or suspected acute IPF 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	87	8	9.2	9.10	87	9	10.3	9.92	1.13	(0.43, 3.02)	0.8010	
Age												0.9018
<65 years	17	1	5.9	5.99	20	2	10.0	9.01	1.33	(0.12, 15.27)	0.8203	
>=65 years	70	7	10.0	9.83	67	7	10.4	10.22	1.12	(0.39, 3.25)	0.8310	
Sex												0.9762
Male	68	5	7.4	7.29	68	5	7.4	7.01	1.11	(0.32, 3.91)	0.8692	
Female	19	3	15.8	15.52	19	4	21.1	20.59	1.08	(0.24, 4.92)	0.9218	
Baseline FVC percent predicted												
<=70%	24	6	25.0		19	3	15.8					
>70%	63	2	3.2		68	6	8.8					
Region												
Europe	14	1	7.1		12	1	8.3					
Asia	41	4	9.8		49	5	10.2					
Canada and USA	13	2	15.4		14	3	21.4					
Rest of the World	19	1	5.3		12	0	0.0					

Study: 1305-0014. Based on a Cox regression model estimated in overall with categorical treatment, continuous age, baseline FVC % predicted, baseline DLCO % predicted (corrected for Hb).
The subgroup model additionally includes the subgroup and treatment by subgroup interaction.
Subgroups will only be 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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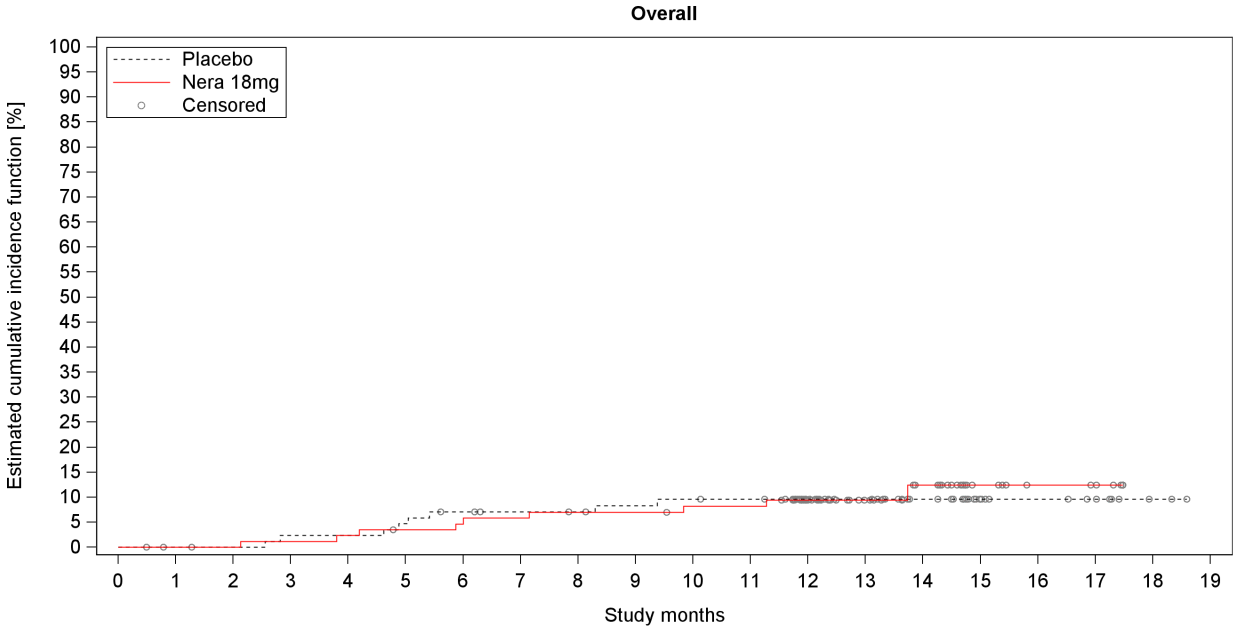

Number at risk (percentage relative to baseline)

Placebo	87	86	85	83	83	81	78	76	75	73	72	71	46	36	28	13	9	7	2	0
%	100.0	98.9	97.7	95.4	95.4	93.1	89.7	87.4	86.2	83.9	82.8	81.6	52.9	41.4	32.2	14.9	10.3	8.0	2.3	0.0
Nera 18mg	87	86	86	85	84	82	81	80	79	79	77	77	52	34	27	12	7	6	0	0
%	100.0	98.9	98.9	97.7	96.6	94.3	93.1	92.0	90.8	90.8	88.5	88.5	59.8	39.1	31.0	13.8	8.0	6.9	0.0	0.0

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

Placebo	0	1	2	2	2	2	3	5	6	7	7	8	33	43	51	66	70	72	77	79
%	0.0	1.1	2.3	2.3	2.3	2.3	3.4	5.7	6.9	8.0	8.0	9.2	37.9	49.4	58.6	75.9	80.5	82.8	88.5	90.8
Nera 18mg	0	1	1	1	1	2	2	2	2	2	3	3	27	45	51	66	71	72	78	78
%	0.0	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	3.4	3.4	31.0	51.7	58.6	75.9	81.6	82.8	89.7	89.7

Study: 1305-0014

Figure H.2.2.3.2: 5 Time to first confirmed or suspected acute IPF 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 Wirksamkeit in den Einzelstudien aus dem Jahr 2026

4.1.1.1 Analysis #1

4.1.1.1.1 Time to first confirmed acute IPF exacerbation (based on adjudication)

Table 1.1.1.1.1 Time to first confirmed acute IPF exacerbation (based on adjudication)
OC - Treated Set - Study 1199.32

	Placebo				Nint 150bid			
	Number at risk [1]	Failure N (%)	Censored N (%)	Survival	Number at risk [1]	Failure N (%)	Censored N (%)	Survival
0 - Week 52	204	1 (0.5)	203 (99.5)	0.995	309	2 (0.6)	307 (99.4)	0.993
Comparison vs Placebo [2]								
p-value [3]						0.7977		
Hazard ratio [4]						1.37		
95% Confidence interval						(0.12, 15.61)		

[1] Cumulative number of patients entering the respective time interval
[2] Based on data collected up to 372 days after randomization (52 weeks + 7 days margin)
[3] Based on a Log-rank test
[4] Based on a Cox´s regression model with terms for treatment, gender, age and height
Survival represents the probability of event-free survival. Failure means event.

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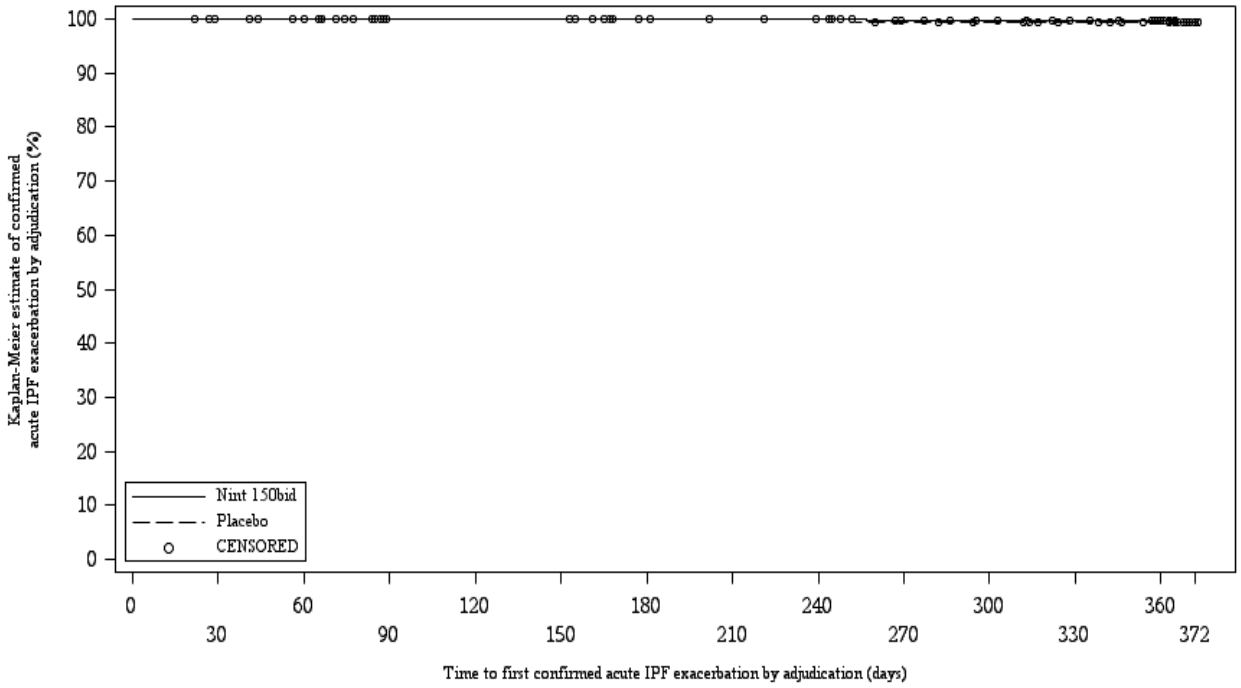

Figure 1.1.1.1.2 Time to first confirmed acute IPF exacerbation (based on adjudication)
OC - Treated Set - Study 1199.32

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Table 1.1.1.1.3 Time to first confirmed acute IPF exacerbation (based on adjudication)
OC - Treated Set - Study 1199.34

	Placebo				Nint 150bid			
	Number at risk [1]	Failure N (%)	Censored N (%)	Survival	Number at risk [1]	Failure N (%)	Censored N (%)	Survival
0 - Week 52	219	3 (1.4)	216 (98.6)	0.986	329	2 (0.6)	327 (99.4)	0.993
Comparison vs Placebo [2]								
p-value [3]						0.3561		
Hazard ratio [4]						0.45		
95% Confidence interval						(0.07, 2.69)		

[1] Cumulative number of patients entering the respective time interval
[2] Based on data collected up to 372 days after randomization (52 weeks + 7 days margin)
[3] Based on a Log-rank test
[4] Based on a Cox´s regression model with terms for treatment, gender, age and height
Survival represents the probability of event-free survival. Failure means event.

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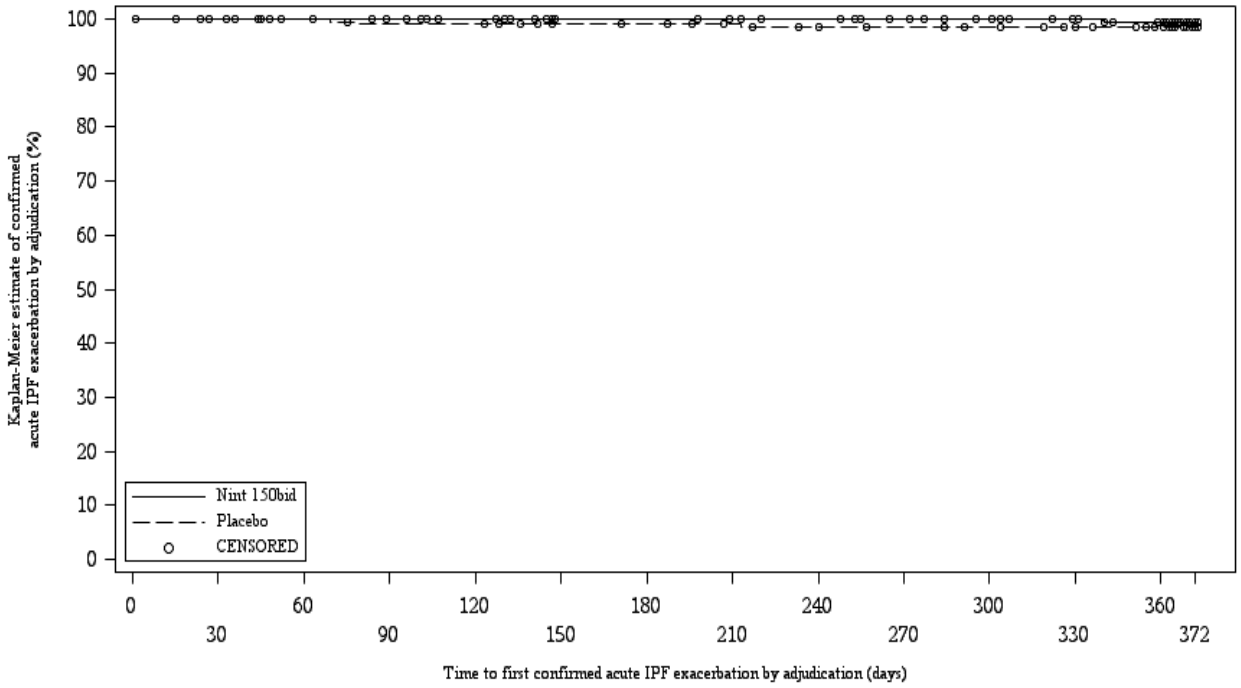

Number at risk

Nint 150bid	329	326	323	320	316	309	309	307	305	301	297	292	285	265
Placebo	219	218	215	212	212	207	206	203	200	198	196	193	188	177

Figure 1.1.1.1.4 Time to first confirmed acute IPF exacerbation (based on adjudication)
OC - Treated Set - Study 1199.34

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Table 1.1.1.1.5 Time to first confirmed acute IPF exacerbation (based on adjudication)
OC - Treated Set - Study 1199.187 (blinded period)

	Placebo				Nint 150bid			
	Number at risk [1]	Failure N (%)	Censored N (%)	Survival	Number at risk [1]	Failure N (%)	Censored N (%)	Survival
Blinded period	57	2 (3.5)	55 (96.5)	0.942	56	1 (1.8)	55 (98.2)	0.952
Comparison vs Placebo [2]								
p-value [3]						0.5859		
Hazard ratio [4]						0.38		
95% Confidence interval						(0.03, 4.97)		

[1] Cumulative number of patients entering the respective time interval
[2] Based on data collected over blinded period
[3] Based on a Log-rank test
[4] Based on a Cox´s regression model with terms for treatment, gender, age and height
Survival represents the probability of event-free survival. Failure means event.

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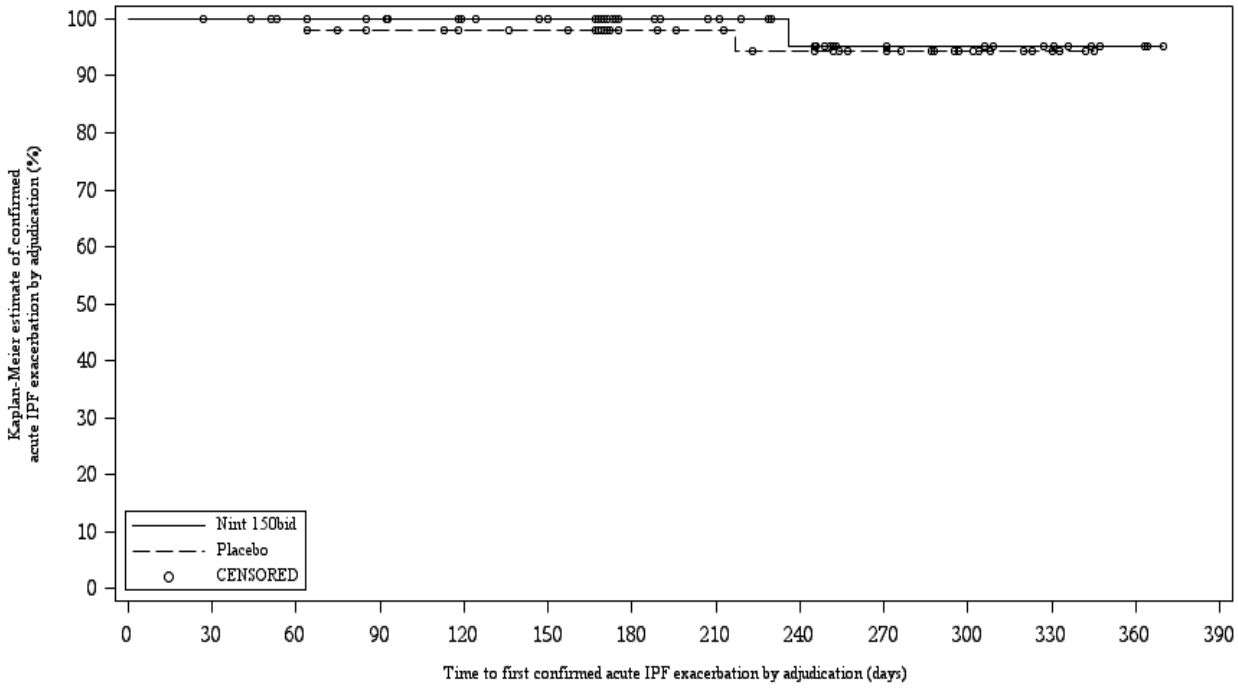

Number at risk

Nint 150bid	56	56	55	53	48	46	28	25	20	12	11	8	3	0
Placebo	57	56	54	50	48	47	29	26	23	18	12	5	0	0

Figure 1.1.1.1.6 Time to first confirmed acute IPF exacerbation (based on adjudication)
OC - Treated Set - Study 1199.187 (blinded period)

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4.1.1.1.2 Time to first confirmed acute IPF exacerbation (based on adjudication) or death

Table 1.1.1.2.1 Time to first confirmed acute IPF exacerbation (based on adjudication) or death
OC - Treated Set - Study 1199.32

	Placebo				Nint 150bid			
	Number at risk [1]	Failure N (%)	Censored N (%)	Survival	Number at risk [1]	Failure N (%)	Censored N (%)	Survival
0 - Week 52	204	14 (6.9)	190 (93.1)	0.930	309	14 (4.5)	295 (95.5)	0.954
Comparison vs Placebo [2]								
p-value [3]						0.2672		
Hazard ratio [4]						0.63		
95% Confidence interval						(0.30, 1.34)		

[1] Cumulative number of patients entering the respective time interval
[2] Based on data collected up to 372 days after randomization (52 weeks + 7 days margin)
[3] Based on a Log-rank test
[4] Based on a Cox´s regression model with terms for treatment, gender, age and height
Survival represents the probability of event-free survival. Failure means event.

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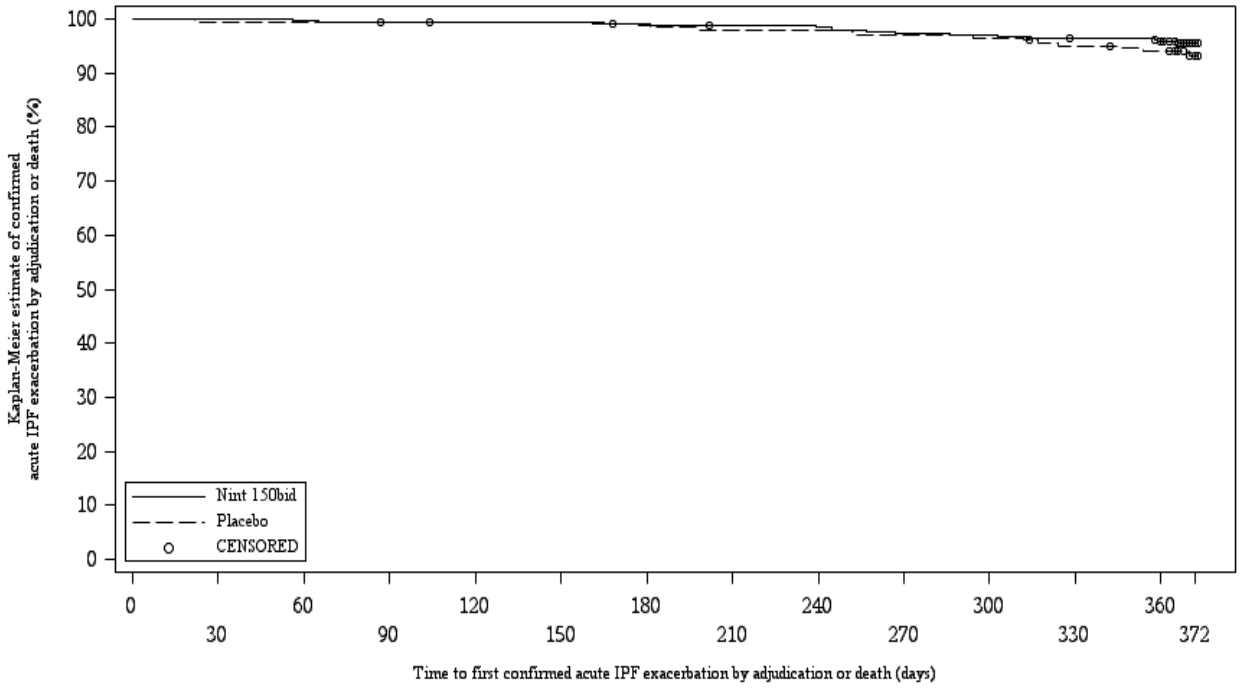

Number at risk

Nint 150bid	309	309	308	307	306	306	303	302	301	298	297	294	289	256
Placebo	204	203	203	202	202	202	201	199	199	197	196	192	189	176

Figure 1.1.1.2.2 Time to first confirmed acute IPF exacerbation (based on adjudication) or death
OC - Treated Set - Study 1199.32

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Table 1.1.1.2.3 Time to first confirmed acute IPF exacerbation (based on adjudication) or death
OC - Treated Set - Study 1199.34

	Placebo				Nint 150bid			
	Number at risk [1]	Failure N (%)	Censored N (%)	Survival	Number at risk [1]	Failure N (%)	Censored N (%)	Survival
0 - Week 52	219	20 (9.1)	199 (90.9)	0.908	329	24 (7.3)	305 (92.7)	0.926
Comparison vs Placebo [2]								
p-value [3]						0.4362		
Hazard ratio [4]						0.80		
95% Confidence interval						(0.44, 1.46)		

[1] Cumulative number of patients entering the respective time interval
[2] Based on data collected up to 372 days after randomization (52 weeks + 7 days margin)
[3] Based on a Log-rank test
[4] Based on a Cox´s regression model with terms for treatment, gender, age and height
Survival represents the probability of event-free survival. Failure means event.

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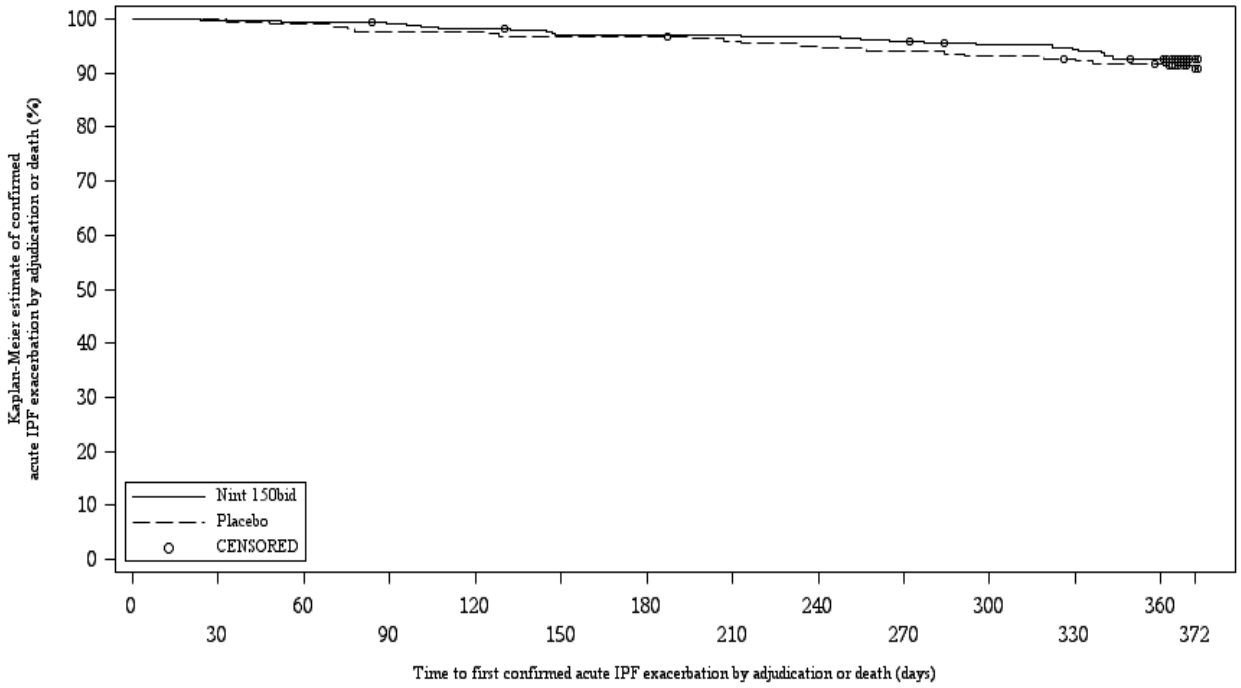

Figure 1.1.1.2.4 Time to first confirmed acute IPF exacerbation (based on adjudication) or death
OC - Treated Set - Study 1199.34

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Table 1.1.1.2.5 Time to first confirmed acute IPF exacerbation (based on adjudication) or death
OC - Treated Set - Study 1199.187 (blinded period)

	Placebo				Nint 150bid			
	Number at risk [1]	Failure N (%)	Censored N (%)	Survival	Number at risk [1]	Failure N (%)	Censored N (%)	Survival
Blinded period	57	5 (8.8)	52 (91.2)	0.890	56	1 (1.8)	55 (98.2)	0.952
Comparison vs Placebo [2]								
p-value [3]						0.1083		
Hazard ratio [4]						0.13		
95% Confidence interval						(0.01, 1.11)		

[1] Cumulative number of patients entering the respective time interval
[2] Based on data collected over blinded period
[3] Based on a Log-rank test
[4] Based on a Cox´s regression model with terms for treatment, gender, age and height
Survival represents the probability of event-free survival. Failure means event.

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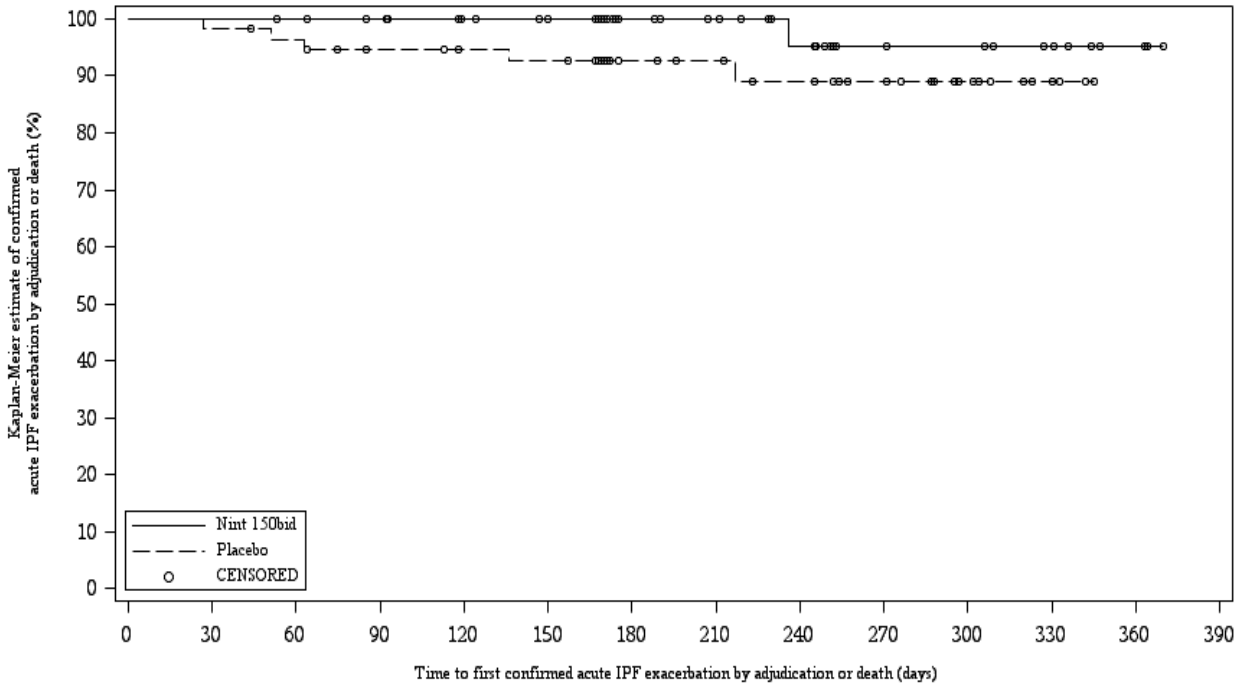

Number at risk

Nint 150bid	56	56	55	53	48	46	28	25	20	12	11	8	3	0
Placebo	57	56	54	50	48	47	29	26	23	18	12	5	0	0

Figure 1.1.1.2.6 Time to first confirmed acute IPF exacerbation (based on adjudication) or death
OC - Treated Set - Study 1199.187 (blinded period)

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4.1.1.1.3 Time to first acute IPF exacerbation (based on adjudication) or death

Table 1.1.1.3.1 Time to first acute IPF exacerbation (based on adjudication) or death
OC - Treated Set - Study 1199.32

	Placebo				Nint 150bid			
	Number at risk [1]	Failure N (%)	Censored N (%)	Survival	Number at risk [1]	Failure N (%)	Censored N (%)	Survival
0 - Week 52	204	17 (8.3)	187 (91.7)	0.916	309	18 (5.8)	291 (94.2)	0.941
Comparison vs Placebo [2]								
p-value [3]						0.2796		
Hazard ratio [4]						0.67		
95% Confidence interval						(0.35, 1.31)		

[1] Cumulative number of patients entering the respective time interval
[2] Based on data collected up to 372 days after randomization (52 weeks + 7 days margin)
[3] Based on a Log-rank test
[4] Based on a Cox´s regression model with terms for treatment, gender, age and height
Survival represents the probability of event-free survival. Failure means event.

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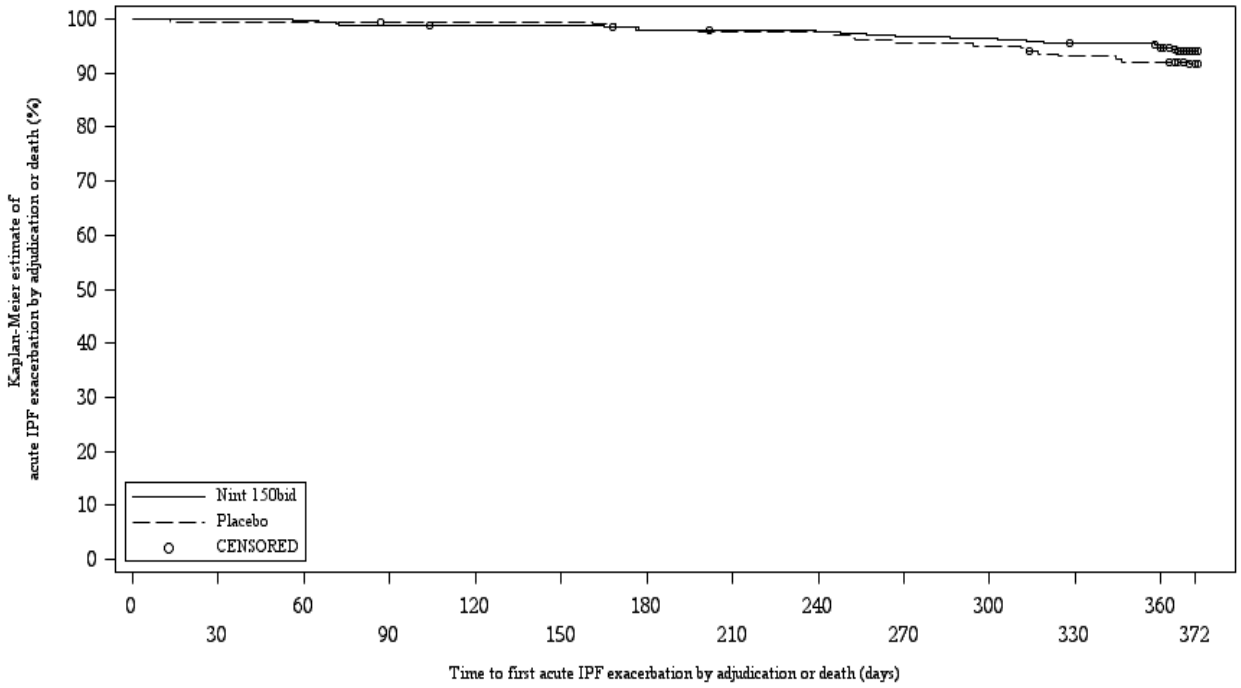

Figure 1.1.1.3.2 Time to first acute IPF exacerbation (based on adjudication) or death
OC - Treated Set - Study 1199.32

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Table 1.1.1.3.3 Time to first acute IPF exacerbation (based on adjudication) or death
OC - Treated Set - Study 1199.34

	Placebo				Nint 150bid			
	Number at risk [1]	Failure N (%)	Censored N (%)	Survival	Number at risk [1]	Failure N (%)	Censored N (%)	Survival
0 - Week 52	219	27 (12.3)	192 (87.7)	0.876	329	26 (7.9)	303 (92.1)	0.920
Comparison vs Placebo [2]								
p-value [3]						0.0889		
Hazard ratio [4]						0.63		
95% Confidence interval						(0.37, 1.09)		

[1] Cumulative number of patients entering the respective time interval
[2] Based on data collected up to 372 days after randomization (52 weeks + 7 days margin)
[3] Based on a Log-rank test
[4] Based on a Cox´s regression model with terms for treatment, gender, age and height
Survival represents the probability of event-free survival. Failure means event.

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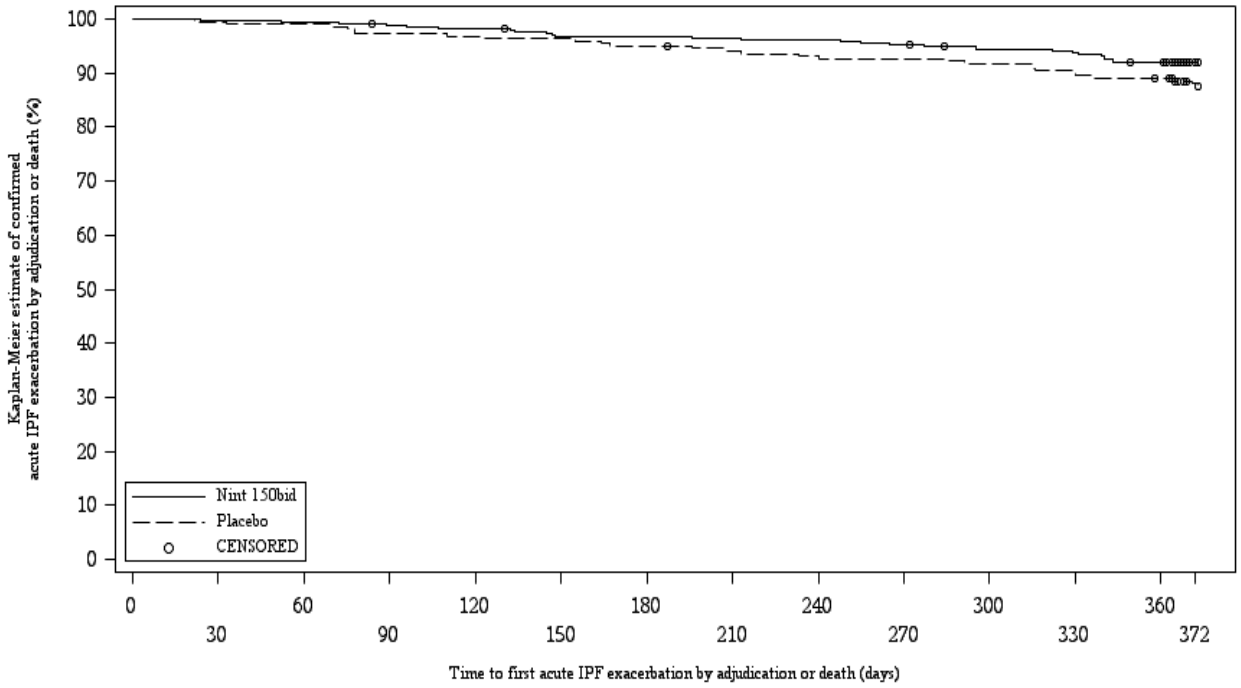

Number at risk

Nint 150bid	329	328	327	324	322	316	316	315	314	311	307	305	298	271
Placebo	219	218	217	213	212	211	208	205	203	202	200	196	193	178

Figure 1.1.1.3.4 Time to first acute IPF exacerbation (based on adjudication) or death
OC - Treated Set - Study 1199.34

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Table 1.1.1.3.5 Time to first acute IPF exacerbation (based on adjudication) or death
OC - Treated Set - Study 1199.187 (blinded period)

	Placebo				Nint 150bid			
	Number at risk [1]	Failure N (%)	Censored N (%)	Survival	Number at risk [1]	Failure N (%)	Censored N (%)	Survival
Blinded period	57	5 (8.8)	52 (91.2)	0.890	56	1 (1.8)	55 (98.2)	0.979
Comparison vs Placebo [2]								
p-value [3]						0.1061		
Hazard ratio [4]						0.13		
95% Confidence interval						(0.01, 1.14)		

[1] Cumulative number of patients entering the respective time interval
[2] Based on data collected over blinded period
[3] Based on a Log-rank test
[4] Based on a Cox´s regression model with terms for treatment, gender, age and height
Survival represents the probability of event-free survival. Failure means event.

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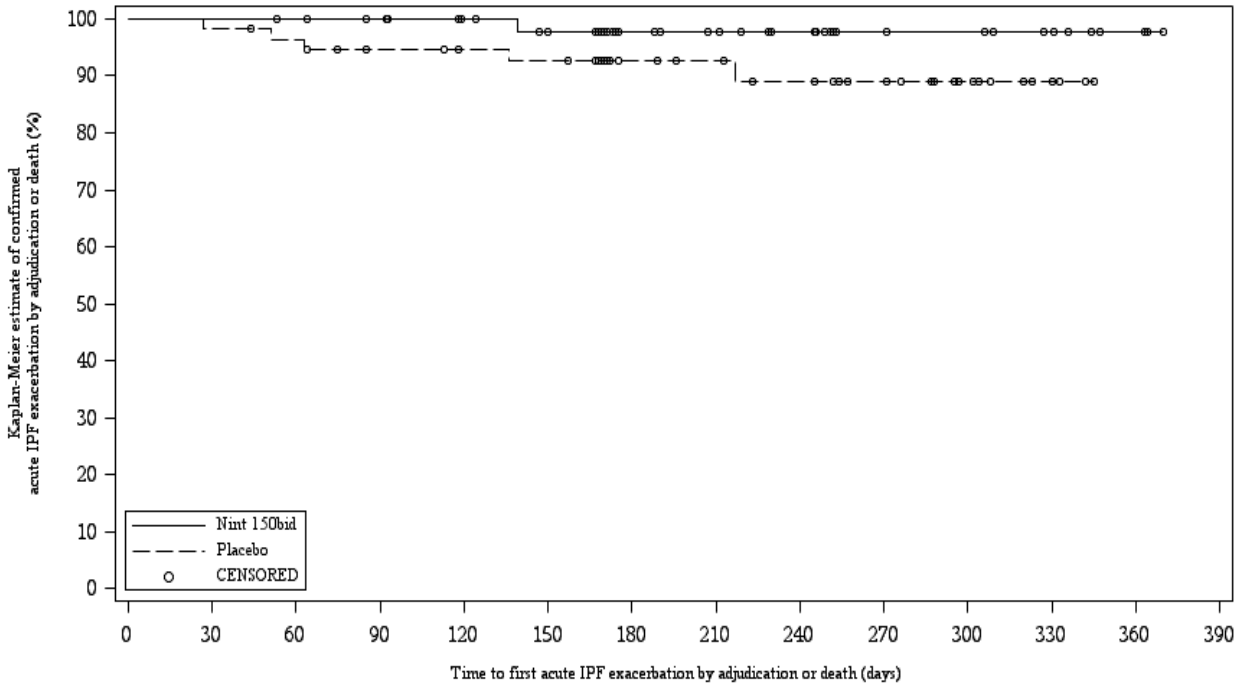

Figure 1.1.1.3.6 Time to first acute IPF exacerbation (based on adjudication) or death
OC - Treated Set - Study 1199.187 (blinded period)

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4.1.1.1.4 Time to first acute IPF exacerbation (based on investigators reporting) or death

Table 1.1.1.4.1 Time to first acute IPF exacerbation (based on investigators reporting) or death
OC - Randomized Set - Study 1199.30 (period 1)

	Placebo				Nint 150bid			
	Number at risk [1]	Failure N (%)	Censored N (%)	Survival	Number at risk [1]	Failure N (%)	Censored N (%)	Survival
0 - Week 52	87	15 (17.2)	72 (82.8)	0.821	86	8 (9.3)	78 (90.7)	0.905
Comparison vs Placebo [2]								
p-value [3]						0.1043		
Hazard ratio [4]						0.51		
95% Confidence interval						(0.21, 1.21)		

[1] Cumulative number of patients entering the respective time interval
[2] Based on data collected up to 372 days after randomization (52 weeks + 7 days margin)
[3] Based on a Log-rank test
[4] Based on a Cox´s regression model with terms for treatment, gender, age, height and region

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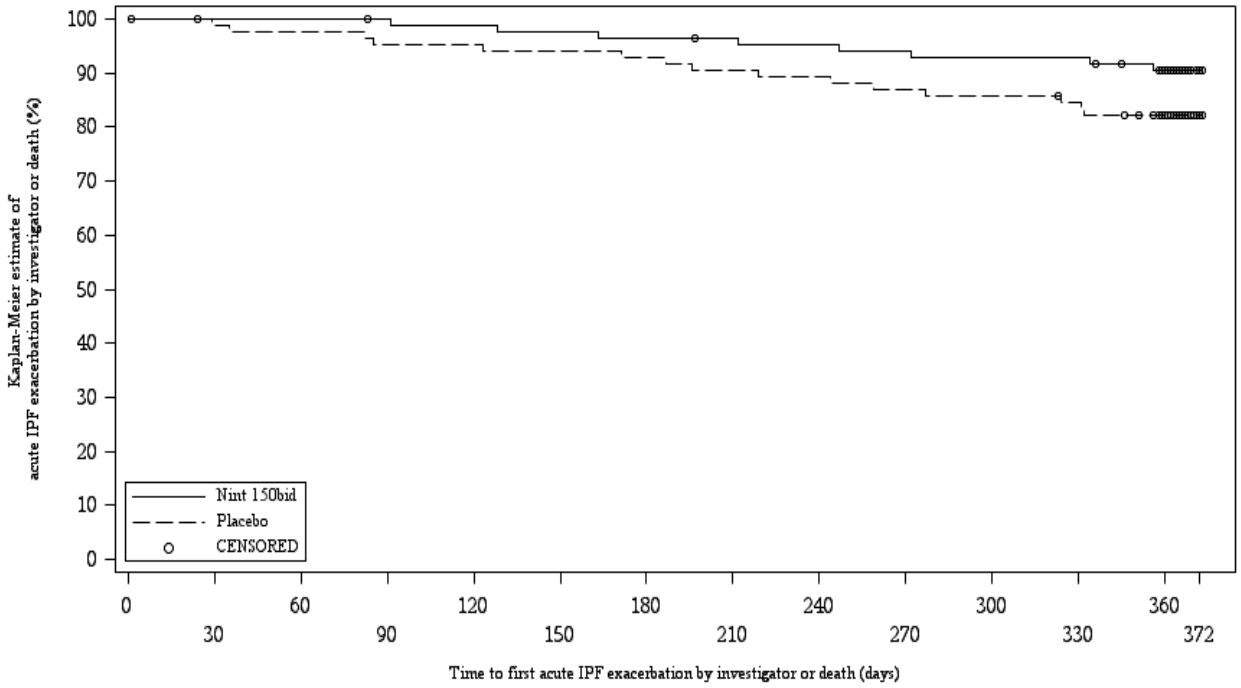

Figure 1.1.1.4.2 Time to first acute IPF exacerbation (based on investigators reporting) or death
OC - Randomized Set - Study 1199.30 (period 1)

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2.2 Kaplan-Meier-Plots zu den Einzelstudien aus dem Jahr 2019

B.1 – Kaplan-Meier-Kurven zu Ergebnissen der Studie INPULSIS 1

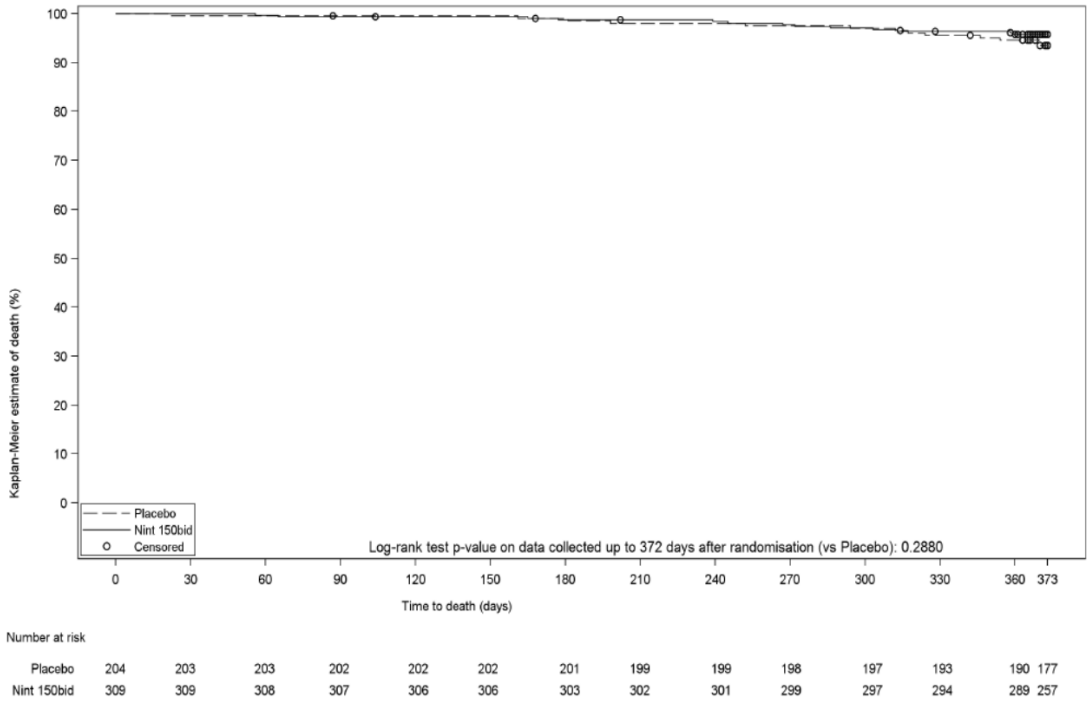

Abbildung 16: Kaplan-Meier-Kurve für Gesamtüberleben – RCT, direkter Vergleich: Nintedanib + BSC vs. Placebo + BSC

Abbildung 16 aus [1].

B.2 – Kaplan-Meier-Kurven zu Ergebnissen der Studie INPULSIS 2

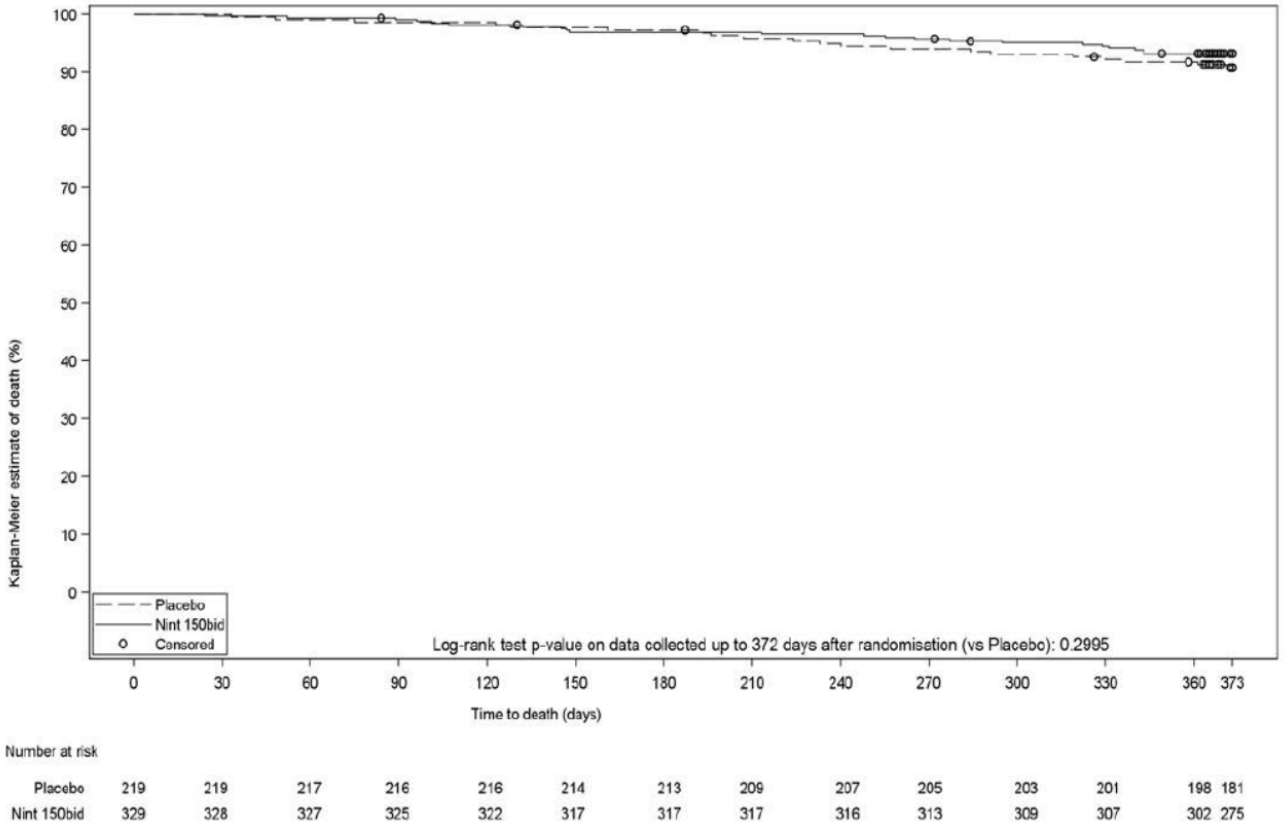

Abbildung 18: Kaplan-Meier-Kurve für Gesamtüberleben – RCT, direkter Vergleich: Nintedanib + BSC vs. Placebo + BSC

Abbildung 18 aus [1].

2.3 Auswertungen zu Unerwünschten Ereignissen in den Einzelstudien aus dem Jahr 2026

Table 1.1.2.1 Safety analysis section 1 - Treated Set

Patients with any adverse event

Trial	Treatment	N	Events	(%)	Risk Difference (95% CI)*	Risk Ratio (95% CI)*	Odds Ratio (95% CI)*	p-value#
1199_0030 P1	Placebo	85	77	(90.6)				
	Nint 150bid	85	80	(94.1)	3.53 (-4.44, 11.50)	1.04 (0.95, 1.13)	1.66 (0.52, 5.30)	0.3866
1199_0032	Placebo	204	181	(88.7)				
	Nint 150bid	309	298	(96.4)	7.71 (2.91, 12.52)	1.09 (1.03, 1.15)	3.44 (1.64, 7.23)	0.0006
1199_0034	Placebo	219	198	(90.4)				
	Nint 150bid	329	311	(94.5)	4.12 (-0.49, 8.73)	1.05 (0.99, 1.10)	1.83 (0.95, 3.53)	0.0663
1199_0187 P1	Placebo	57	52	(91.2)				
	Nint 150bid	56	55	(98.2)	6.99 (-1.14, 15.11)	1.08 (0.99, 1.18)	5.29 (0.60, 46.79)	0.0977

Only treatment emergent AEs are considered.
Percentages are calculated using total number of patients per treatment as the denominator.
* 95% confidence interval for risk ratio, odds ratio and risk difference use normal approximation. A value less than 1 indicates less risk for Nint 150bid in Odds ratio and Risk ratio. A value less than 0 indicates less risk for Nint 150bid in Risk difference.
# p-value based on Chi-square test.
MedDRA version used for reporting: 28.0

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Table 1.1.2.1 Safety analysis section 1 - Treated Set

Patients with any Renal and urinary disorders SOC adverse event

Trial	Treatment	N	Events	(%)	Risk Difference (95% CI)*	Risk Ratio (95% CI)*	Odds Ratio (95% CI)*	p-value#
1199_0030 P1	Placebo	85	5	(5.9)				
	Nint 150bid	85	2	(2.4)	-3.53 (-9.48, 2.42)	0.40 (0.08, 2.01)	0.39 (0.07, 2.04)	0.2469
1199_0032	Placebo	204	17	(8.3)				
	Nint 150bid	309	15	(4.9)	-3.48 (-7.97, 1.01)	0.58 (0.30, 1.14)	0.56 (0.27, 1.15)	0.1108
1199_0034	Placebo	219	11	(5.0)				
	Nint 150bid	329	16	(4.9)	-0.16 (-3.87, 3.55)	0.97 (0.46, 2.05)	0.97 (0.44, 2.12)	0.9326
1199_0187 P1	Placebo	57	4	(7.0)				
	Nint 150bid	56	2	(3.6)	-3.45 (-11.67, 4.78)	0.51 (0.10, 2.67)	0.49 (0.09, 2.79)	0.4140

Only treatment emergent AEs are considered.
Percentages are calculated using total number of patients per treatment as the denominator.
* 95% confidence interval for risk ratio, odds ratio and risk difference use normal approximation. A value less than 1 indicates less risk for Nint 150bid in Odds ratio and Risk ratio. A value less than 0 indicates less risk for Nint 150bid in Risk difference.
# p-value based on Chi-square test.
MedDRA version used for reporting: 28.0

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Table 1.1.2.2 Safety analysis section 2 - Treated Set

Patients with any adverse event (excl. acute IPF exacerbations based on investigators reporting)

Trial	Treatment	N	Events	(%)	Risk Difference (95% CI)*	Risk Ratio (95% CI)*	Odds Ratio (95% CI)*	p-value#
1199_0030 P1	Placebo	85	77	(90.6)				
	Nint 150bid	85	80	(94.1)	3.53 (-4.44, 11.50)	1.04 (0.95, 1.13)	1.66 (0.52, 5.30)	0.3866

Only treatment emergent AEs are considered.
Percentages are calculated using total number of patients per treatment as the denominator.
* 95% confidence interval for risk ratio, odds ratio and risk difference use normal approximation. A value less than 1 indicates less risk for Nint 150bid in Odds ratio and Risk ratio. A value less than 0 indicates less risk for Nint 150bid in Risk difference.
# p-value based on Chi-square test.
MedDRA version used for reporting: 28.0

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Table 1.1.2.2 Safety analysis section 2 - Treated Set

Patients with any serious adverse event (excl. acute IPF exacerbations based on investigators reporting)

Trial	Treatment	N	Events	(%)	Risk Difference (95% CI)*	Risk Ratio (95% CI)*	Odds Ratio (95% CI)*	p-value#
1199_0030 P1	Placebo	85	24	(28.2)				
	Nint 150bid	85	22	(25.9)	-2.35 (-15.70, 11.00)	0.92 (0.56, 1.50)	0.89 (0.45, 1.75)	0.7299

Only treatment emergent AEs are considered.
Percentages are calculated using total number of patients per treatment as the denominator.
* 95% confidence interval for risk ratio, odds ratio and risk difference use normal approximation. A value less than 1 indicates less risk for Nint 150bid in Odds ratio and Risk ratio. A value less than 0 indicates less risk for Nint 150bid in Risk difference.
# p-value based on Chi-square test.
MedDRA version used for reporting: 28.0

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Table 1.1.2.2 Safety analysis section 2 - Treated Set

Patients with any adverse event leading to treatment discontinuation (excl. acute IPF exacerbations based on investigators reporting)

Trial	Treatment	N	Events	(%)	Risk Difference (95% CI)*	Risk Ratio (95% CI)*	Odds Ratio (95% CI)*	p-value#
1199_0030 P1	Placebo	85	19	(22.4)				
	Nint 150bid	85	25	(29.4)	7.06 (-6.07, 20.18)	1.32 (0.79, 2.20)	1.45 (0.72, 2.89)	0.2934

Only treatment emergent AEs are considered.
Percentages are calculated using total number of patients per treatment as the denominator.
* 95% confidence interval for risk ratio, odds ratio and risk difference use normal approximation. A value less than 1 indicates less risk for Nint 150bid in Odds ratio and Risk ratio. A value less than 0 indicates less risk for Nint 150bid in Risk difference.
# p-value based on Chi-square test.
MedDRA version used for reporting: 28.0

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Table 1.1.2.3 Safety analysis section 3 - Treated Set

Patients with any adverse event (excl. acute IPF exacerbations based on investigators reporting)

Trial	Treatment	N	Events	(%)	Risk Difference (95% CI)*	Risk Ratio (95% CI)*	Odds Ratio (95% CI)*	p-value#
1199_0032	Placebo	204	180	(88.2)				
	Nint 150bid	309	296	(95.8)	7.56 (2.60, 12.51)	1.09 (1.03, 1.15)	3.04 (1.51, 6.11)	0.0012
1199_0034	Placebo	219	196	(89.5)				
	Nint 150bid	329	311	(94.5)	5.03 (0.29, 9.78)	1.06 (1.00, 1.11)	2.03 (1.07, 3.85)	0.0283
1199_0187 P1	Placebo	57	52	(91.2)				
	Nint 150bid	56	55	(98.2)	6.99 (-1.14, 15.11)	1.08 (0.99, 1.18)	5.29 (0.60, 46.79)	0.0977

Only treatment emergent AEs are considered.
Percentages are calculated using total number of patients per treatment as the denominator.
* 95% confidence interval for risk ratio, odds ratio and risk difference use normal approximation. A value less than 1 indicates less risk for Nint 150bid in Odds ratio and Risk ratio. A value less than 0 indicates less risk for Nint 150bid in Risk difference.
# p-value based on Chi-square test.
MedDRA version used for reporting: 28.0

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Table 1.1.2.3 Safety analysis section 3 - Treated Set

Patients with any serious adverse event (excl. acute IPF exacerbations based on investigators reporting)

Trial	Treatment	N	Events	(%)	Risk Difference (95% CI)*	Risk Ratio (95% CI)*	Odds Ratio (95% CI)*	p-value#
1199_0032	Placebo	204	51	(25.0)				
	Nint 150bid	309	86	(27.8)	2.83 (-4.93, 10.60)	1.11 (0.83, 1.50)	1.16 (0.77, 1.73)	0.4780
1199_0034	Placebo	219	66	(30.1)				
	Nint 150bid	329	93	(28.3)	-1.87 (-9.65, 5.92)	0.94 (0.72, 1.22)	0.91 (0.63, 1.33)	0.6367
1199_0187 P1	Placebo	57	8	(14.0)				
	Nint 150bid	56	7	(12.5)	-1.54 (-14.04, 10.97)	0.89 (0.35, 2.29)	0.88 (0.29, 2.60)	0.8100

Only treatment emergent AEs are considered.
Percentages are calculated using total number of patients per treatment as the denominator.
* 95% confidence interval for risk ratio, odds ratio and risk difference use normal approximation. A value less than 1 indicates less risk for Nint 150bid in Odds ratio and Risk ratio. A value less than 0 indicates less risk for Nint 150bid in Risk difference.
# p-value based on Chi-square test.
MedDRA version used for reporting: 28.0

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Table 1.1.2.3 Safety analysis section 3 - Treated Set

Patients with any adverse event leading to treatment discontinuation (excl. acute IPF exacerbations based on investigators reporting)

Trial	Treatment	N	Events	(%)	Risk Difference (95% CI)*	Risk Ratio (95% CI)*	Odds Ratio (95% CI)*	p-value#
1199_0032	Placebo	204	19	(9.3)				
	Nint 150bid	309	59	(19.1)	9.78 (3.85, 15.71)	2.05 (1.26, 3.33)	2.30 (1.32, 3.99)	0.0025
1199_0034	Placebo	219	25	(11.4)				
	Nint 150bid	329	56	(17.0)	5.61 (-0.24, 11.46)	1.49 (0.96, 2.31)	1.59 (0.96, 2.64)	0.0701
1199_0187 P1	Placebo	57	2	(3.5)				
	Nint 150bid	56	7	(12.5)	8.99 (-0.90, 18.88)	3.56 (0.77, 16.41)	3.93 (0.78, 19.81)	0.0776

Only treatment emergent AEs are considered.
Percentages are calculated using total number of patients per treatment as the denominator.
* 95% confidence interval for risk ratio, odds ratio and risk difference use normal approximation. A value less than 1 indicates less risk for Nint 150bid in Odds ratio and Risk ratio. A value less than 0 indicates less risk for Nint 150bid in Risk difference.
# p-value based on Chi-square test.
MedDRA version used for reporting: 28.0

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2.4 Metaanalyse der Nintedanib-Studien aus dem Jahr 2026

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L.2 Meta-analysis of Nintedanib trials (additions to 2019 assessment of Nintedanib)

L.2.1 Efficacy Analysis

L.2.1.1 Time to event analyses

L.2.1.1.1 Analyses of composite endpoints

L.2.1.1.1.1 Time to first confirmed acute IPF exacerbation or death over the whole trial

Table L.2.1.1.1.1: 1 Meta-analysis comparing Nintedanib versus Placebo for time to first confirmed acute IPF exacerbation or death over the whole trial

				Random-effects model (Knapp-Hartung)					
				Nin 150bid vs Placebo			Heterogeneity		
Trial number	Treatment	n / N (%)	Hazard ratio (95% CI)	Hazard ratio (95% CI)	p-value	I^2	p-value	tau^2 (PM)	tau^2 (DL)
1199-0032									
	Placebo	14 / 204 (6.9)							
	Nin 150bid	14 / 309 (4.5)							
			0.63 (0.30 , 1.34)						
1199-0034									
	Placebo	20 / 219 (9.1)							
	Nin 150bid	24 / 329 (7.3)							
			0.80 (0.44 , 1.46)						
1199-0187									
	Placebo	5 / 57 (8.8)							
	Nin 150bid	1 / 56 (1.8)							
			0.13 (0.01 , 1.11)						
				0.61 (0.12, 3.08)	0.3165	24%	0.2668	0.20	0.07

The random effects estimate and its Knapp-Hartung adjusted confidence interval were derived using the Paule-Mandel (PM) estimator for between study variance (tau^2). The DerSimonian-Laird (DL) tau^2 estimate is provided for supportive comparison. Heterogeneity p-value was based on Cochran's Q test. N = number of patients, n = number of patients with at least one event.
The trial-level estimates are based on Cox regression models estimated in overall, including categorical treatment, sex and continuous age and height.

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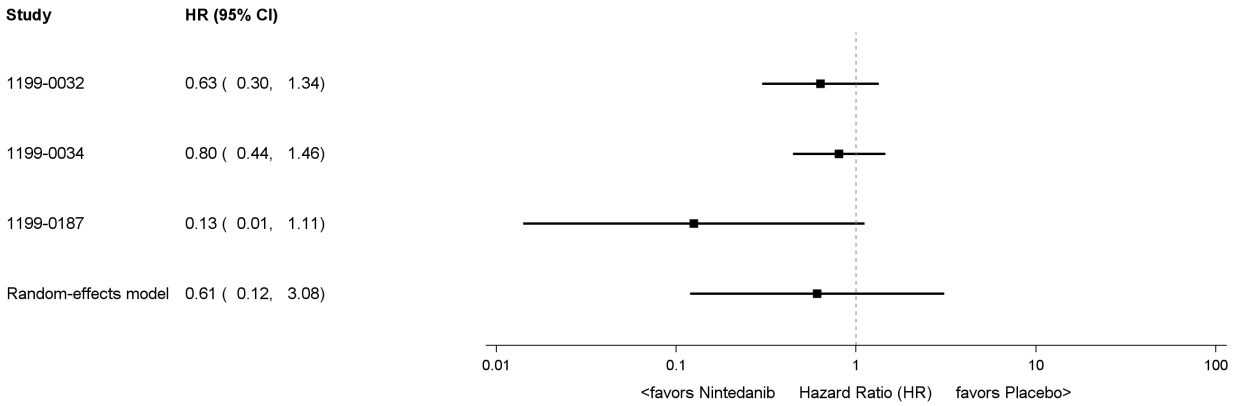

Figure L.2.1.1.1.1: 1 Forest Plot comparing Nintedanib versus Placebo for time to first confirmed acute IPF exacerbation or death over the whole trial

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L.2.1.1.1.2 Time to first confirmed or suspected acute IPF exacerbation or death over the whole trial

Table L.2.1.1.1.2: 1 Meta-analysis comparing Nintedanib versus Placebo for time to first confirmed or suspected acute IPF exacerbation or death over the whole trial

				Random-effects model (Knapp-Hartung)				
				Nin 150bid vs Placebo		Heterogeneity		
Trial number	Treatment	n / N (%)	Hazard ratio (95% CI)	Hazard ratio (95% CI)	p-value	I^2	p-value	tau^2 (PM)	tau^2 (DL)
1199-0032									
	Placebo	17 / 204 (8.3)							
	Nin 150bid	18 / 309 (5.8)							
			0.67 (0.35 , 1.31)						
1199-0034									
	Placebo	27 / 219 (12.3)							
	Nin 150bid	26 / 329 (7.9)							
			0.63 (0.37 , 1.09)						
1199-0187									
	Placebo	5 / 57 (8.8)							
	Nin 150bid	1 / 56 (1.8)							
			0.13 (0.01 , 1.14)						
1199-0030									
	Placebo	15 / 87 (17.2)							
	Nin 150bid	8 / 86 (9.3)							
			0.51 (0.21 , 1.21)						
				0.59 (0.35, 0.99)	0.0488	0%	0.5291	0.00	0.00

The random effects estimate and its Knapp-Hartung adjusted confidence interval were derived using the Paule-Mandel (PM) estimator for between study variance (tau^2). The DerSimonian-Laird (DL) tau^2 estimate is provided for supportive comparison. Heterogeneity p-value was based on Cochran's Q test. N = number of patients, n = number of patients with at least one event.
The trial-level estimates are based on Cox regression models estimated in overall, including categorical treatment, sex and continuous age and height. In trial 1199-0030, categorical region is additionally included.

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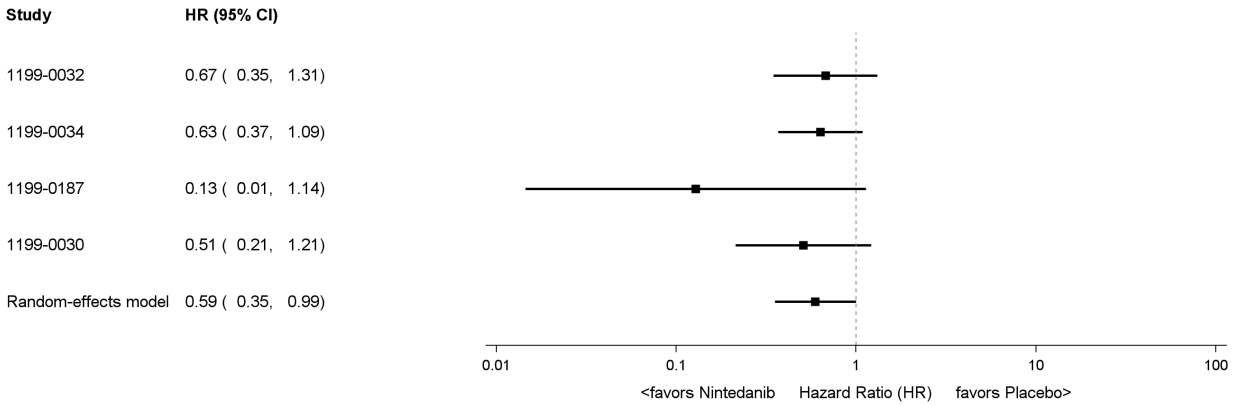

Cochran's Q pvalue: 0.5291
I^2: 0.0

Figure L.2.1.1.1.2: 1 Forest Plot comparing Nintedanib versus Placebo for time to first confirmed or suspected acute IPF exacerbation or death over the whole trial

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L.2.1.1.2 Analyses of single endpoints

L.2.1.1.2.1 Time to first confirmed acute IPF exacerbation over the whole trial

Table L.2.1.1.2.1: 1 Meta-analysis comparing Nintedanib versus Placebo for time to first confirmed acute IPF exacerbation over the whole trial

				Random-effects model (Knapp-Hartung)					
				Nin 150bid vs Placebo			Heterogeneity		
Trial number	Treatment	n / N (%)	Hazard ratio (95% CI)	Hazard ratio (95% CI)	p-value	I^2	p-value	tau^2 (PM)	tau^2 (DL)
1199-0032									
	Placebo	1 / 204 (0.5)							
	Nin 150bid	2 / 309 (0.6)							
			1.37 (0.12 ,15.61)						
1199-0034									
	Placebo	3 / 219 (1.4)							
	Nin 150bid	2 / 329 (0.6)							
			0.45 (0.07 , 2.69)						
1199-0187									
	Placebo	2 / 57 (3.5)							
	Nin 150bid	1 / 56 (1.8)							
			0.38 (0.03 , 4.97)						
				0.58 (0.12, 2.84)	0.2783	0%	0.7185	0.00	0.00

The random effects estimate and its Knapp-Hartung adjusted confidence interval were derived using the Paule-Mandel (PM) estimator for between study variance (tau^2). The DerSimonian-Laird (DL) tau^2 estimate is provided for supportive comparison. Heterogeneity p-value was based on Cochran's Q test. N = number of patients, n = number of patients with at least one event.
The trial-level estimates are based on Cox regression models estimated in overall, including categorical treatment, sex and continuous age and height.

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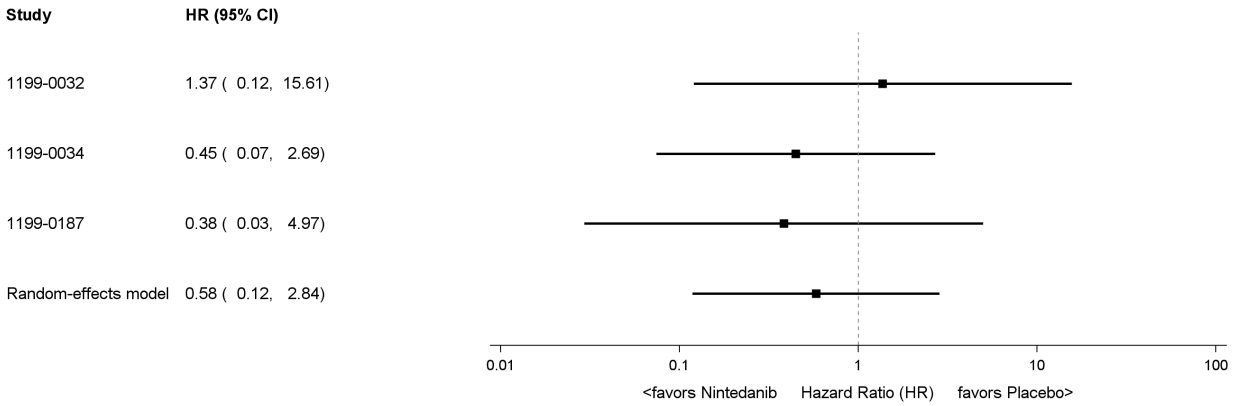

Cochran's Q pvalue: 0.7185
I²: 0.0

Figure L.2.1.1.2.1: 1 Forest Plot comparing Nintedanib versus Placebo for time to first confirmed acute IPF exacerbation over the whole trial

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L.2.2 Safety Analysis

Table L.2.2: 1 Meta-analysis comparing Nintedanib versus Placebo for patients with any adverse event over the whole trial

				Random-effects model (Knapp-Hartung)					
				Nin 150bid vs Placebo			Heterogeneity		
Trial number	Treatment	n / N (%)	Risk Ratio (95% CI)	Risk Ratio (95% CI)	p-value	I^2	p-value	tau^2 (PM)	tau^2 (DL)
1199-0032									
	Placebo	181 / 204 (88.7)							
	Nin 150bid	298 / 309 (96.4)							
			1.09 (1.03 , 1.15)						
1199-0034									
	Placebo	198 / 219 (90.4)							
	Nin 150bid	311 / 329 (94.5)							
			1.05 (0.99 , 1.10)						
1199-0187									
	Placebo	52 / 57 (91.2)							
	Nin 150bid	55 / 56 (98.2)							
			1.08 (0.99 , 1.18)						
1199-0030									
	Placebo	77 / 85 (90.6)							
	Nin 150bid	80 / 85 (94.1)							
			1.04 (0.95 , 1.13)						
				1.06 (1.03, 1.10)	0.0119	0%	0.6983	0.00	0.00

The random effects estimate and its Knapp-Hartung adjusted confidence interval were derived using the Paule-Mandel (PM) estimator for between study variance (tau^2). The DerSimonian-Laird (DL) tau^2 estimate is provided for supportive comparison. Heterogeneity p-value was based on Cochran's Q test. N = number of patients, n = number of patients with at least one event.
Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0030) are displayed.

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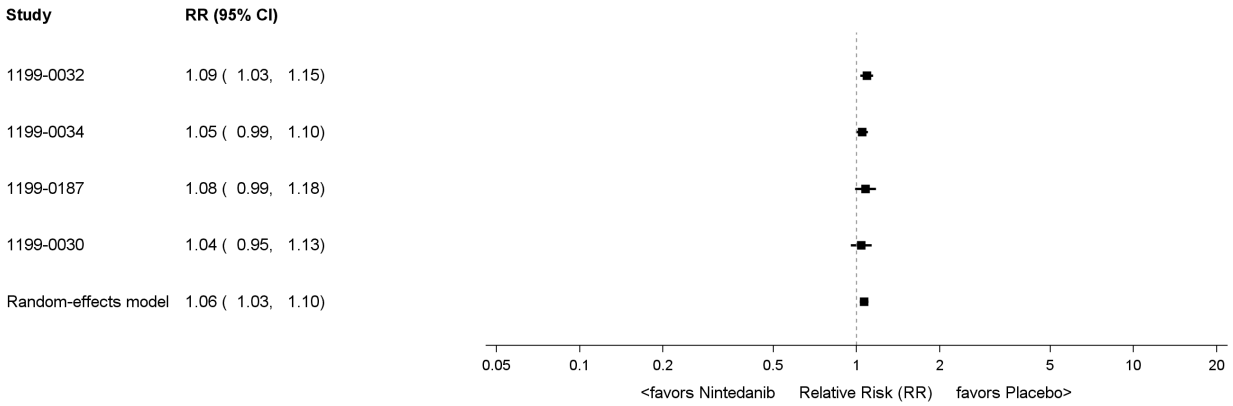

Cochran's Q pvalue: 0.6983
I²: 0.0

Figure L.2.2: 1 Forest Plot comparing Nintedanib versus Placebo for patients with any adverse event over the whole trial

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Table L.2.2: 2 Meta-analysis comparing Nintedanib versus Placebo for patients with any adverse event (excluding disease-related events) over the whole trial

				Random-effects model (Knapp-Hartung)				
				Nin 150bid vs Placebo			Heterogeneity	
Trial number	Treatment	n / N (%)	Risk Ratio (95% CI)	Risk Ratio (95% CI)	p-value	I^2	p-value	τ^2 (PM)	τ^2 (DL)
1199-0032									
	Placebo	180 / 204 (88.2)							
	Nin 150bid	296 / 309 (95.8)							
			1.09 (1.03 , 1.15)						
1199-0034									
	Placebo	196 / 219 (89.5)							
	Nin 150bid	311 / 329 (94.5)							
			1.06 (1.00 , 1.11)						
1199-0187									
	Placebo	52 / 57 (91.2)							
	Nin 150bid	55 / 56 (98.2)							
			1.08 (0.99 , 1.18)						
1199-0030									
	Placebo	77 / 85 (90.6)							
	Nin 150bid	80 / 85 (94.1)							
			1.04 (0.95 , 1.13)						
				1.07 (1.04, 1.10)	0.0059	0%	0.8197	0.00	0.00

The random effects estimate and its Knapp-Hartung adjusted confidence interval were derived using the Paule-Mandel (PM) estimator for between study variance (τ^2). The DerSimonian-Laird (DL) τ^2 estimate is provided for supportive comparison. Heterogeneity p-value was based on Cochran's Q test. N = number of patients, n = number of patients with at least one event.
Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0030) are displayed.
Disease-related events were defined as acute IPF exacerbations based on investigators reporting.

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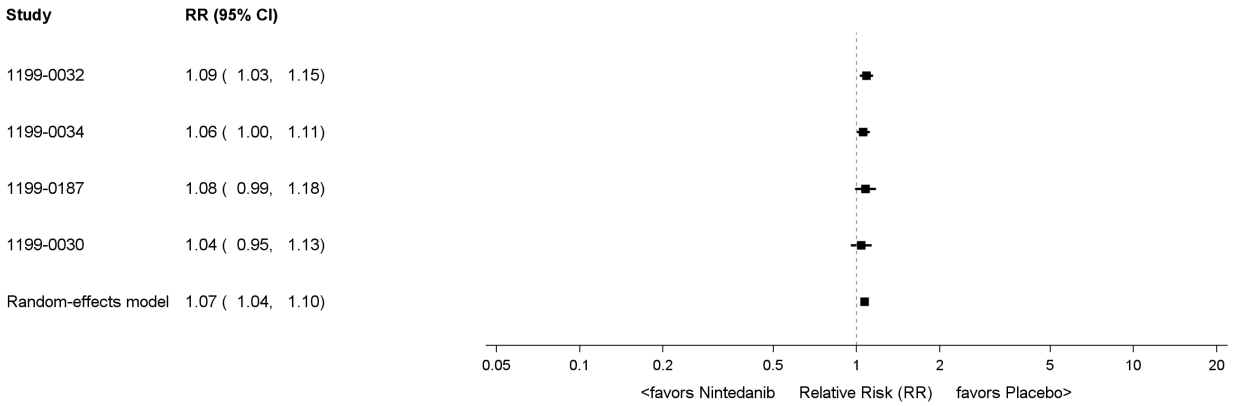

Cochran's Q pvalue: 0.8197
I²: 0.0

Figure L.2.2: 2 Forest Plot comparing Nintedanib versus Placebo for patients with any adverse event (excluding disease-related events) over the whole trial

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Table L.2.2: 3 Meta-analysis comparing Nintedanib versus Placebo for patients with any serious adverse event (excluding disease-related events) over the whole trial

				Random-effects model (Knapp-Hartung)					
				Nin 150bid vs Placebo			Heterogeneity		
Trial number	Treatment	n / N (%)	Risk Ratio (95% CI)	Risk Ratio (95% CI)	p-value	I^2	p-value	tau^2 (PM)	tau^2 (DL)
1199-0032									
	Placebo	51 / 204 (25.0)							
	Nin 150bid	86 / 309 (27.8)							
			1.11 (0.83 , 1.50)						
1199-0034									
	Placebo	66 / 219 (30.1)							
	Nin 150bid	93 / 329 (28.3)							
			0.94 (0.72 , 1.22)						
1199-0187									
	Placebo	8 / 57 (14.0)							
	Nin 150bid	7 / 56 (12.5)							
			0.89 (0.35 , 2.29)						
1199-0030									
	Placebo	24 / 85 (28.2)							
	Nin 150bid	22 / 85 (25.9)							
			0.92 (0.56 , 1.50)						
				0.99 (0.85, 1.17)	0.9110	0%	0.8266	0.00	0.00

The random effects estimate and its Knapp-Hartung adjusted confidence interval were derived using the Paule-Mandel (PM) estimator for between study variance (tau^2). The DerSimonian-Laird (DL) tau^2 estimate is provided for supportive comparison. Heterogeneity p-value was based on Cochran's Q test. N = number of patients, n = number of patients with at least one event.
Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0030) are displayed.
Disease-related events were defined as acute IPF exacerbations based on investigators reporting.

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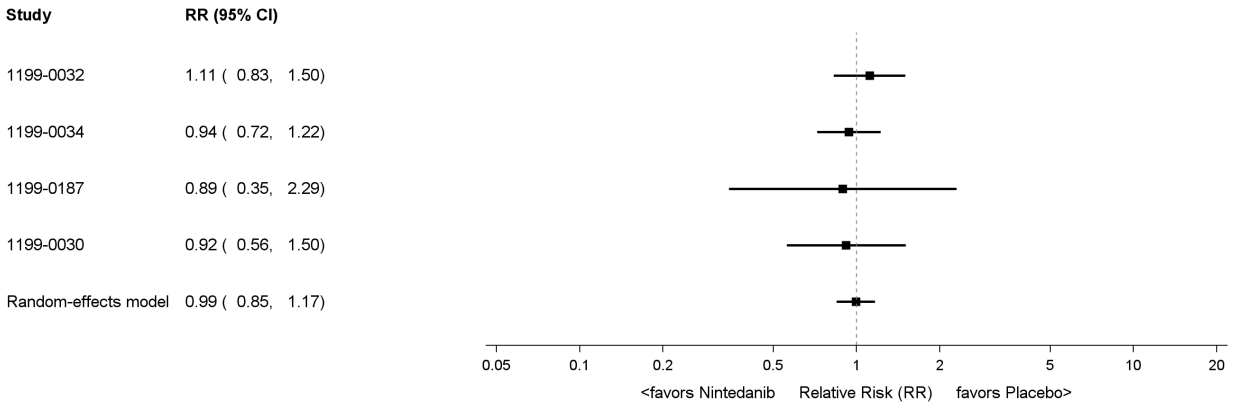

Cochran's Q pvalue: 0.8266
I^2: 0.0

Figure L.2.2: 3 Forest Plot comparing Nintedanib versus Placebo for patients with any serious adverse event (excluding disease-related events) over the whole trial

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Table L.2.2: 4 Meta-analysis comparing Nintedanib versus Placebo for patients with any adverse event leading to treatment discontinuation (excluding disease-related events) over the whole trial

				Random-effects model (Knapp-Hartung)					
				Nin 150bid vs Placebo			Heterogeneity		
Trial number	Treatment	n / N (%)	Risk Ratio (95% CI)	Risk Ratio (95% CI)	p-value	I^2	p-value	tau^2 (PM)	tau^2 (DL)
1199-0032									
	Placebo	19 / 204 (9.3)							
	Nin 150bid	59 / 309 (19.1)							
			2.05 (1.26 , 3.33)						
1199-0034									
	Placebo	25 / 219 (11.4)							
	Nin 150bid	56 / 329 (17.0)							
			1.49 (0.96 , 2.31)						
1199-0187									
	Placebo	2 / 57 (3.5)							
	Nin 150bid	7 / 56 (12.5)							
			3.56 (0.77 ,16.41)						
1199-0030									
	Placebo	19 / 85 (22.4)							
	Nin 150bid	25 / 85 (29.4)							
			1.32 (0.79 , 2.20)						
				1.63 (1.08, 2.48)	0.0329	0%	0.4431	0.00	0.00

The random effects estimate and its Knapp-Hartung adjusted confidence interval were derived using the Paule-Mandel (PM) estimator for between study variance (tau^2). The DerSimonian-Laird (DL) tau^2 estimate is provided for supportive comparison. Heterogeneity p-value was based on Cochran's Q test. N = number of patients, n = number of patients with at least one event.
Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0030) are displayed.
Disease-related events were defined as acute IPF exacerbations based on investigators reporting.

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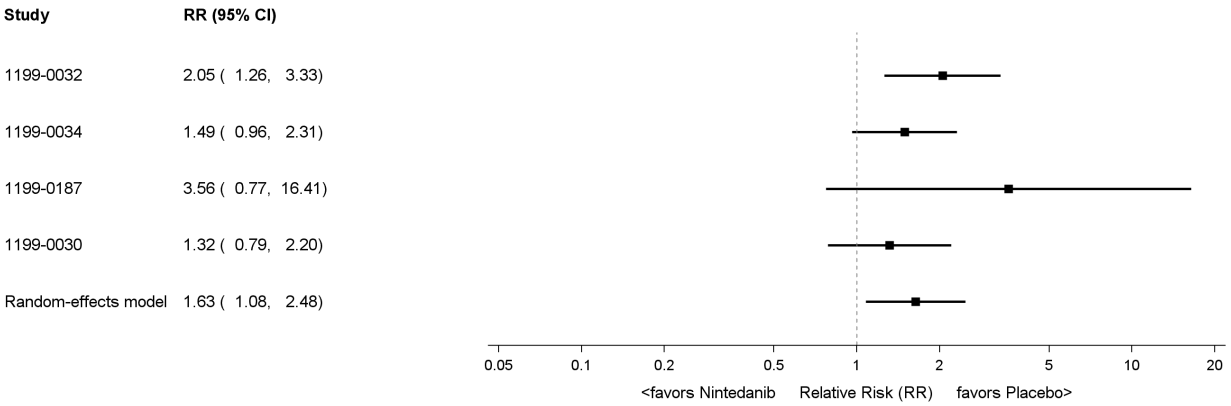

Cochran's Q pvalue: 0.4431
I²: 0.0

Figure L.2.2: 4 Forest Plot comparing Nintedanib versus Placebo for patients with any adverse event leading to treatment discontinuation (excluding disease-related events) over the whole trial

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Table L.2.2: 5 Meta-analysis comparing Nintedanib versus Placebo for 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
SOC: Renal and urinary disorders

				Random-effects model (Knapp-Hartung)					
				Nin 150bid vs Placebo					
						Heterogeneity			
Trial number	Treatment	n / N (%)	Risk Ratio (95% CI)	Risk Ratio (95% CI)	p-value	I^2	p-value	tau^2 (PM)	tau^2 (DL)
1199-0032									
	Placebo	17 / 204 (8.3)							
	Nin 150bid	15 / 309 (4.9)							
			0.58 (0.30 , 1.14)						
1199-0034									
	Placebo	11 / 219 (5.0)							
	Nin 150bid	16 / 329 (4.9)							
			0.97 (0.46 , 2.05)						
1199-0187									
	Placebo	4 / 57 (7.0)							
	Nin 150bid	2 / 56 (3.6)							
			0.51 (0.10 , 2.67)						
1199-0030									
	Placebo	5 / 85 (5.9)							
	Nin 150bid	2 / 85 (2.4)							
			0.40 (0.08 , 2.01)						
				0.68 (0.39, 1.16)	0.1061	0%	0.6608	0.00	0.00

The random effects estimate and its Knapp-Hartung adjusted confidence interval were derived using the Paule-Mandel (PM) estimator for between study variance (tau^2). The DerSimonian-Laird (DL) tau^2 estimate is provided for supportive comparison. Heterogeneity p-value was based on Cochran's Q test. N = number of patients, n = number of patients with at least one event.
Only treatment-emergent adverse events with an onset date between the first intake of the trial drug and the last intake +28 days (+7 days in 1199-0030) are displayed.

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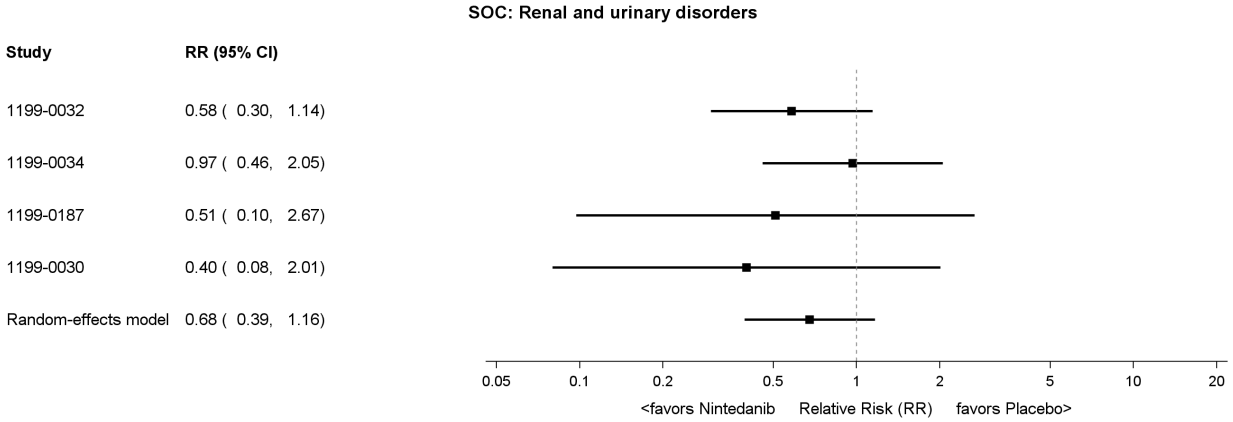

Figure L.2.2: 5 Forest Plot comparing Nintedanib versus Placebo for patients with frequent AEs by SOC
(incidence in either arm >= 10% or both incidence >=1% and >=10 patients affected in either arm) over the whole trial

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2.5 Forest-Plots der Metaanalyse der Nintedanib-Studien aus dem Jahr 2019

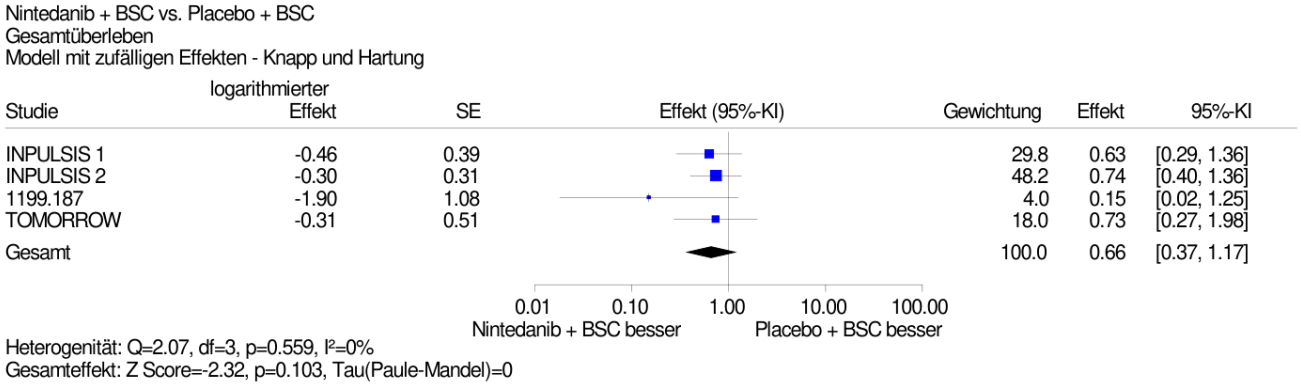


Abbildung 2: Metaanalyse, Gesamtüberleben, Nintedanib + BSC vs. Placebo + BSC; Effektschätzer: Hazard Ratio

Abbildung 2 aus [1].

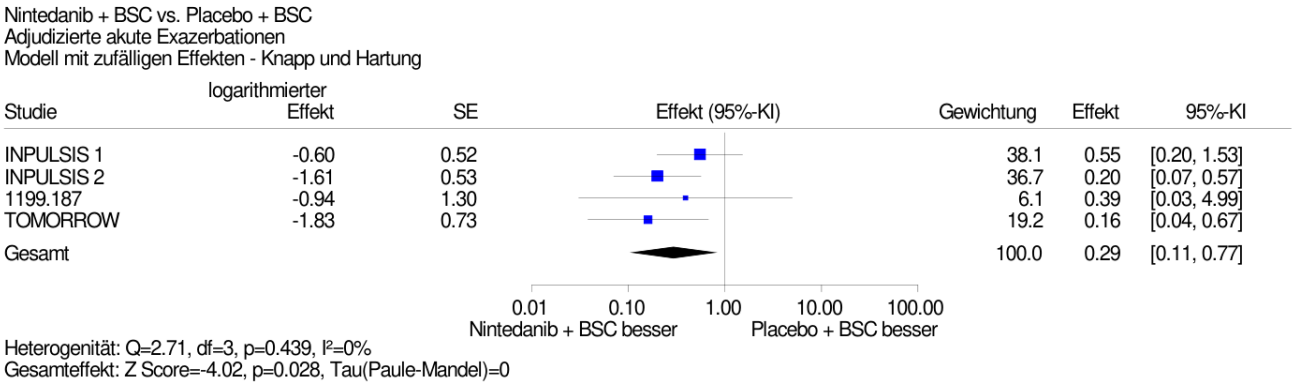
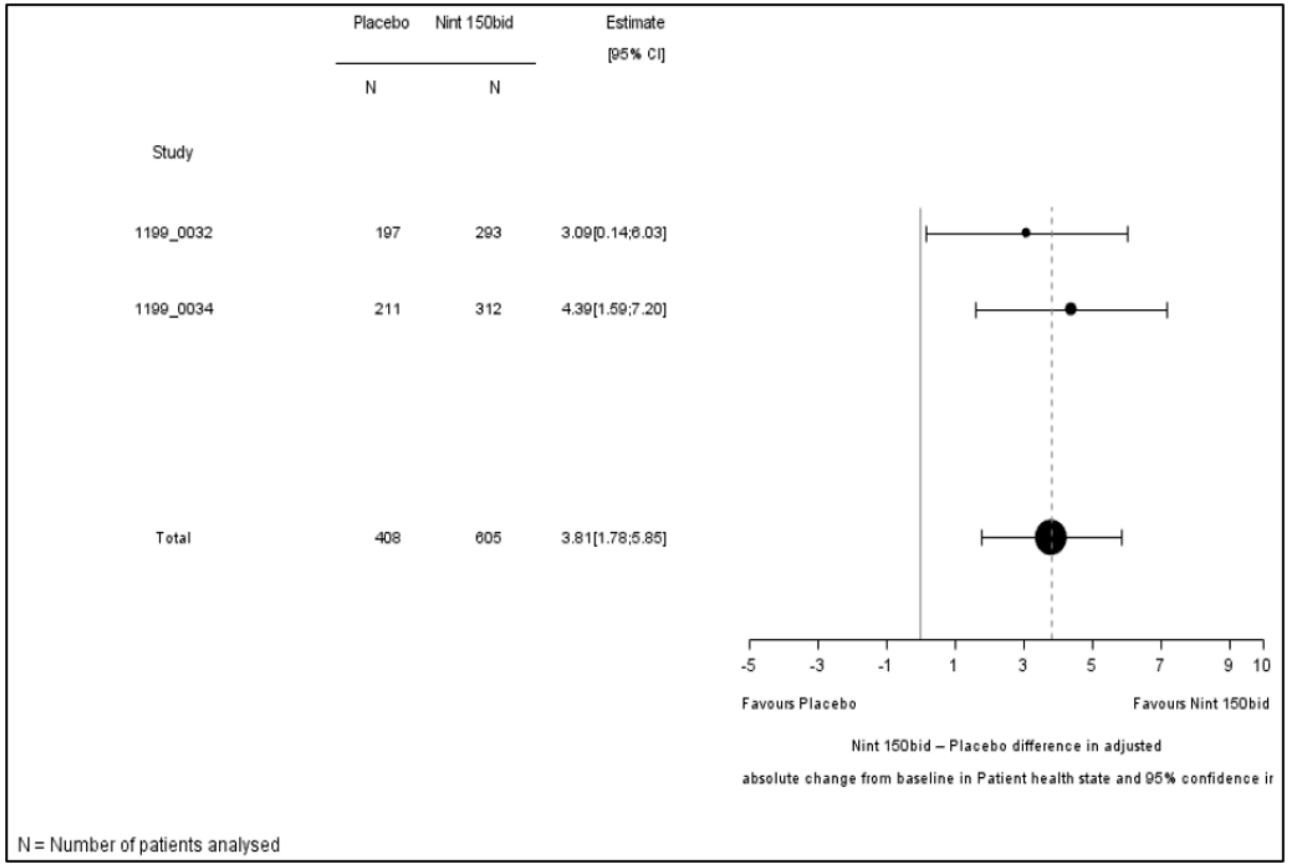


Abbildung 3: Metaanalyse, adjudizierte akute Exazerbationen, Nintedanib + BSC vs. Placebo + BSC; Effektschätzer: Hazard Ratio

Abbildung 3 aus [1].



Quelle: (Boehringer Ingelheim Pharma GmbH & Co. KG, 2018a)

Abbildung 32: Forest-Plot zur Meta-Analyse für den Endpunkt *Veränderung EQ-5D-VAS* - RCT mit dem zu bewertenden Arzneimittel

Abbildung 32 aus [2].

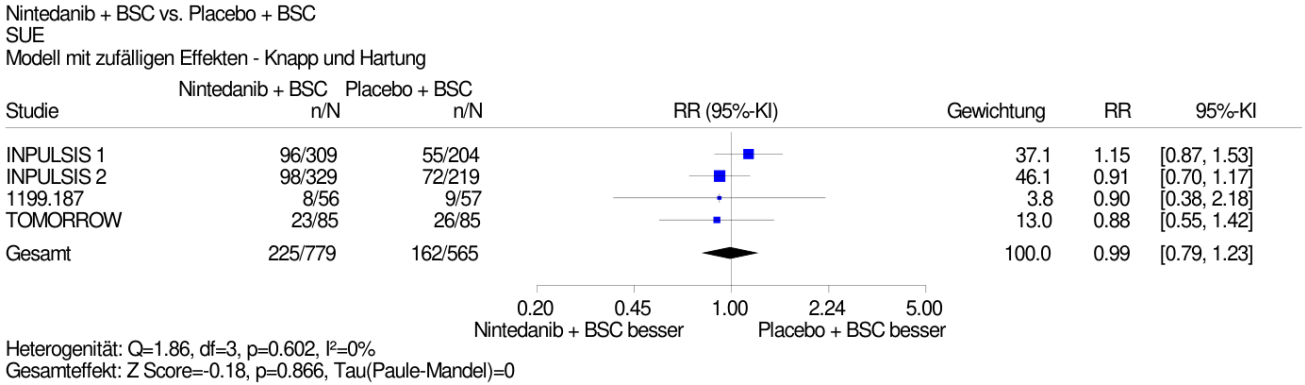


Abbildung 9: Metaanalyse, SUEs, Nintedanib + BSC vs. Placebo + BSC; Effektschätzer: relatives Risiko

Abbildung 9 aus [1].

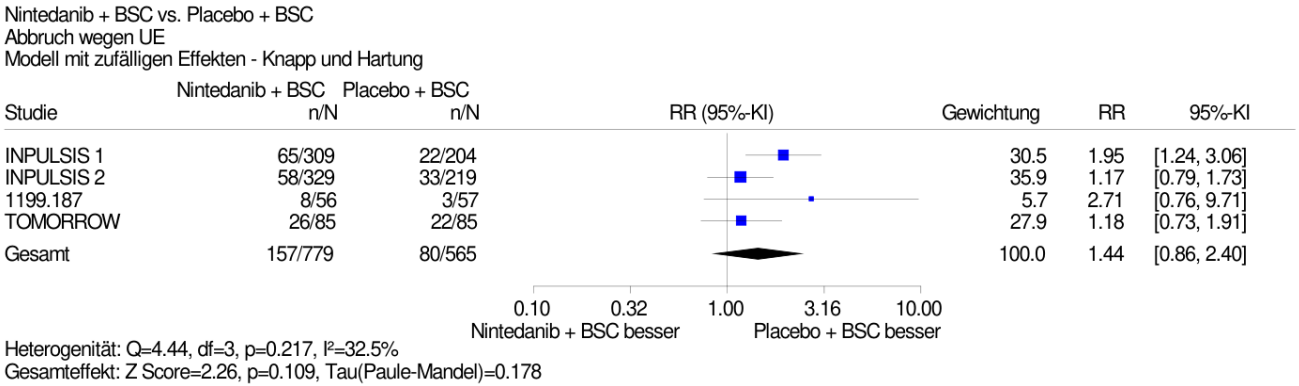


Abbildung 10: Metaanalyse, Abbruch wegen UEs, Nintedanib + BSC vs. Placebo + BSC; Effektschätzer: relatives Risiko

Abbildung 10 aus [1].

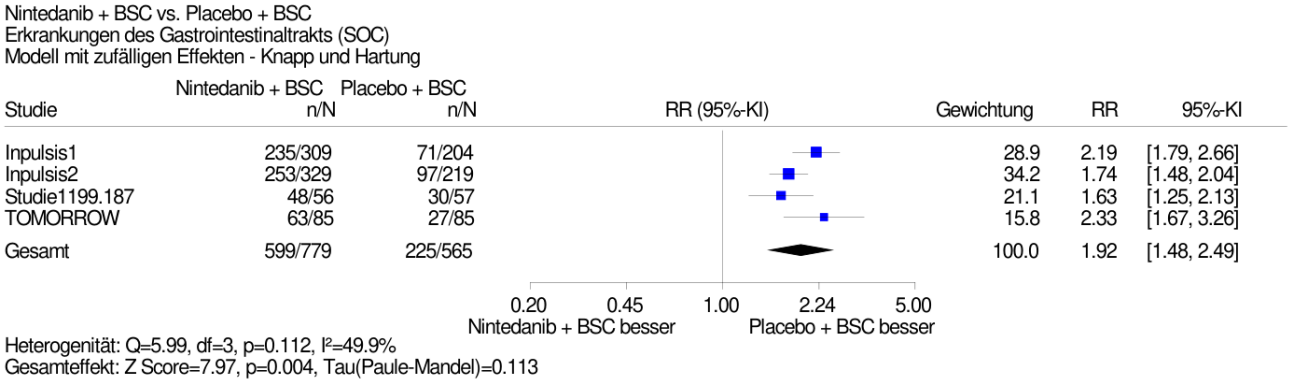


Abbildung 11: Metaanalyse, Erkrankungen des Gastrointestinaltrakts, Nintedanib + BSC vs. Placebo + BSC; Effektschätzer: relatives Risiko

Abbildung 11 aus [1].

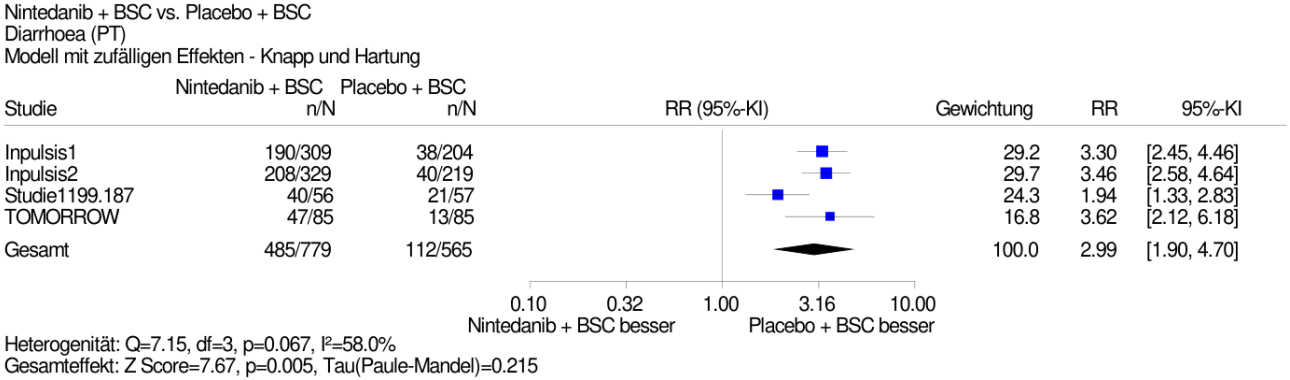


Abbildung 12: Metaanalyse, Diarrhö (PT), Nintedanib + BSC vs. Placebo + BSC; Effektschätzer: relatives Risiko

Abbildung 12 aus [1].

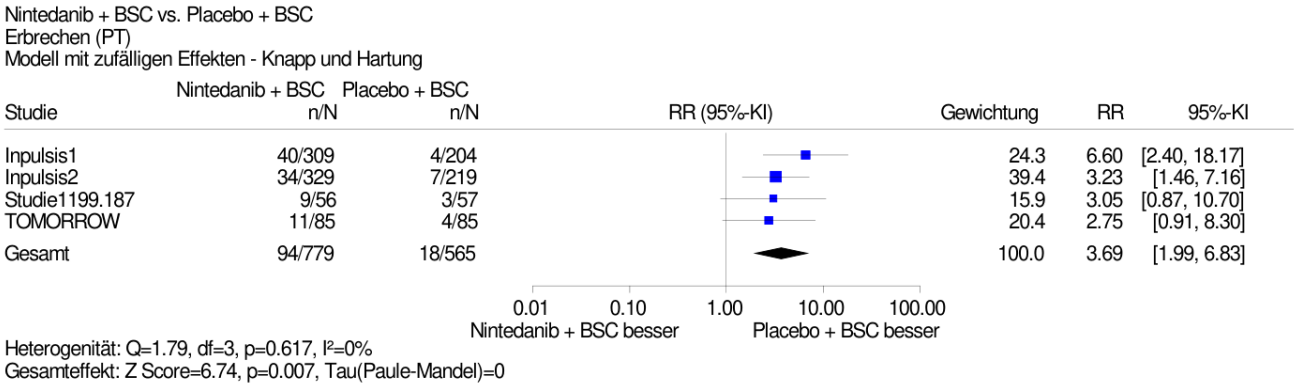


Abbildung 13: Metaanalyse, Erbrechen (PT), Nintedanib + BSC vs. Placebo + BSC; Effektschätzer: relatives Risiko

Abbildung 13 aus [1].

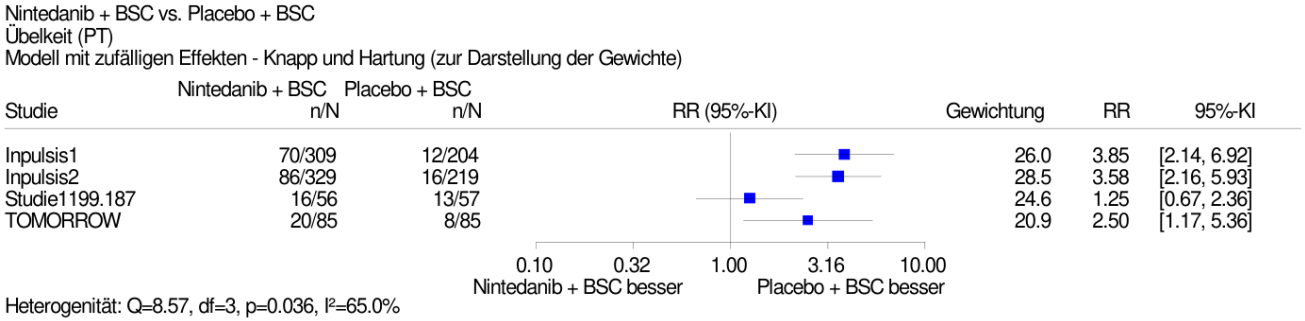


Abbildung 14: Metaanalyse, Übelkeit (PT), Nintedanib + BSC vs. Placebo + BSC; Effektschätzer: relatives Risiko

Abbildung 14 aus [1].

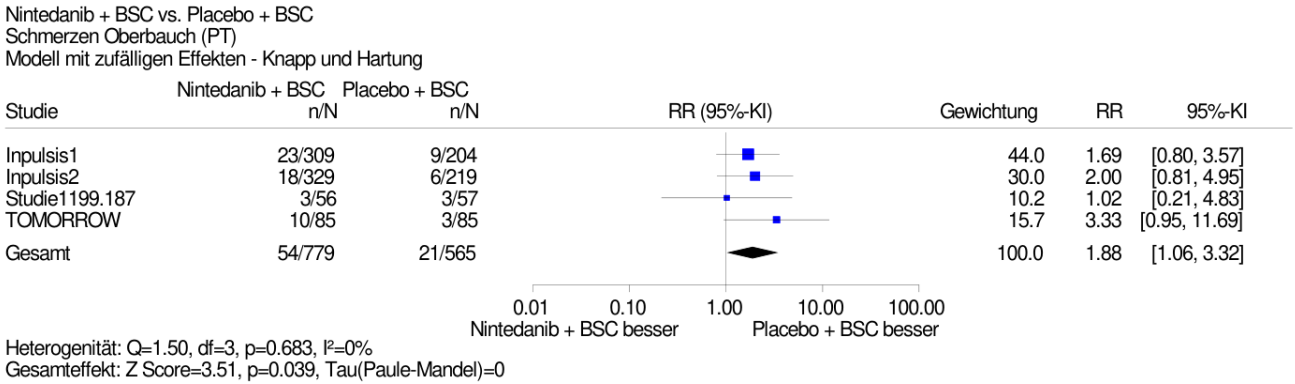


Abbildung 15: Metaanalyse, Schmerzen Oberbauch (PT), Nintedanib + BSC vs. Placebo + BSC; Effektschätzer: relatives Risiko

Abbildung 15 aus [1].

Anhang 4-G

3 Auswertungen zum indirekten Vergleich

3.1 Indirekter Vergleich von FIBRONEER®-IPF und Metaanalyse der Nintedanib-Studien aus dem Jahr 2019

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L.1 Nerandomilast versus Nintedanib (based on 2019 assessment of Nintedanib)

L.1.1 Efficacy Analysis

L.1.1.1 Time to event analyses

L.1.1.1.1 Analyses of single endpoints

L.1.1.1.1.1 Time to death

Table L.1.1.1.1.1: 1 Indirect treatment comparison for time to death over the whole trial

Subgroup	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
Overall	0.25 (0.07, 0.93)	0.66 (0.37, 1.17)	0.38 (0.09, 1.59)	0.1855

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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L.1.1.1.1.2 Time to first confirmed or suspected acute IPF exacerbation over the whole trial

Table L.1.1.1.1.2: 1 Indirect treatment comparison for time to first confirmed or suspected acute IPF exacerbation over the whole trial

Subgroup	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
Overall	1.01 (0.43, 2.38)	0.29 (0.11, 0.77)	3.48 (0.95, 12.72)	0.0593

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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L.1.1.2 Analyses of continuous variables

L.1.1.2.1 MMRM Analysis

Table L.1.1.2.1: 1 Indirect treatment comparison for the absolute change from baseline in EQ-5D VAS at week 52

Subgroup	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
Overall	2.1 (-2.6 , 6.7)	3.8 (1.8 , 5.9)	-1.8 (-6.9 , 3.3)	0.5006

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032 and 1199-0034.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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L.1.2.1 Safety analysis over the whole trial

L.1.2.1.1 Adverse events overall over the whole trial

Table L.1.2.1.1: 1 Indirect treatment comparison for the proportion of patients with serious adverse events over the whole trial

Subgroup	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
Overall	0.71 (0.50, 1.03)	0.99 (0.79, 1.23)	0.72 (0.47, 1.10)	0.1318

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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L.1.2.1.2 Adverse events leading to treatment discontinuation over the whole trial

Table L.1.2.1.2: 1 Indirect treatment comparison for the proportion of patients with any adverse events leading to treatment discontinuation over the whole trial

Subgroup	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
Overall	0.73 (0.31, 1.72)	1.44 (0.86, 2.40)	0.51 (0.19, 1.38)	0.1816

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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L.1.2.1.3 Adverse events on SOC level over the whole trial

Table L.1.2.1.3: 1 Indirect treatment comparison for the proportion of patients with frequent AEs by SOC over the whole trial
SOC: Gastrointestinal disorders

Subgroup	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
Overall	1.44 (0.98, 2.13)	1.92 (1.48, 2.49)	0.75 (0.47, 1.20)	0.2345

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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L.1.2.1.4 Adverse events on PT level over the whole trial

Table L.1.2.1.4: 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	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
Overall	3.43 (1.56, 7.54)	2.99 (1.90, 4.70)	1.15 (0.46, 2.84)	0.7678

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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L.1.2.1.5 Further safety analysis

Table L.1.2.1.5: 1 Indirect treatment comparison for the proportion of patients with specific adverse events over the whole trial

SOC: Gastrointestinal disorders

Subgroup	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
Overall	1.44 (0.98, 2.13)	1.92 (1.48, 2.49)	0.75 (0.47, 1.20)	0.2345

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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Table L.1.2.1.5: 1 Indirect treatment comparison for the proportion of patients with specific adverse events over the whole trial

PT: Abdominal pain upper

Subgroup	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
Overall	1.00 (0.14, 6.94)	1.88 (1.06, 3.32)	0.53 (0.07, 4.01)	0.5401

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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Table L.1.2.1.5: 1 Indirect treatment comparison for the proportion of patients with specific adverse events over the whole trial

PT: Diarrhoea

Subgroup	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
Overall	3.43 (1.56, 7.54)	2.99 (1.90, 4.70)	1.15 (0.46, 2.84)	0.7678

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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Table L.1.2.1.5: 1 Indirect treatment comparison for the proportion of patients with specific adverse events over the whole trial

PT: Vomiting

Subgroup	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
Overall	2.00 (0.38, 10.64)	3.69 (1.99, 6.83)	0.54 (0.09, 3.22)	0.5004

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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3.2 Indirekter Vergleich von FIBRONEER®-IPF und Metaanalyse der Nintedanib-Studien aus dem Jahr 2026

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L.3 Nerandomilast versus Nintedanib (based on additions to 2019 assessment of Nintedanib)

L.3.1 Efficacy Analysis

L.3.1.1 Time to event analyses

L.3.1.1.1 Analyses of composite endpoints

L.3.1.1.1.1 Time to first confirmed acute IPF exacerbation or death over the whole trial

Table L.3.1.1.1.1: 1 Indirect treatment comparison for time to first confirmed acute IPF exacerbation or death over the whole trial

Subgroup	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
Overall	0.64 (0.29, 1.45)	0.61 (0.12, 3.08)	1.06 (0.17, 6.54)	0.9485

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034 and 1199-0187.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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L.3.1.1.1.2 Time to first confirmed or suspected acute IPF exacerbation or death over the whole trial

Table L.3.1.1.1.2: 1 Indirect treatment comparison for time to first confirmed or suspected acute IPF exacerbation or death over the whole trial

Subgroup	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
Overall	0.63 (0.30, 1.32)	0.59 (0.35, 0.99)	1.07 (0.44, 2.63)	0.8818

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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L.3.1.1.2 Analyses of single endpoints

L.3.1.1.2.1 Time to first confirmed acute IPF exacerbation over the whole trial

Table L.3.1.1.2.1: 1 Indirect treatment comparison for time to first confirmed acute IPF exacerbation over the whole trial

Subgroup	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
Overall	1.15 (0.41, 3.23)	0.58 (0.12, 2.84)	1.98 (0.30, 13.18)	0.4818

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034 and 1199-0187.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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L.3.2 Safety Analysis

Table L.3.2: 1 Indirect treatment comparison for patients with any adverse event over the whole trial

Subgroup	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
Overall	0.93 (0.88, 0.99)	1.06 (1.03, 1.10)	0.88 (0.82, 0.94)	0.0001

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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Table L.3.2: 2 Indirect treatment comparison for patients with any adverse event (excluding disease-related events) over the whole trial

Subgroup	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
Overall	0.94 (0.89, 1.00)	1.07 (1.04, 1.10)	0.88 (0.83, 0.95)	0.0003

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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Table L.3.2: 3 Indirect treatment comparison for patients with any serious adverse event (excluding disease-related events) over the whole trial

Subgroup	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
Overall	0.71 (0.49, 1.03)	0.99 (0.85, 1.17)	0.71 (0.47, 1.07)	0.0991

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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Table L.3.2: 4 Indirect treatment comparison for patients with any adverse event leading to treatment discontinuation (excluding disease-related events) over the whole trial

Subgroup	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
Overall	0.73 (0.31, 1.72)	1.63 (1.08, 2.48)	0.44 (0.17, 1.16)	0.0969

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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Table L.3.2: 5 Indirect treatment comparison for patients with frequent AEs by SOC over the whole trial

SOC: Renal and urinary disorders

Subgroup	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
Overall	4.33 (1.28, 14.67)	0.68 (0.39, 1.16)	6.40 (1.68, 24.33)	0.0064

Estimates for the comparison of Nintedanib versus Placebo are from a meta-analysis of studies 1199-0032, 1199-0034, 1199-0187 and 1199-0030.
Estimates for the comparison of Nerandomilast versus Placebo refer to the 18 mg dosage of Nerandomilast in the non-AF background population of trial 1305-0014.

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